

Ventricular Intrinsic Preference (VIP™) Technology Reduces Heart Failure Hospitalizations and Associated Medical Costs in Pacemaker Patients

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Disclosures

- Dr. Faulknier – Speaker’s Bureau as a 1 (Cardionet)
 - West Virginia University Physicians of Charleston, Charleston, West Virginia
- Dr. Richards-Consulting fees/honoraria and Speaker’s Bureau as a 1 (St. Jude Medical)
 - Ohio Cardiology Consultants, Toledo, Ohio
- Dr. Thakur – Nothing to disclose
 - Thoracic Cardiovascular Healthcare Foundation, Michigan State University, Lansing, Michigan
- Xiaoyi Min and Jeff Snell
 - St. Jude Medical Employees



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Background

- Conventional RV pacing
 - Produces iatrogenic LBBB¹
 - In some individuals:
 - Leads to irreversible LV dysfunction²
 - Higher values of intraventricular dyssynchrony²
 - LV remodeling²
 - Dilatation²
 - Hypertrophy²
 - Lower cardiac output and exercise performance²
 - Altered cardiac histology³

¹ Manolis AS et al. Pacing Clin Electrophysiol 2006;29:298-315.

² Thambo J-B et al. Circulation 2004; 110:3766-3772.

³ Karpawich PP et al. Pacing Clin Electrophysiol 1999; 22:1372-1377.



Ventricular Intrinsic Preference (VIP™) Technology

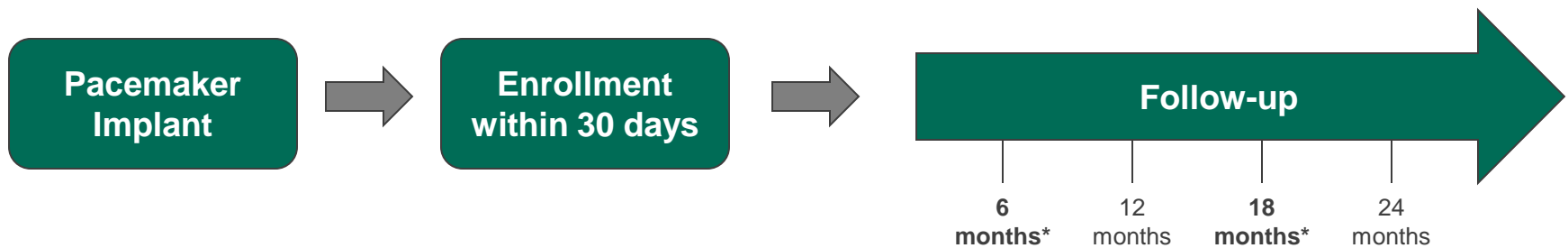
- VIP technology is available in St. Jude Medical dual chamber pacemakers
- In DDD mode, VIP technology provides for beat-by-beat ventricular support, optimizing patient safety
 - Designed to always support the ventricle every non-conducted beat
- VIP technology allows for AV delay extension up to 450 ms
 - This promotes intrinsic activity and maintains physiologic heart rhythm
- VIP technology prevents potentially arrhythmogenic pauses by maintaining continuous AV synchrony

Hypothesis

- VIP™ feature will reduce:
 - Percent RV pacing
 - Heart failure hospitalizations and cardiac death
 - Cost burden associated with heart failure associated hospitalizations

BRADYCARE Overview

- BRADYCARE: Advanced BRADYCARdia Device Feature Utilization and Clinical Outcomes
 - Registry Design: 3,389 pts (US only); 150 centers; 24 month post-implant follow-up period
- Enrollment Criteria
 - Patient has a current indication for a single chamber (SR) or dual chamber (DR) pacemaker or CRT-P device
 - Patient is implant with a St. Jude Medical Accent™ SR/DR, Accent™ RF SR/DR, Anthem™ CRT-P, Anthem™ RF CRT-P or newer SJM pacemaker
 - Patient's life expectancy is > 24 months
 - Patient is not pregnant or planning to become pregnant
 - Patient is > 18 years of age



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* Remote follow-up with Merlin.net™ Patient Care Network

Methods

- For the current analysis, all non-CRT-P pacemaker patients from BRADYCARE that completed at least a 6 month follow-up (2,812 pts) were investigated
- 1,530 patients had VIP™ feature ON and 1,282 had VIP™ feature OFF or was not applicable given the clinical situation (i.e. patients with a no tracking pacemaker mode).
 - 14 patients were excluded because of programmed VIP™ feature changes during unscheduled follow-ups
- Cox proportional hazards model was used to compare the event-free survival from heart failure hospitalization ± cardiac death between both pairs of groups.
- Cost Analysis: The costs associated with HF hospitalizations were based upon Medicare reimbursement data available to each facility for the associated Diagnosis Related Group (DRG) codes for inpatient hospital services and Ambulatory Payment Classification (APC) codes for outpatient services using MediRegs software.



Baseline Patient Characteristics by VIP™ Feature On or Off

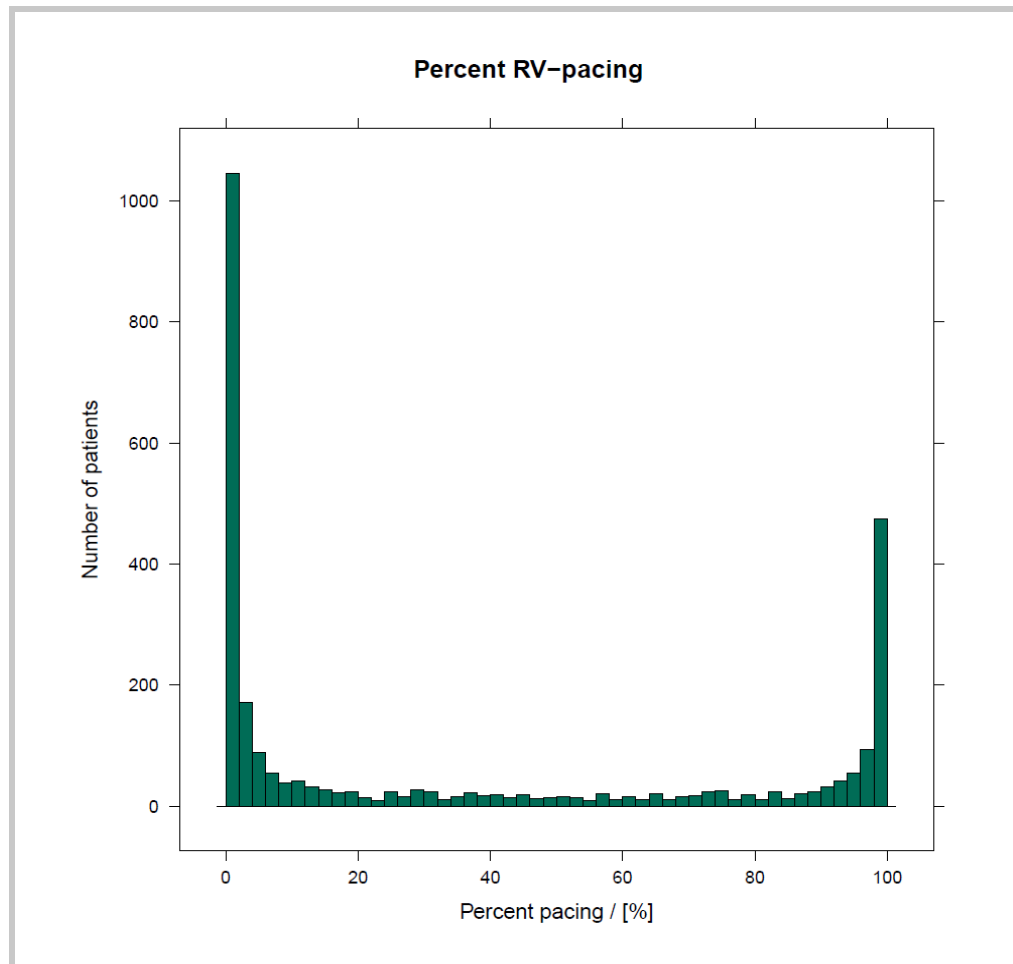
Baseline Characteristics	VIP™ Feature Off	VIP™ Feature On
N	1282	1530
Age (years)	75.7 ± 10.8	74 ± 11.2*
Age > 70 years	933 (73%)	1042 (68%)
Left Ventricular Ejection Fraction	56.5 ± 9.45% (n=940)	58.2 ± 9.0%*(n=1181)
LVEF < 25%	2	0
Baseline QRS (ms)	102.8 ± 60.7 ms	97.0 ± 34.2 ms*
QRS > 120 ms	849 (66%)	1190 (78%)
Gender (female)	560 (44%)	712 (47%)
SAS	2.1 ± 0.99	2.1 ± 0.97
SAS > II	39%	39%
Comorbidity	(n=1213)	(n=1436)
• Ischemia	537 (44%)	661 (46%)
• Diabetes	309 (26%)	390 (27%)
• Hypertension	979 (81%)	1200 (84%)
• Renal Disease	107 (8%)	147 (10%)
• AF prevalence	677 (56%)	632 (44%)*
• Stroke	135 (11%)	168 (12%)
• Anemia	47 (4%)	71 (5%)
• PVD	85(7%)	113(8%)
• COPD	130 (10%)	130 (9%)

Baseline Patient Characteristics by VIP™ Feature On or Off-Continued

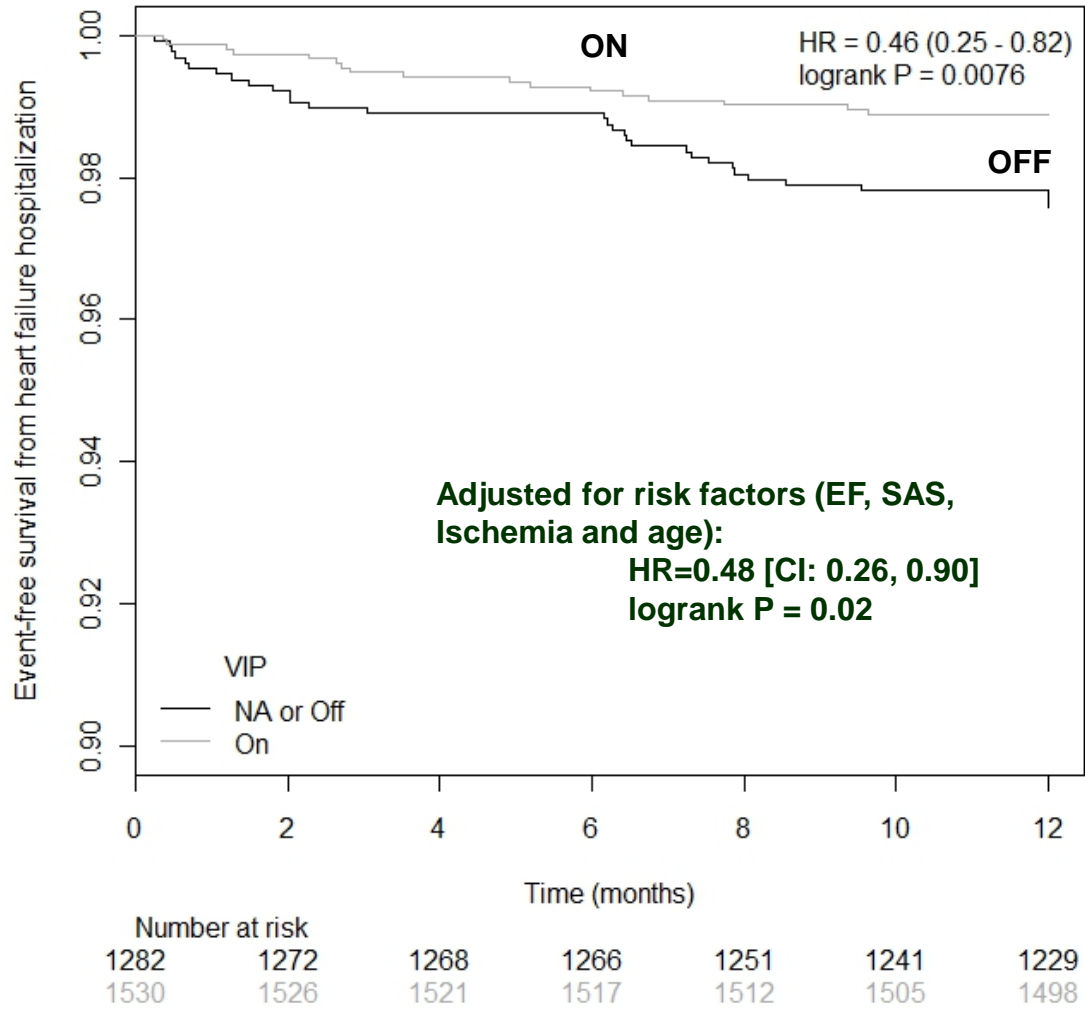
Baseline Characteristics	VIP™ Feature Off	VIP™ Feature On
Medications:	(n=1209)	(n=1434)
• Ace Inhibitors	443 (37%)	531 (37%)
• Beta Blockers	612 (51%)	731 (51%)
• Calcium Channel Blockers	343 (28%)	447 (31%)
• Diuretics	477 (39%)	457 (32%)*
• Antiplatelet	655 (54%)	884 (62%)*
• ARB	202 (17%)	257 (18%)
• Anticoagulants	483 (40%)	353 (25%)*
• Anti Arrhythmia Class 3	115 (10%)	177 (12%)*
• Anti Arrhythmia Class 1	34 (3%)	50 (3%)
• Nitrates	139 (11%)	164 (11%)
• Cardiac glycosides	99 (8%)	92 (6%)
• Aldosterone inhibitor	36 (30%)	19 (13%)*
• Renin inhibitor	1 (0%)	0 (0%)
• Positive inotrope	7 (1%)	1 (0%)*
Primary Indication:	(n=1282)	(n=1530)
• AV BLOCK	384(30%)	252(16%)*
• HF WITH WIDE QRS	2 (0.16%)	1 (0.06%)
• PACEMAKER UPGRADE	143 (11%)	105 (6.9%)*
• PAVE	25(2%)	0 *
• PREVENTION/TERMINATION OF TACHYARRHYTHMIAS BY PACING	1(0.08%)	6 (0.4%)
• SINUS NODE DYSFUNCTION	663 (52%)	1037(68%) *
• SYNCOPE	64 (5%)	127 (8.3%)*



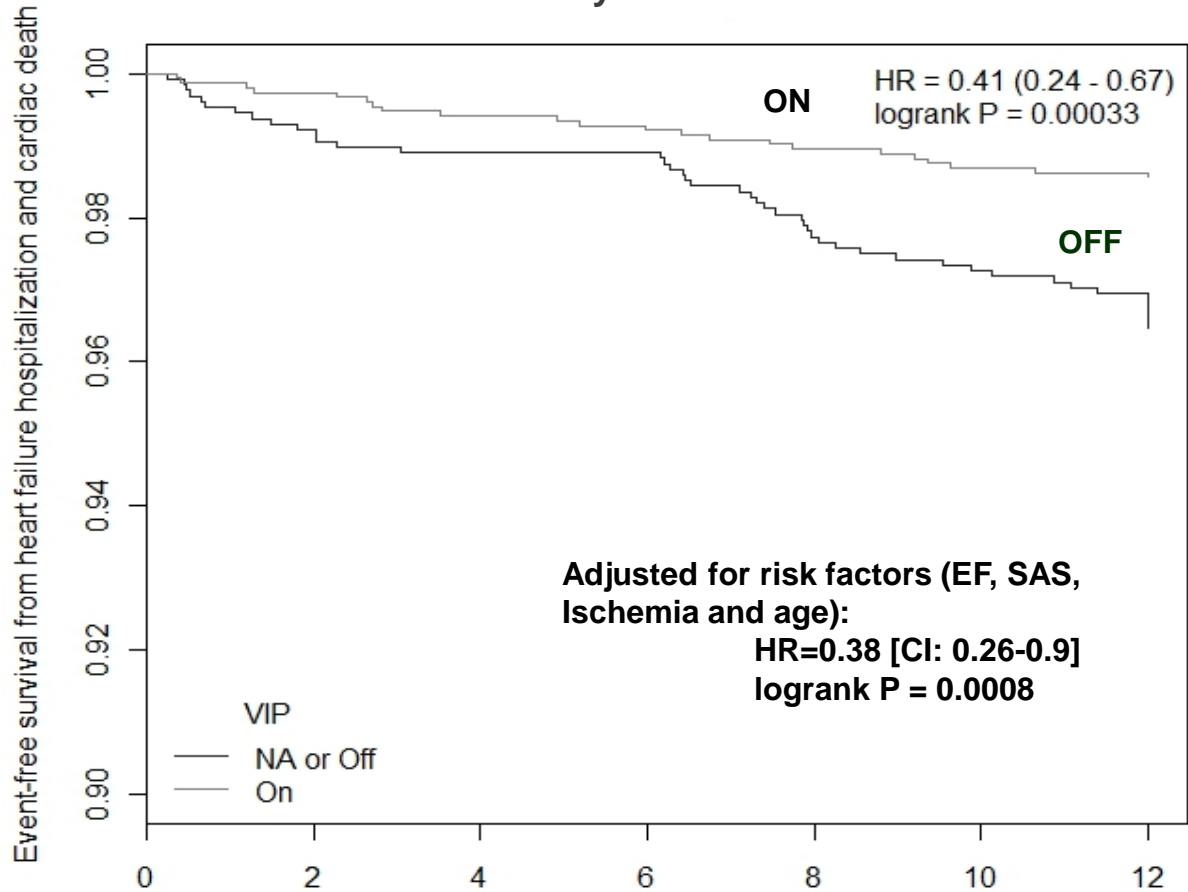
Distribution of Cumulative Percent RV Pacing



Heart failure hospitalization stratified by VIP™ feature on or off



Heart failure hospitalization and cardiac death stratified by VIP™ feature on or off



Number at risk		0	2	4	6	8	10	12
NA or Off	1282	1272	1268	1266	1249	1236	1225	
On	1530	1526	1521	1517	1511	1502	1497	



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Effect of VIP™ Technology on percent pacing in patients with different levels of heart block (HB)

- The overall percent of patients with HB is small, 23% (636 pts out of 2812).
- In pts with VIP™ feature OFF and HB, 63%, had history of 3rd degree AV block
 - Percent RVP >98%: 90% pts, have VIP™ feature OFF, of which 71% of these pts had 3rd degree AV block and 87% have either 2nd degree type 2 or 3rd degree AV block.

Economic benefit of VIP™ Feature

- The VIP™ feature ON group incurred significantly fewer HF hosp expenditures per pt-year than the VIP™ feature OFF group (\$67.63 per pt-yr vs. \$152.86 per pt-yr, $p=0.01$)

Conclusions

- In the pacemaker cohort tested, the use of Ventricular Intrinsic Preference (VIP™) Technology, was associated with:
 - Reduced heart failure hospitalization
 - Reduced combined heart failure hospitalization and cardiac death
 - Reduced cost burden associated with HF hospitalization
- This analysis suggests that individuals who have “normal” left ventricular systolic function at the time of pacemaker implantation would benefit by utilizing the VIP™ feature.
- The use of cardiac resynchronization may confer a greater benefit when a high degree of right ventricular pacing is clinically anticipated.

Study Limitations

- Retrospective analysis
- While promoting longer atrioventricular intervals has invoked clinical concern in some patient groups, none of these concerns materialized in this analysis.
- Longer term follow-up would be advantageous.

Disclaimer

Rx Only

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

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