A Treatise on Canine AV nodal function Under Conditions of exertion

Date 10/17/19

Regional Health

Leadless Pacing and Device Diagnostics

Ethan Levine, DO FHRS

Regional Health

Leadless Pacing

Why?

Current State

Future

Leadless Pacing

Why?

- "In fact, the implanted defibrillator system represents an imperfect solution in search of a plausible and practical application"
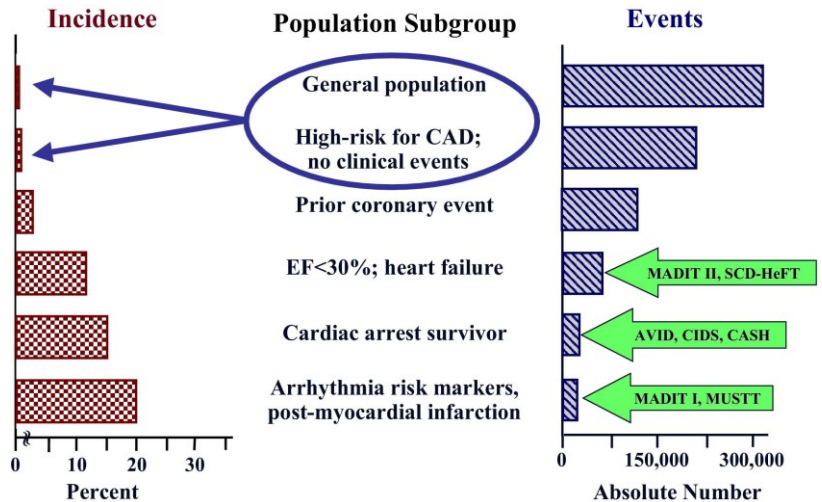
Myerburg Paradox

Sometimes you don't know what you don't know.

Roughly 200,000 Pacemakers Implanted in the U.S. Annually

Complication Rate 10%

Incidence — Percent

Population Subgroup
- General population
- High-risk for CAD; no clinical events
- Prior coronary event
- EF<30%; heart failure
- Cardiac arrest survivor
- Arrhythmia risk markers, post-myocardial infarction

Events — Absolute Number
- MADIT II, SCD-HeFT
- AVID, CIDS, CASH
- MADIT I, MUSTT

Danish Pacemaker Registry

Lead Related Complications (re-op)
- 28,860 patients
- 1997-2008
- PPM and CRT-P
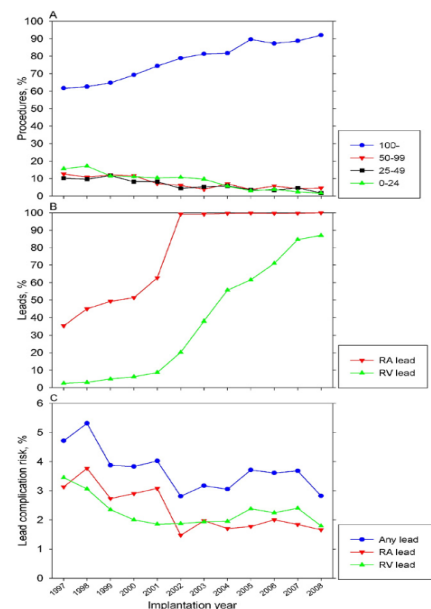
5.4% Lead Related Complication
- Non VVI device
- Operator Experience/Non-Academic Center
- Passive Fixation Leads
- Procedure Time

3

FOLLOWPACE

1517 pts from 23 Centers in the Netherlands

5.8 year Follow up

12.4% Acute Complication

9.2% Late complication

  15.6 % at 1 year

  18.3 % at 3 years
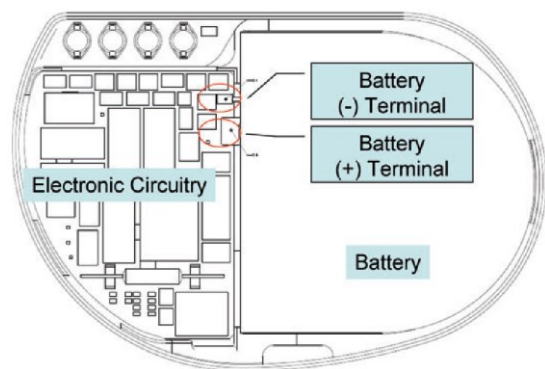
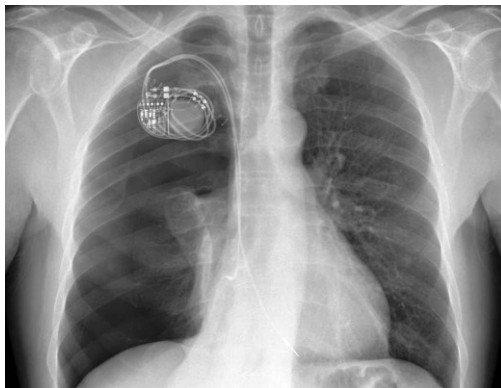 19.7 % at 5 years

0.33 % Generator Related
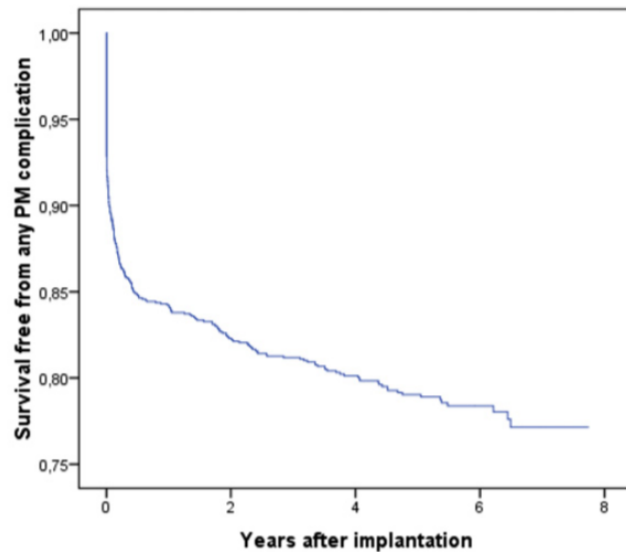
Transvenous Pacing System

Failure Points

Leads, Circuit, Pocket, Access, Header, Connections, Battery, Patient…….

Leadless Pacing System
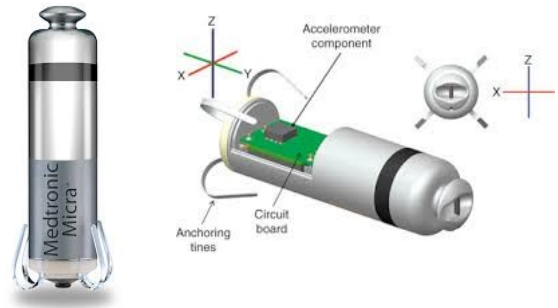
No Pocket, No leads, No header

Regional Health

Leadless Delivery and Fixation

Catheter Delivery   **Nitinol Fixation**
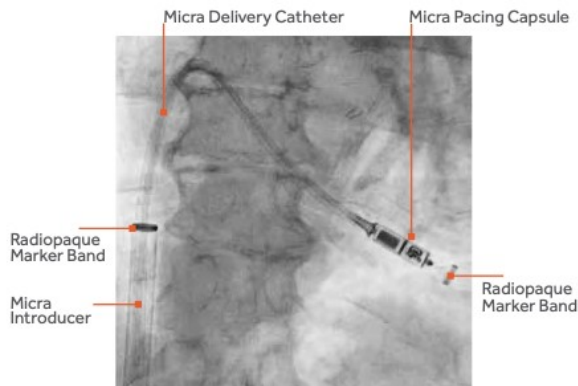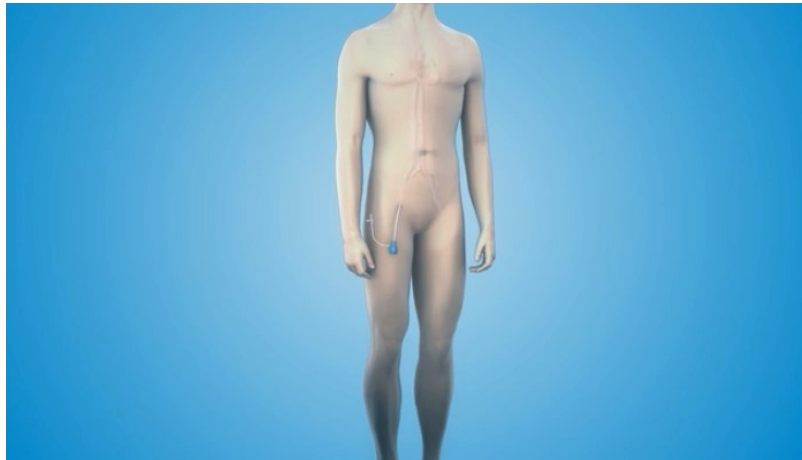
Regional Health

PMSS/Regsistry

795 patients

99.6 % successful implants

Major Complication rate 1.51%
　　(Lower than approval trials)

Table 2　Major Complications Through 30 Days Post Implant

Adverse Event	No. (Patients, %)
Total Major Complications	13 (12, 1.51)
Deep Vein Thrombosis	1 (1, 0.13)
Events at Groin Puncture Site	6 (6, 0.75)
Arteriovenous fistula	1 (1, 0.13)
Hematoma	2 (2, 0.25)
Incision site hemorrhage	1 (1, 0.13)
Persistent lymphatic fistula	1 (1, 0.13)
Vascular pseudoaneurysm	1 (1, 0.13)
Cardiac Effusion/Perforation	1 (1, 0.13)
Pacing Issues	2 (2, 0.25)
Device dislodgement	1 (1, 0.13)
Device pacing issue	1 (1, 0.13)
Other	3 (3, 0.38)
Chest pain	1 (1, 0.13)
Pulmonary edema	1 (1, 0.13)
Sepsis	1 (1, 0.13)

Leadless Pacing

Future Directions

  Micra Accelerometer Sub Study (MASS)

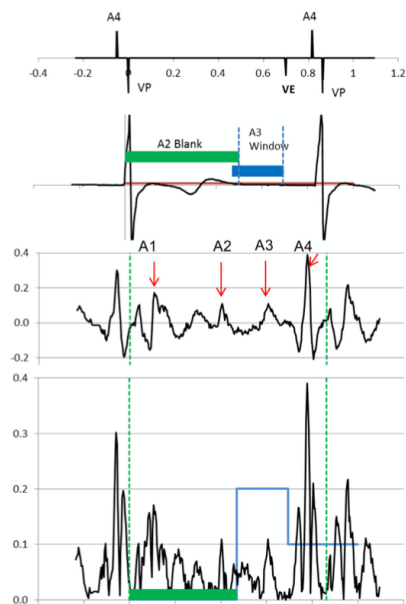 Micra Atrial Tracking Using a Ventricular Accelerometer (MARVEL)

MASS

A1 – AV Valve Closure

A2 – Aortic and Pulmonic Closure

A3 – Passive Ventricular Filling

A4 – Atrial Contraction

Blanking manually set

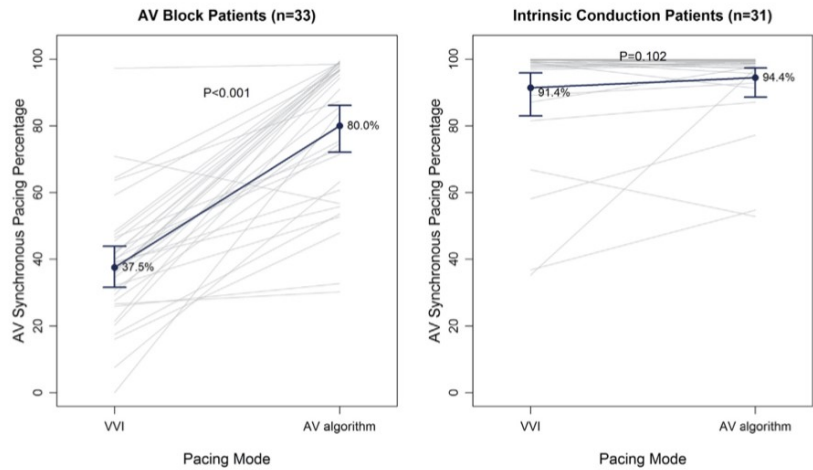Two Sensitivity choices to compensate for S3/S4 Fusion at higher rates

MARVEL
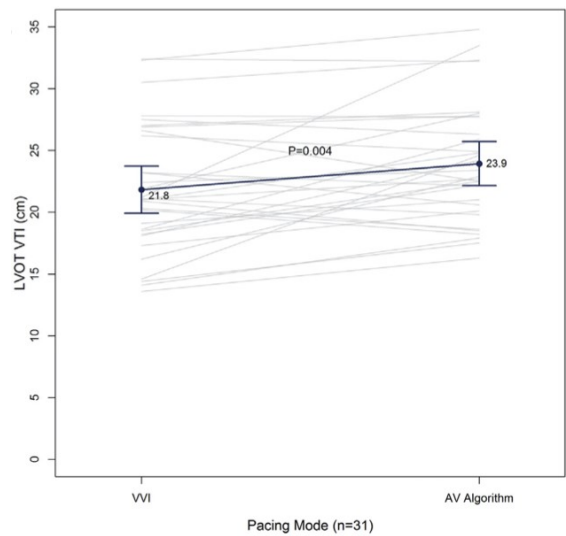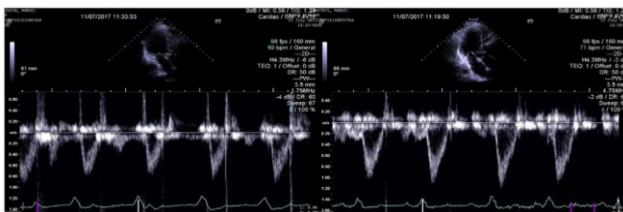
AVS increased from
37.5% to 80 % in AV
block patients.

MARVEL
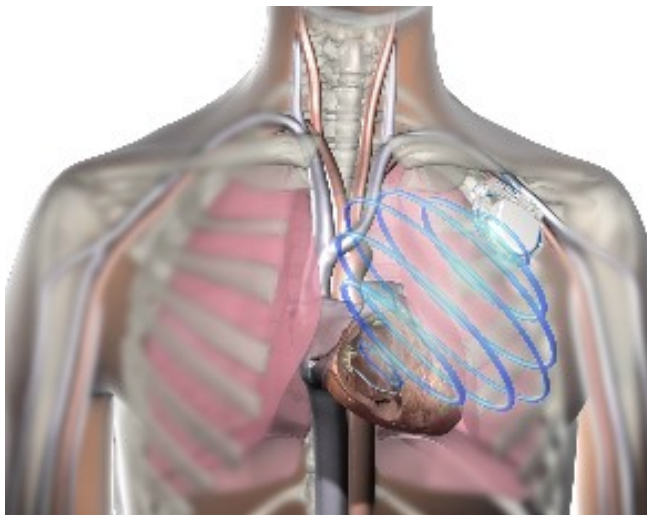
LVOT VTI

The CEID as a Diagnostic Tool

CEID as Diagnostic Tools

Rhythm

Rate

Respiratory Rate

Activity

Position

HRV

Inotropy

Temperature
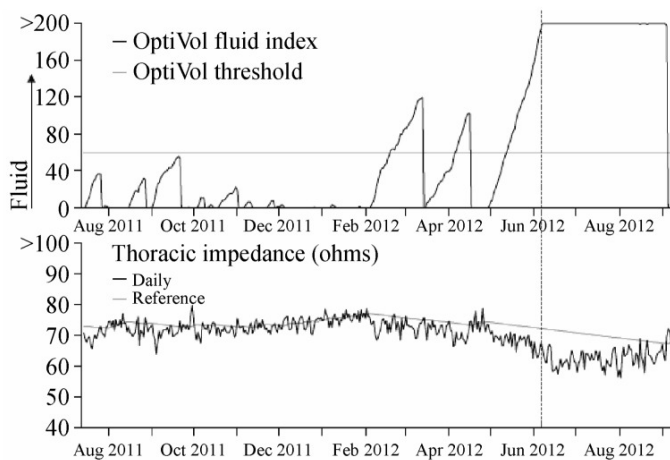
Thoracic Fluid

Heart Sounds

Thoracic Impedance

Low level current changes

Regional Health

Thoracic Impedance

Opti-Vol

60% sensitivity

60% False Positive

Regional Health

FAST Trial

Impedance Change vs Daily Weights

156 patients with 537 day follow up

65 HFE's of which Impedance predicted 76% and weights predicted 22%

Impedance picked up 40 events missed by Weight
Weight picked up 8 events missed by impedance

88% of impedance events were false positives

PARTNERS HF

694 Patients followed for 11.7 months

Parameter	Cutoff Value
Fluid Index	>60 Ohm/days
AT/AF Duration	> 6h but not persistent
V rate in AF	> 90 for 24H
Activity	< 1 H over 1 week average
Nocturnal HR	>85 bpm for 7 consecutive days
CRT Pacing	< 90% for 5 of 7 days
Shocks	Any
HRV	< 60 ms for 7 consecutive days

5.5 fold increase in HF hospitalization within 30 days
With any 2 positive Criteria or if Fluid index >100

Partners HF

Room for Improvement

Manual Calculation

NYHA III (95%)

All CRT

No Automated Alerts

40% pts Intermediate Risk

MULTISENSE
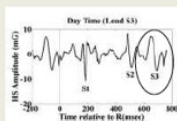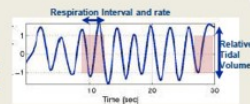
Heart Sounds
Signs of elevated filling pressure (S3)

Respiration
Rapid breathing and reduced tidal volume – shortness of breath

Thoracic Impedance
Fluid accumulation and pulmonary edema

Posture
Increased night elevation angle as indicator of Orthopnea or PND

Activity Response
Physiologic changes as a result of activity – such as signs of dyspnea on exertion
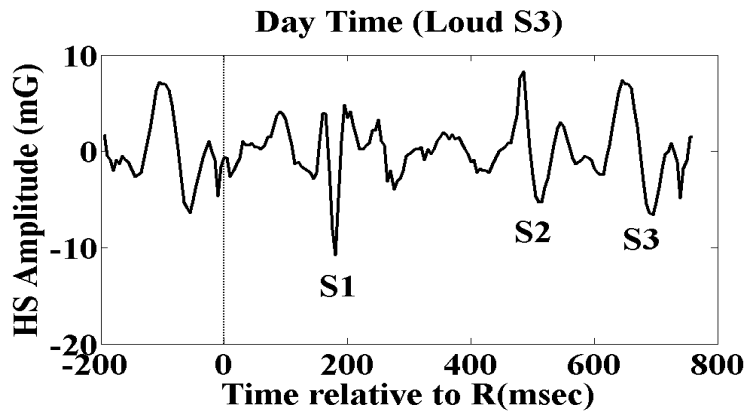

Heart Rate and Arrhythmias
Heart rates as indicator of cardiac status; atrial arrhythmias related to HF status

CEID detected heart sounds

Day Time (Loud S3)

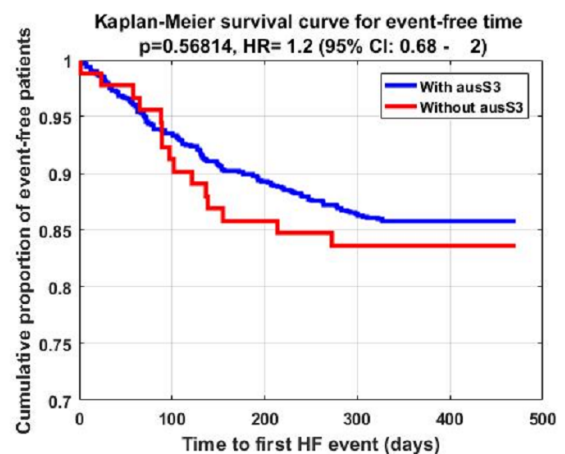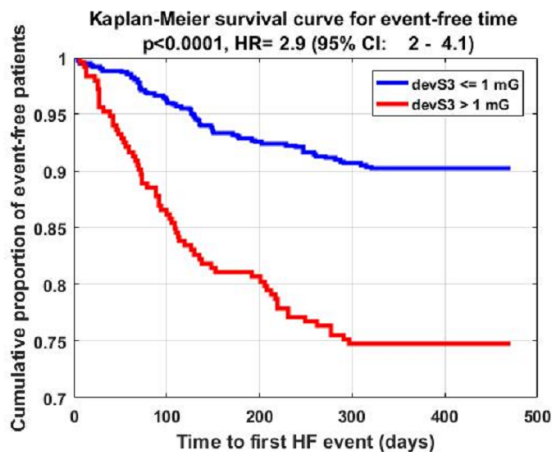S1, S2, S3 labeled

Siejko KZ, *et al.* PACE 2013; 36:334-346.

S3 detection and significance

Kaplan-Meier survival curve for event-free time
p<0.0001, HR= 2.9 (95% CI: 2 - 4.1)

devS3 <= 1 mG
devS3 > 1 mG

Kaplan-Meier survival curve for event-free time
p=0.56814, HR= 1.2 (95% CI: 0.68 - 2)

With ausS3
Without ausS3

Impedance Driven Respiration/MV/RSBI

Minute Ventilation = Rate x Tidal Volume

Respiratory Data

Respiration Rate

Tidal Volume

Rapid Shallow Breathing Index

MULTISENSE Combined Data

Heart Sounds
Signs of elevated filling pressure (S3)

Respiration
Rapid breathing and reduced tidal volume (shortness of breath)

Thoracic Impedance
Fluid accumulation and pulmonary edema

Heart Rate
Indicator of cardiac status

Activity
Global patient status and fatigue

MULTISENSE

900 patients Followed for 1 year

500 patients algorithm development

400 patients validation arm

Followed for 1 year

MULTISENSE Results

70% Sensitivity Detection of HF Event

Alert triggers a mean of 34 days prior to HFE

89% of HFE had alert trigger at least 2 weeks prior

10 fold elevation in HFE in alert state
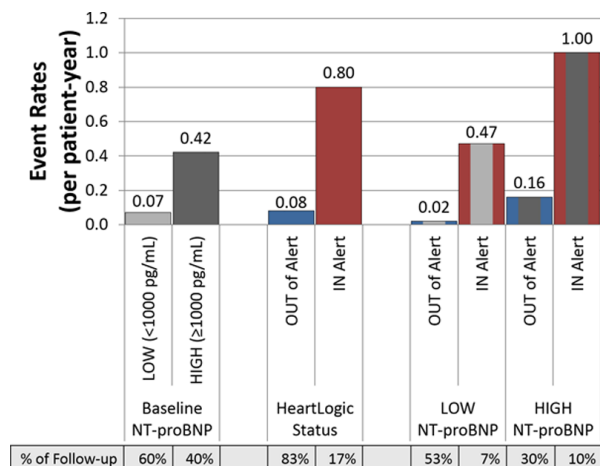
83% of patient days out of alert state

MULTISENSE with NT-proBNP

23 fold increase in HFE with low BNP in Alert

50 fold increase in HFE with high BNP in Alert

Low BNP our of alert has lowest HFE and were majority of follow up

	Baseline NT-proBNP		HeartLogic Status		LOW NT-proBNP		HIGH NT-proBNP	
% of Follow-up	60%	40%	83%	17%	53%	7%	30%	10%

MULTISENSE

Superior risk stratification

Automatic Calculation

Automated Alerts

Related to patient baseline characteristics

Ongoing outcome trials

Workflow optimization

New applications

Thank You

MAKE A DIFFERENCE. EVERY DAY.

Regional Health