

An Approach to the Cardiac Implantable Electronic Device Nearing End of Its Life

Michael Mohareb, MD, FRCPC



- Inexperience
- Lack of confidence
- Inability to match clothes well
- Laugh at my own jokes



- 97F admitted with Corynebacterium sepsis
- VVI PPM followed at a different centre
- In lieu of her regular appointment, while an inpatient, she is interrogated



System Summary				
Last Program Date:		31-JU	L-2007	
Brady Parameters				
Mode		E	OL-SSI	
LRL				min-1
MTR/MSR			/	min-1
Sense	2.5	mV	BI	
Output	2.5	v e	0.40	ms
Sensor			Off	
Clinical Events				
Battery at EOL				
Threshold Test Results				
06-SEP-2016	0.8	v e	0.40	ms
Counters				
Since		06-SE	P-2016	
s	= 3 %	P	- 92	-
Battery Status		,		
Current Status		1	EOL	
Magnet Rate		1	85	
Longevity Remaining © Current Pacing Percentage(s)		/	<0.5	years



- What do you recommend for this patient?
 - A. Let her recover from her illness and follow up as an outpatient
 - B. Replace her pack/generator while she is admitted
 - C. Place a temporary transvenous pacemaker until she has finished her antibiotic therapy then replace
 - D. You need more information



- 65F seen in routine PPM clinic follow-up
- Had a DDD PPM implanted 8yrs previously for vasovagal syncope with pauses

Séminaire
Winter Arrhythmia
School

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Boston Scientific			INSI	GNIA I	AVT	rrhythmia Meeting
System Summary	4					ology, University of Toronto
Last Program Date:		23-JU	IL-2015			
Brady Parameters						
Mode			DDD			
LRL			_	min-l		15/11/1
MTR/MSR		130	/ 130	min-1		
A-Sense	0.75		BI			
A-Output	2.8		0.50	ms		
v-Sense	AUTO		BI			
V-Output	AUTO	V @	0.40	ms		
Sensor			Off			
A-Tachy Response			On			
AV Delay (paced)	D	YN		ms		
Clinical Events						
Sudden Brady Response						
Threshold Test Results						
23-JUL-2015	A 1.1	V B	0.50	THAT		199
06-JAN-2016	V 1.7		0.40			
Counters						
Since		23-JU	L-2015		Λb	0%
	AsVs = 99 %	AsVp	- 1	1	Ar	7/0
	ApVs = 0 %	ApVp		*	VY	11%
ATR Mode Switches			8			1
ATR Mode Switch Time			0	*		
Battery Status						
Current Status			Good			
Magnet Rate			100	min-1		
Longevity Remaining @ Current Pacing Percent	age(s)		1.5	years		

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- What would you recommend for this patient?
 - A. Go ahead with a DDD PPM pack change
 - B. Tell her she obviously does not need her pacemaker and take the current device out (and cap the leads)
 - C. Tell her she obviously does not need her pacemaker and leave the device in situ
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- 85F with poor functional status is seen in routine pacemaker clinic follow-up
- She has a VVI PPM implanted 6yrs earlier
- Her other past medical history includes stroke, dementia (fully dependent)



Underlying Heart Rhythm: Complete Heart Block Rate: < 40 bpm

Dependancy: 4

Ventricular Capture Threshold: 0.70 V @ 0.40 ms Ventricular Sensing Threshold: No R waves detected

Final Settings: 1.2 V (Auto) @ 0.40 ms @ 2.50 mV

Minimum Pacing Rate: 60 ppm Maximum Sensor Rate: 130 ppm

Nurse's Comments: Device has reached Elective Replacement Indicator (ERI). Magnet noted

at 90 min-1, longevity recorded at 1.0 year.

Pre-op and OR date will be arranged by resource nurse.

Magnet rate, lead impedance and battery voltage were appropriate.

No R-waves sensed, stable thresholds on testing.

Diagnostics indicated pacing at 100% with limited rate

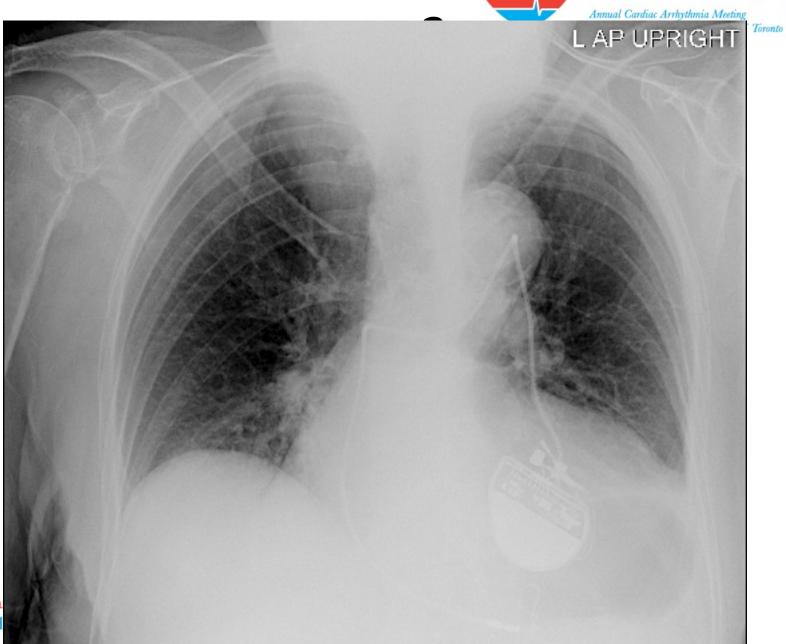
distribution noted on the Histogram.

Arrhythmia logbook recorded 2 episodes, EGM's appear to have recorded noise on the lead,

Pacemaker incision site is satisfactory.

Device is visible and prominent beneath the skin, no erosion noted.





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- What would you recommend?
 - A. Proceed with pack change and attempt a new RV lead
 - B. Proceed with pack change only
 - C. Recommend against any procedures in this woman
 - D. You need more information



- 84F with DDD PPM comes for routine visit
- Her medications include apixaban, HCTZ, candesartan, acetaminophen

	Brady Parameters			е
	Mode	Initial Value VVIR	Present Value VVIR	er Arrhythmia Arrhythmia Meeting School iology, University of Toronto
	Lower Rate Limit Max Tracking Rate Max Sensor Rate AV Delay (paced)	130	60 mi mi 130 mi ms	n-1 n-1
	Atrial Pulse Width Amplitude Sensitivity Refractory (PVARP)	=======================================	ms V mV	
	Ventricular Pulse Width Amplitude Sensitivity Refractory	0.60 3.0 1.0 250	0.60 ms 3.0 V 1.0 mV 250 ms	
	AV Delay			
	Dynamic AV Delay Maximum Delay Minimum Delay Sensed AV Offset	Initial Value 	Present Value ms ms	
	Sensor(s)			
14 th Annual Collingwood, Ontario, February 10 -12, 2017	Accelerometer Activity Threshold Reaction Time Response Factor Recovery Time	Initial Value On Medium 20 8 5	Present Value On Medium 20 se 8	ec in

Measured Data- Lead I	mpedance					
Date of last test	Previ 11-JAN	Atrial ous Pr 1-2017	esent	Ve Previo		lar Present
Impedance Amplitude Pulse Width Current		680 3.5 .60		:	820 3.0 .60	
Lead Config. (paced) Energy	Bipo 1	lar 0.8		Bipo	4 lar 5.6	
Measured Data- Intrins	ic Ampl	itude				
Date of last test Chamber Tested		Previo	2017	Present		
Measured Amplitude Lead Configuration (se	nsed)	Bipol	2.4 lar		mV	
Measured Data- Intrins	ic Ampli	itude				
Date of last test Chamber Tested		Previo 11-JAN-2 Ventrio	2017	Present		
Measured Amplitude Lead Configuration (se	nsed)	Bipol	.4 ar		mV	



Counters		Annual Cardiae Ary le
Date of Last Reset	11-JAN-2017	Since Last Reset
Paced and Sensed A-sensed / V-sensed A-sensed / V-paced A-paced / V-sensed A-paced / V-paced	50 X 0 X 0 X	1.3M 1.4M 0
Atrial Paced Sensed	0 X	0
Ventricular Paced Sensed	50 % 50 %	1.4M 1.3M
A-Tachy Response Mode Switches Total Time Maximum Time Average Time	0 %	0.0 min 0.0 min 0.0 min
Ectopic Beats PACs Single or Double PVCs Three or More PVCs Atrial Tachy Detections Ventricular Tachy Detections		0 0 0 0
Rate Hysteresis Searches Successful Searches		0
Pacemaker Wenckebach Counters		0

Battery Status

Date of last test Battery Status Magnet Rate

Longevity Remaining

© Current Pacing Percentage(s)

Previous 11-JAN-2017

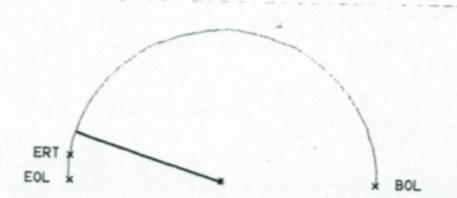
11-JAN-2017 Good 90

Present

Good 90 (0.5

minyear

r Arrhythmia
School
logy, University of Toronto



BOL- Beginning of life ERT- Elective Replacement Time EOL- End of Life

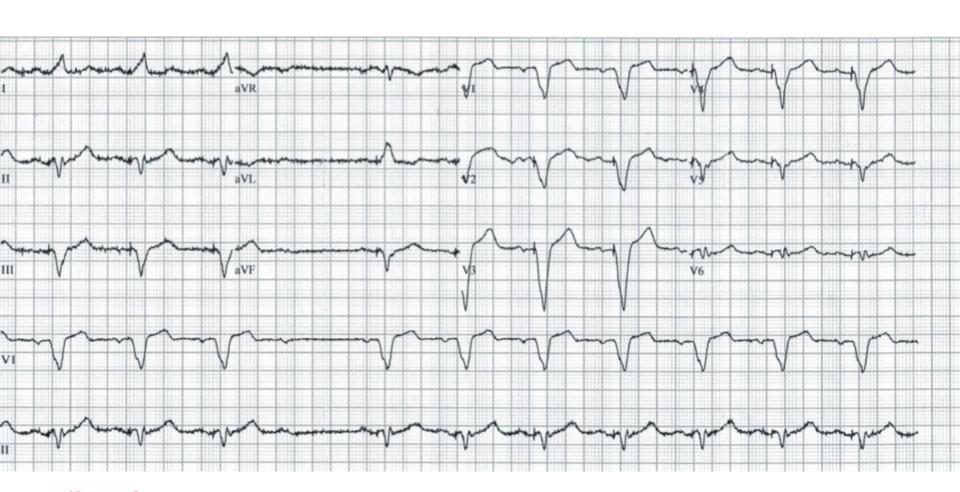


- What would you recommend?
 - A. Proceed with DDD PPM pack change
 - B. Other



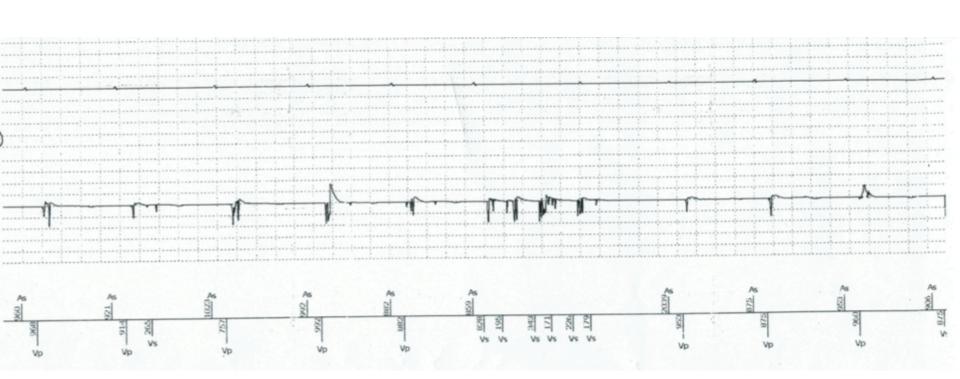
- 66M with DDD PPM for complete AV block approaching ERI
- Dependent on RV
- Has been getting recent syncopal episodes

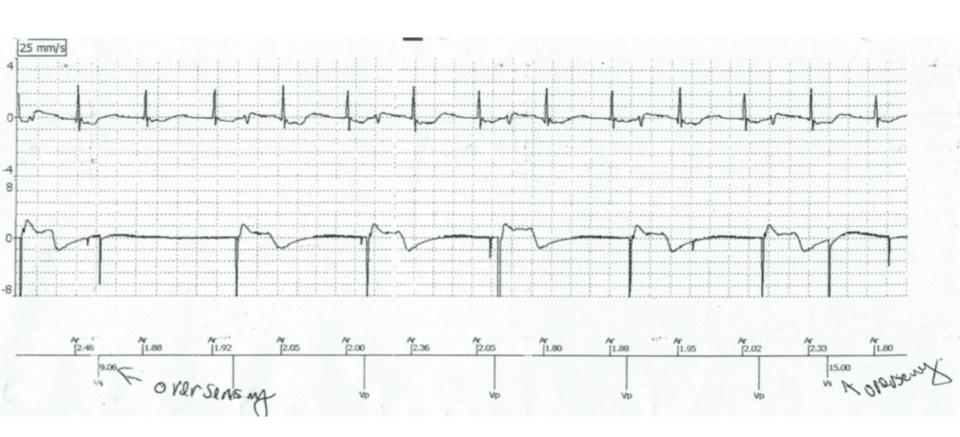




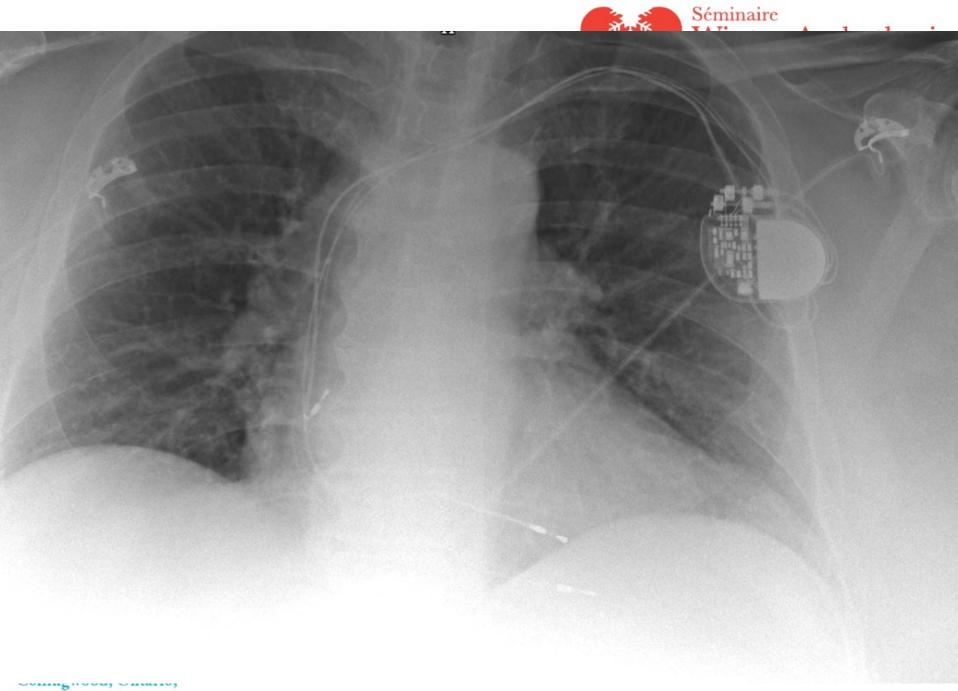
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- What would you recommend?
 - A. Proceed with DDD PPM pack change and new RV lead and cap the old RV lead
 - B. Proceed with lead extraction, new device and RV lead
 - C. Proceed with new DDD PPM on the right side



- 65M with DDD PPM for complete AV block tripped ERI last month
- Dependent on the RV
- At implant, had normal LV function
- 2 years ago had angiogram because of LV dysfunction (LVEF 40%), no HF

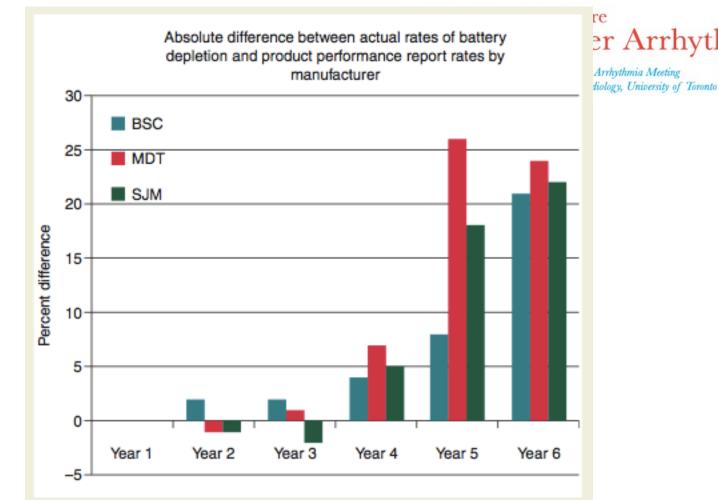


- What would you recommend?
 - A. Proceed with DDD PPM pack change
 - B. Proceed with CRT-D upgrade by adding RV and LV leads
 - C. Proceed with CRT-P upgrade by adding LV lead
 - D. You need more information





- ERI = elective replacement indicator
- ERN = elective replacement near
- ERT = estimated replacement time
- RRT = recommended replacement time
- EOL = end of life



School

Figure 2 Bar graph showing the absolute difference in battery longevity between the measured longevity according to our data and the product performance report estimated longevity as published by each device manufacturer for each year after device implantation. Note the an increase in absolute overestimation by the product performance report particularly past 4 years from implantation.

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open access to scientific and medical research



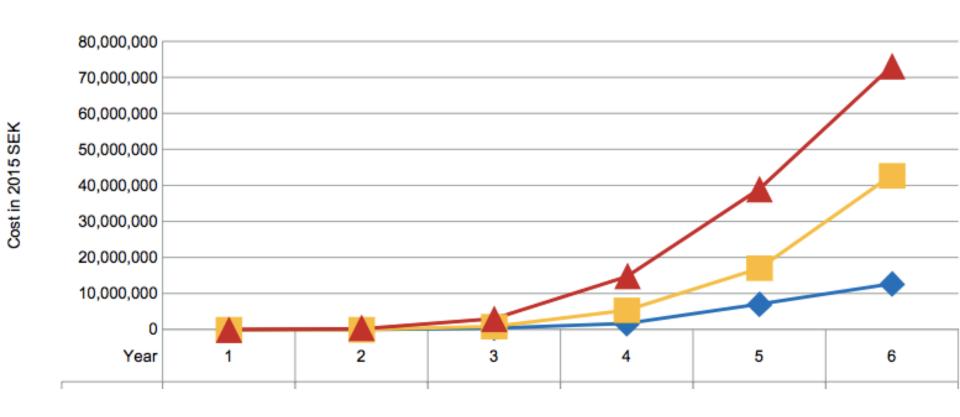
ORIGINAL RESEARCH

Economic impact of longer battery life of cardiac resynchronization therapy defibrillators in Sweden

Event-free battery survival (ie, percentage of devices with functional batteries and not requiring replacement)²²

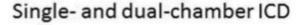
Year I	100.000	100.000	100.000
Year 2	100.000	100.000	99.727
Year 3	99.180	98.361	94.812
Year 4	97.246	90.687	77.596
Year 5	88.048	75.410	51.639
Year 6	87.978	40.816	31.694

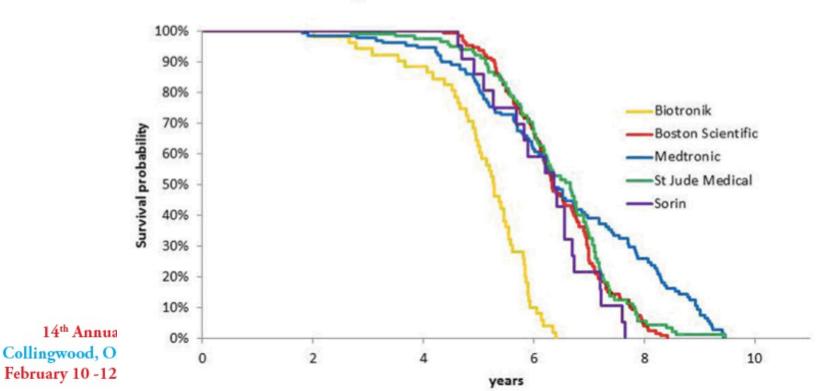
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Device Longevity in a Contemporary Cohort of ICD/CRT-D Patients Undergoing Device Replacement

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M.D.,** GIUSEPPE STABILE, M.D.,†† DOMENICO ROSARIO POTENZA, M.D.,‡‡
GIANNI PASTORE, M.D.,* MATTEO IORI, M.D.,§§ CONCETTO LA ROSA, M.D.,¶¶ and
MAURO BIFFI, M.D.,†





BOL Beginning of Life	GOOD	100 ppm	 Expected battery status at implant. All device features are available. 	 Normal implant and pre-discharge monitoring.
Gauge points between BOL	GOOD	100 ppm	 Corresponds to a battery status gauge that is greater than ERT. All device features are available. 	 Normal follow-up schedule per individual clinic guidelines.
and ERT	GOOD	90 ppm ERN	 Elective Replacement Near ERN is not a permanent/latching indicator, and will not appear on the battery status line (GOOD will appear). A Magnet Rate of 90ppm may revert to 100ppm with decreased pacing demands or programming changes. All device features remain available. 	 Approximately one year or less remaining to ERT. Intensified follow-up is recommended.
ERT Elective Replacement Time	ERT	85 ppm	Mode will change to a non-adaptive-rate mode (i.e., DDDR to DDD, VVIR to VVI). The following features will be disabled: Sensors Stored and Real-time EGMs Trending Beat-to-beat Autocapture Event Markers Activity Log EP Test Commanded Autothreshold The ERT indicator is a permanent state. Even with decreased pacing demands or programming changes, the device will not revert to ERN or GOOD.	Schedule replacement. NOTE: Unlike Boston Scientific defibrillators, Boston Scientific pacemakers do not include a beeper to indicate replacement time.
EOL End of Life	EOL	≤ 85 ppm	 Three months after ERT, as the battery continues to deplete, the device will reach EOL. EOL is a permanent state. Even with decreased pacing demands or programming changes, the device will not revert back to ERT, ERN or GOOD. Dual-chamber pacemakers will change modes to single-chamber operation (DDD and VDD to VVI). The lower rate limit will be lowered to 50 ppm and as the battery continues to deplete, the pacing amplitude will decrease. Telemetry is not guaranteed. The following additional features will be disabled: Dual-chamber Lead impedance measurements Rate Smoothing Threshold Test Arrhythmia logbook Event Counters Temporary parameters Quick Check 	 Three months after ERT, the device will reach EOL. Schedule replacement immediately, as pacing capture and telemetry are no longer guaranteed.



20mos, <8 - 32mos 50% up to 20mos vast majority more at least 8mos minority more than 32mos

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- dad			Batte	ery imp	edanc	e disp	layed a	tiasti	5.0 kΩ	5.5 kΩ	6.0 kΩ	6.5 kΩ	7.0 k	Sch
ended Interval				2.5 kΩ	3.0 kΩ	3.5 kΩ	4.0 kΩ	4.5 kΩ		THE RESERVE OF THE PERSON NAMED IN	NA	NA	NA	
ths)	1.0 kΩ	1.5 kΩ	2.0 kΩ			NA	NA	NA	NA	NA	NA	NA	NA	
34 M	12 M	12 M	12 M	12 M	12 M	NA	NA	NA	NA	NA	-	NA	NA	
33 M	12 M	12 M	12 M	12 M	12 M	A CONTRACTOR AND ADDRESS OF THE PARTY OF THE	NA	NA	NA	NA	NA	NA	NA	
33 M	12 M	12 M	12 M	12 M	12 M	NA	NA	NA	NA	NA	NA	The second secon	NA	
31 M	12 M	12 M	12 M	12 M	12 M	NA	NA	NA	NA	NA	NA	NA	NA	
30 M	12 M	12 M	12 M	12 M	12 M	NA	NA NA	NA	NA	NA	NA	NA		
29 M	12 M	12 M	12 M	12 M	12 M	NA	The state of the s	NA	NA	NA	NA	NA	NA	
28 M	12 M	12 M	12 M	12 M	12 M	NA	NA	NA	NA	NA	NA	NA	NA	
27 M	12 M	12 M	12 M	9 M	9 M	NA	NA		NA	NA	NA	NA	NA	
26 M	12 M	12 M	9 M	9 M	9 M	12 M	NA	NA	NA	NA	NA	NA	NA	
25 M	12 M	12 M	9 M	9 M	9 M	9 M	NA	NA	NA	NA	NA	NA	NA	
24 M	12 M	12 M	9 M	9 M	9 M	9 M	NA	NA		NA	NA	NA	NA	
23 M	12 M	9 M	9 M	9 M	9 M	9 M	NA	NA	NA	NA	NA	NA	NA	
22 M	12 M	9 M	9 M	9 M	9 M	9 M	NA	NA	NA	NA	NA	NA	NA	
21 M			9 M	6 M	9 M	9 M	NA	NA	NA	- I	NA	NA	NA	
20 M		9 M	6 M	6 M	6 M	9 M	NA	NA	NA	NA	NA	NA	NA	
19 M		9 M	6 M	6 M	6 M	6 M	9 M	NA	NA	NA	Contract of the Contract of th	NA NA	NA	
18 M		9 M	6 M	6 M	6 M	6 M	9 M	NA	NA	NA	NA		NA	
17 M		6 M	6 M	6 M	6 M	6 M	6 M	NA	NA	NA	NA	NA		
16 M		6 M	6 M	6 M	6 M	6 M	6 M	NA	NA	NA	NA	NA	NA	
15 M		6 M	6 M	6 M	6 M	6 M	6 M	NA	NA	NA	NA	NA	NA	
13 N				3 M	3 M	6 M	6 M	6 M	NA NA	NA	NA	NA	NA	
12 N				3 M	3 M	3 M	6 M	6 M	NA NA	NA NA	NA	NA	NA	
11 N				3 M	3 M	3 M	3 M	3 M	6 M	NA NA	NA NA	NA	NA	
10 N				3 M	3 M	3 M	3 M	3 M	3 M	NA NA	NA NA	NA	NA	
9 M	3 M	3 M		3 M	3 M	3 M	3 M	3 M	3 M	NA	NA NA	NA	NA	
8 M			3 M	3 M	3 M	3 M	3 M	3 M	3 M	3 M	NA NA	NA NA	NA	
7 M							3 M	3 M	3 M	3 M	NA NA	NA NA	NA	
6 M		The second second second		-	AND DESCRIPTION OF THE PARTY OF			3 M	3 M	3 M	ASAP	NA NA	NA	
5 N	The second second second second	-	The same of the sa			The second second second		ASAP	ASAP	ASAP	ASAP	ASAP	NA	
4 N	ASA	PASA	P ASAF	ASAF	ASAP	ASAP	ASAP	ASAP	ASAP	ASAP	-		NA ASAP	

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Longevity estimates are ESTIMATES

Longevity estimate Winter Arrhythmia ESTIMATES Seminaire Winter Arrhythmia School Division of Cardiology, University of Toronto

- Patient usage (dependency, shocks)
- Programming features
- Lead characteristics (threshold and impedance)
- Probability



PPM vs ICD



History

Examination

Device

Investigations



History

- Symptoms
 - symptoms of too slow
 - symptoms of too fast
 - symptoms of heart failure
 - symptoms of the device
- Allergies
- Past Medical History
- Medications
 - oral anticoagulation

14th Annual dual antiplatelet agents Collingwood, Ontario, February 10 -12, 2017



• Site

Signs of heart failure

- 1. Prior Implant (access, submuscular, complic)
- 2. Battery Longevity
- 3. Do the leads work?
 - threshold, sensing, impedance
 - ***bipolar vs unipolar configuration***
- 4. Does the patient work?
 - %pacing and dependency (-> is a spectrum)
 - histogram
 - new important episodes



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Division of Cardiology, University of Toronto

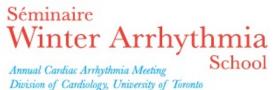
ECG -> always a good idea

- Preprocedure bloodwork
 - creatinine is often the new INR





- 1. Does the patient still need a device?
- 2. Does the patient need the <u>same</u> device?
 - consider upgrade to CRT if
 - LV dysfunction
 - high degree of pacing or underlying LBBB
 - NYHA >= 2
 - consider upgrade to ICD if
 - LVEF <=35%
 - sustained VT



• ECHO

MUGA

6 Minute Walk Test





3. Does the patient need new leads?

ALWAYS A BALANCE

BENEFITS

RISKS

- -old lead drains battery? -new lead same/worse?
- -requires AV synchrony? -PNX/perf/dislodg?
- -lower inf risk concurrently? -slightly higher inf risk?

-are the old leads on advisory?



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No Device

New Device

Pack Change

Upgrade or Revision

HIGHER RISK





- 4. Does the patient need <u>fewer</u> leads?
 - -capping an RA lead
 - -capping an LV lead
 - -downgrading from ICD to PPM end of life, LV recovery, changing evidence

5. Does the patient need a <u>new site</u>? ie: pocket revision, submuscular implant





6. Timing?

- longevity
- dependency
- travel
- recent/upcoming medical issues



Anticoagulation management

Needs a temporary pacemaker?

Follow-up afterwards (especially if upgraded)



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 - D. You need more information



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- What would you recommend for this patient?
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 - B. Tell her she obviously does not need her pacemaker and take the current device out (and cap the leads)
 - C. Tell her she obviously does not need her pacemaker and leave the device in situ
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- 85F with poor functional status is seen in routine pacemaker clinic follow-up
- She has a VVI PPM implanted 6yrs earlier
- Her other past medical history includes stroke, dementia (fully dependent)



Underlying Heart Rhythm: Complete Heart Block Rate: < 40 bpm

Dependancy: 4

Ventricular Capture Threshold: 0.70 V @ 0.40 ms Ventricular Sensing Threshold: No R waves detected

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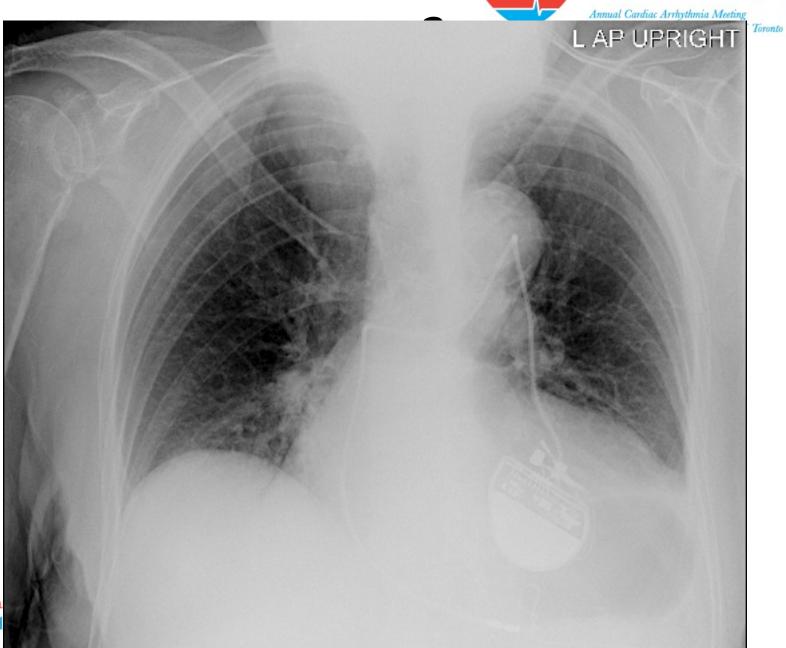
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Pacemaker incision site is satisfactory.

Device is visible and prominent beneath the skin, no erosion noted.





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- What would you recommend?
 - A. Proceed with pack change and attempt a new RV lead
 - B. Proceed with pack change only
 - C. Recommend against any procedures in this woman
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- 84F with DDD PPM comes for routine visit
- Her medications include apixaban, HCTZ, candesartan, acetaminophen

Brady Parameters		
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Ventricular Pulse Width Amplitude Sensitivity Refractory	0.60 3.0 1.0 250	0.60 ms 3.0 V 1.0 mV 250 ms
AV Delay		
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Sensor(s)		
Accelerometer Activity Threshold Reaction Time Response Factor Recovery Time	Initial Value On Medium 20 8	Present Value On Medium 20 sec 8 5 min

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Measured Data- Lead I	mpedance					
Date of last test	Atrial Previous Present 11-JAN-2017		Ventrice Previous 11-JAN-2017		lar Present	
Impedance Amplitude Pulse Width Current	680 3.5 0.60		0			
Lead Config. (paced) Energy	Bipolar 10.8		Bipo			
Measured Data- Intrins	ic Ampl	itude				
Date of last test Chamber Tested		Previo	2017	Present		
Measured Amplitude Lead Configuration (se	nsed)	Bipol	2.4 lar		mV	
Measured Data- Intrins	ic Ampli	itude				
Date of last test Chamber Tested		Previo 11-JAN-2 Ventrio	2017	Present		
Measured Amplitude Lead Configuration (se	nsed)	Bipol	.4 ar		mV	



Counters		Annual Cardiae Ary le
Date of Last Reset	11-JAN-2017	Since Last Reset
Paced and Sensed A-sensed / V-sensed A-sensed / V-paced A-paced / V-sensed A-paced / V-paced	50 X 0 X 0 X	1.3M 1.4M 0
Atrial Paced Sensed	0 X	0
Ventricular Paced Sensed	50 % 50 %	1.4M 1.3M
A-Tachy Response Mode Switches Total Time Maximum Time Average Time	0 %	0.0 min 0.0 min 0.0 min
Ectopic Beats PACs Single or Double PVCs Three or More PVCs Atrial Tachy Detections Ventricular Tachy Detections		0 0 0 0
Rate Hysteresis Searches Successful Searches		0
Pacemaker Wenckebach Counters		0

Battery Status

Date of last test Battery Status Magnet Rate

Longevity Remaining Current Pacing Percentage(s)

Previous 11-JAN-2017

Good 90

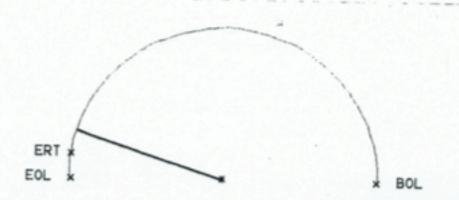
Present

Good 90 (0.5

School rhythmia Meeting logy, University of Toronto

r Arrhythmia

minyear



BOL- Beginning of life ERT- Elective Replacement Time EOL- End of Life

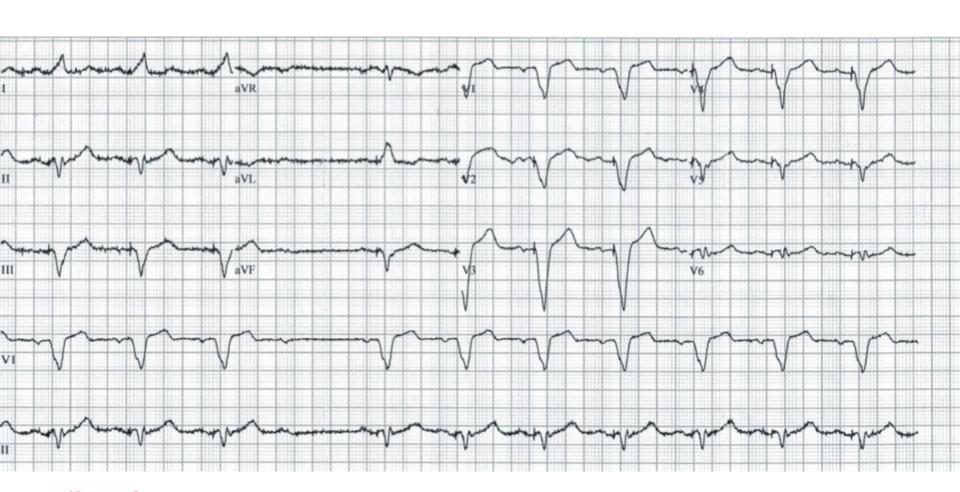


- What would you recommend?
 - A. Proceed with DDD PPM pack change
 - B. Other



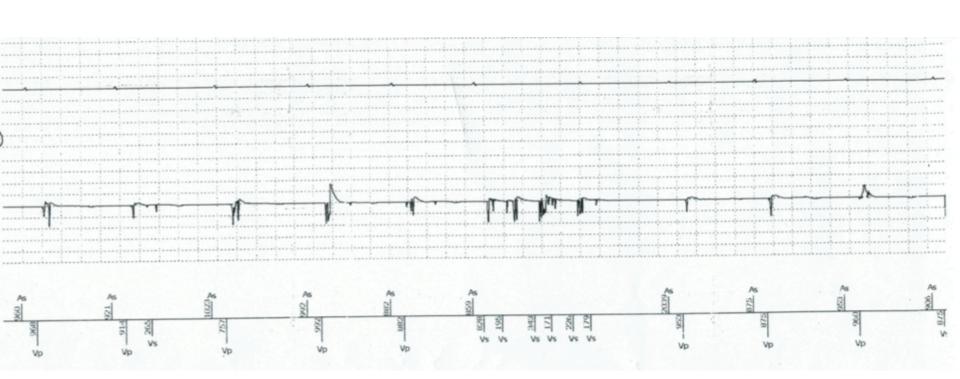
- 66M with DDD PPM for complete AV block approaching ERI
- Dependent on RV
- Has been getting recent syncopal episodes

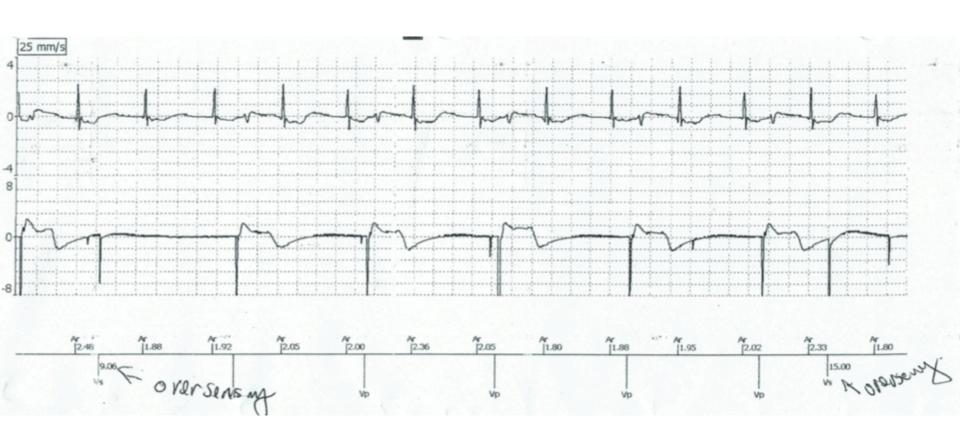




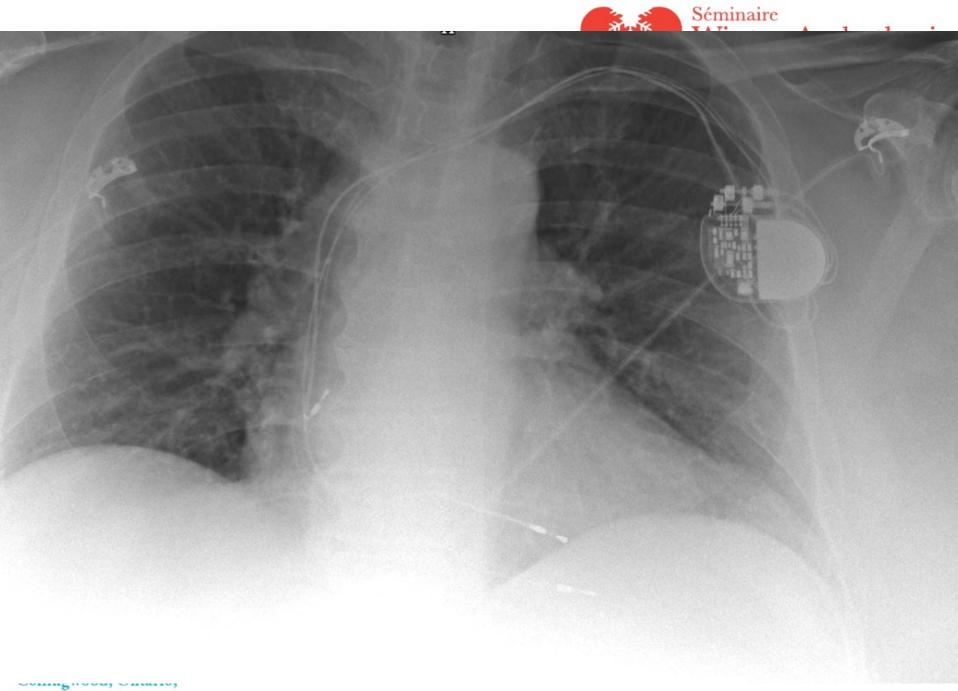
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- What would you recommend?
 - A. Proceed with DDD PPM pack change and new RV lead and cap the old RV lead
 - B. Proceed with lead extraction, new device and RV lead
 - C. Proceed with new DDD PPM on the right side

Transvenous Lead Extraction: Heart Rhythm Society Expert Consensus on Facilities, Training, Indications, and Patient Management

This document was endorsed by the American Heart Association (AHA).

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Class IIa

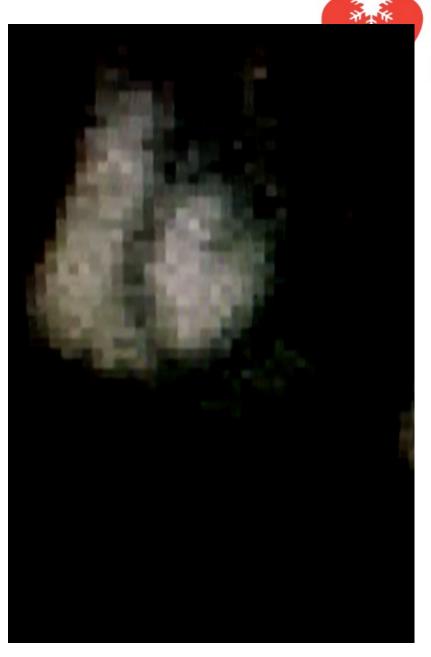
- 1. Lead removal is reasonable in patients with leads that due to their design or their failure pose a threat to the patient, that is not immediate or imminent if left in place. (e.g. Telectronics ACCUFIX without protrusion) (Level of evidence C)
- 2. Lead removal is reasonable in patients if a CIED implantation would require more than 4 leads on one side or more than 5 leads through the SVC. (Level of evidence C)
- 3. Lead removal is reasonable in patients that require specific imaging techniques (e.g. MRI) and can not be imaged due to the presence of the CIED system for which there is no other available imaging alternative for the diagnosis. (Level of evidence: C)



- 65M with DDD PPM for complete AV block tripped ERI last month
- Dependent on the RV
- At implant, had normal LV function
- 2 years ago had angiogram because of LV dysfunction (LVEF 40%), no HF



- What would you recommend?
 - A. Proceed with DDD PPM pack change
 - B. Proceed with CRT-D upgrade by adding RV and LV leads
 - C. Proceed with CRT-P upgrade by adding LV lead
 - D. You need more information



Séminaire
Winter Arrhythmia

Annual Cardiac Arrhythmia Meeting
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Device longevity is an estimate only

 Battery replacement is an opportunity to reevaluate the patient, the device, and anticipate problems

No decision is without uncertainty and risk