Syncope and heart block: pacemaker versus implantable loop recorder

Satish R Raj MD MSCI FACC FHRS
on behalf of the POST3 Investigators

Professor of Cardiac Sciences
Libin Cardiovascular Institute of Alberta
Adjunct Associate Professor of Medicine
Vanderbilt University Medicine Center

Heart Rhythm Congress, Birmingham, UK
October 2018

Heart Rhythm Congress
www.heartrhythmcongress.org

SPRITELY (POST 3)

CIHR IRSC
Canadian Institutes of Health Research | Instituts de recherche en santé du Canada

POST 3 -
The 3rd Prevention of Syncope Trial

*S*YNCOPE: *P*ACING OR *R*ECORDING IN *TH*E *L*ATER *Y*EARS (SPRITELY)

SPRITELY (POST 3)

Background

- Syncope 1.5% of ER visits
  - Bifascicular block ± complete heart block 4.9% of syncope visits
  - Suggests 74/100,000 ER visits per year
- Syncope & Bifascicular Block
  - Obvious cause:
    - intermittent complete heart block
  - Numerous competing co-morbidities:
    - carotid sinus syncope, vasovagal syncope, IOH, orthostatic hypotension, sick sinus syndrome…

SPRITELY (POST 3)

Competing Strategies

Implantable Loop Recorder

Primum Non Nocere

Pacemaker

Primum Succurrere

SPRITELY (POST 3)

The Guidelines

PM for syncope and bifascicular block: IIA

ILR for syncope and bifascicular block: IIA

SPRITELY
(POST 3)

Study Objective

To determine if a strategy of empiric permanent pacing in patients with syncope and bifascicular heart block will provide a better overall reduction of adverse outcomes than a strategy of acting on the results of an implantable loop recorder.

SPRITELY (POST 3)

Study Design

- ***Randomized pragmatic longitudinal, prospective, parallel design, open label, clinical trial***
- Pacemaker vs. ILR
- Funded by CIHR
- Minimum 2-year observation period or until study completion

CIHR IRSC
Canadian Institutes of Health Research
Instituts de recherche en santé du Canada

SPRITELY (POST 3)

Inclusion & Exclusion

- **Inclusion Criteria**
  - ≥1 syncopal spell within 1 preceding year
  - Bifascicular block on a 12-lead ECG
  - Age > 50 years

- **Exclusion Criteria**
  - Previous ILR, pacemaker, ICD
  - Class I indication for pacing
  - LVEF <35%
  - Contraindication to permanent pacing
  - Hypertrophic cardiomyopathy
  - Sustained VT: spontaneous or induced
  - MI in <3 months
  - Epilepsy with (+) EEG
  - Definite documented other cause

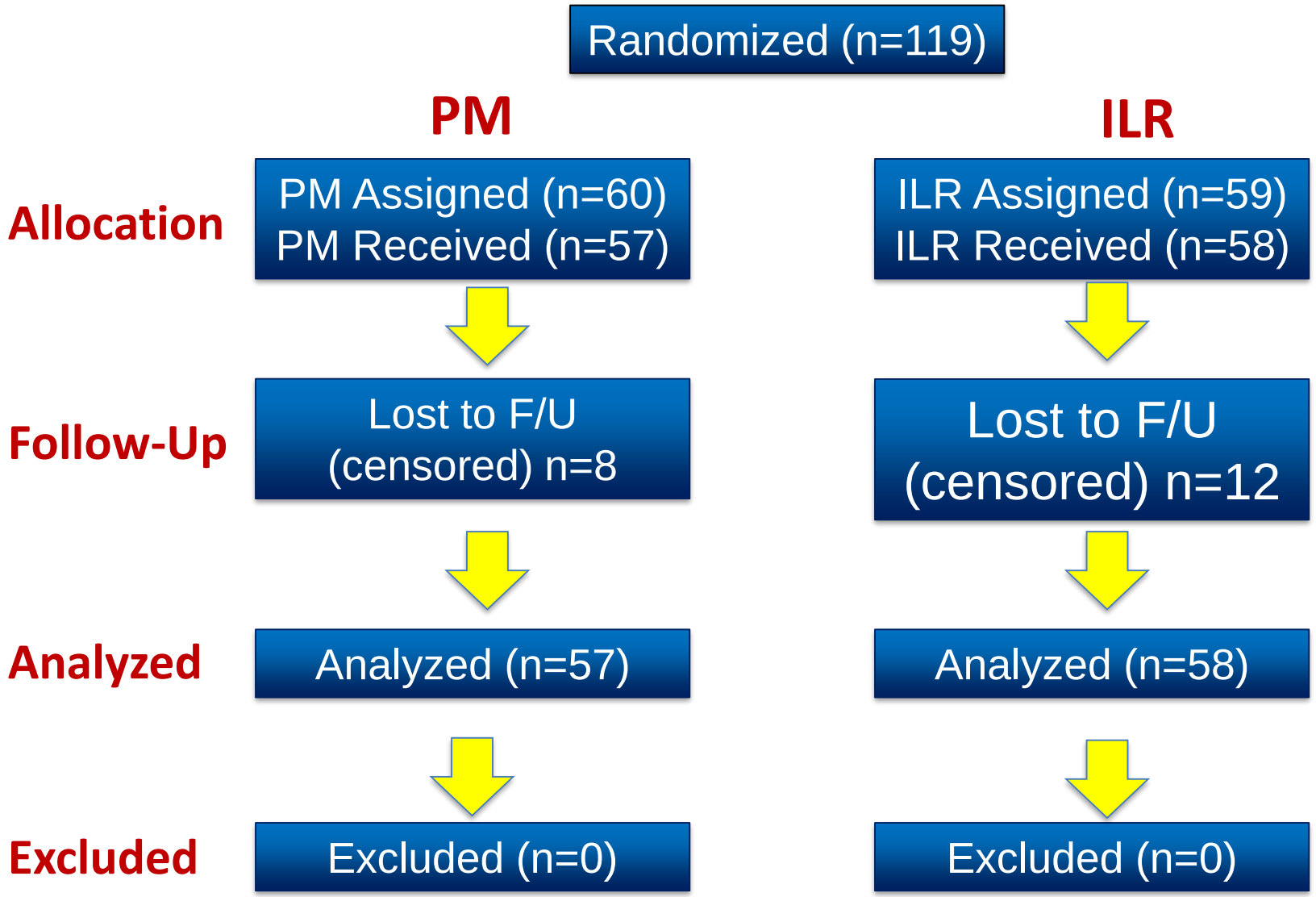
SPRITELY (POST 3)

Primary Outcome

- **MASRE**: **M**ajor **A**dverse **S**tudy-**R**elated **E**vents
  - Syncope
  - Symptomatic bradycardias resulting in intervention
  - Asymptomatic bradycardia resulting in intervention
  - Acute & chronic device complications
  - Cardiovascular death

SPRITELY (POST 3)

SPRITELY: Study Flow



SPRITELY (POST 3)

Baseline Characteristics 1

Characteristic	PM (n=57)	ICM (n=58)
Randomized subjects, n	57	58
Age, y, mean ±SD	75 ± 9	78 ± 9
Female, n	20	14
Syncope history		
Lifetime No. of spells, median (IQR)	2 (1-6)	2 (1-4)
Spells in previous year, median (IQR)	2 (1-3)	2 (1-3)
Duration of symptoms, y, median (IQR)	1 (1-4.5)	1 (1-3.25)
Syncope frequency, spell/year, median (IQR)	1.1 (1-2.8)	1.2 (1-2.6)
Left ventricular ejection fraction, mean ±SD (range)	60±8 (38,81)	58±8 (39,75)

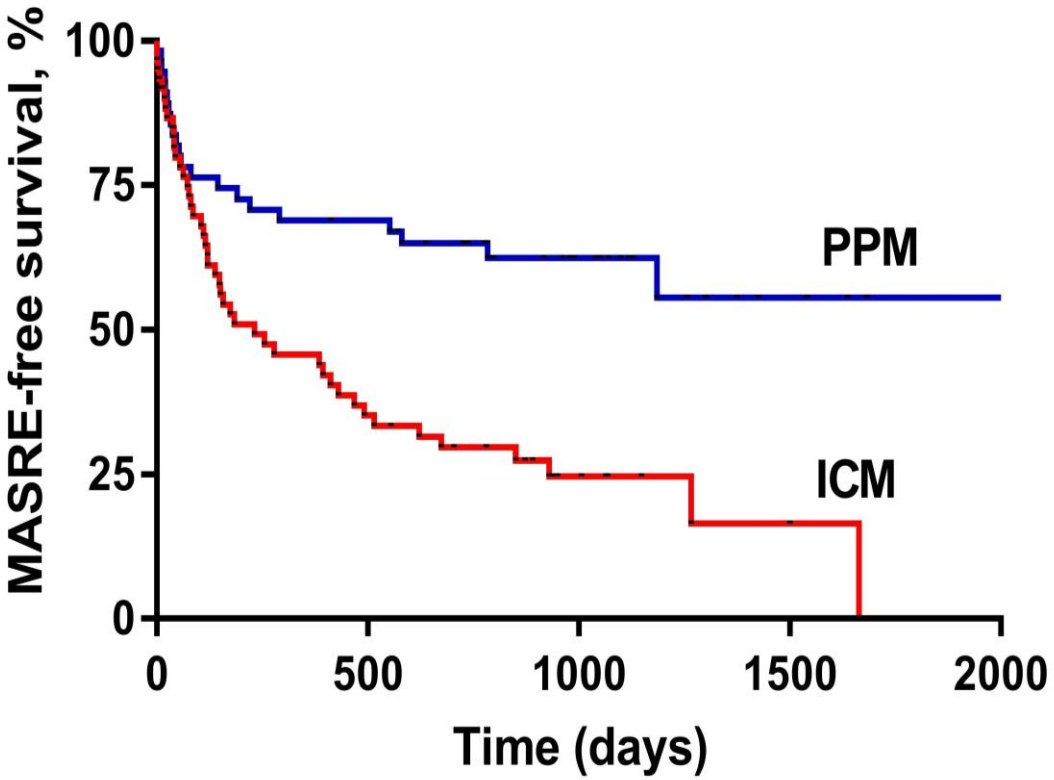
SPRITELY (POST 3)

Baseline Characteristics 2

Characteristic	PM (n=57)	ICM (n=58)
Syncope Symptoms		
Calgary Syncope Symptom Score, Mean (SD)	-4 ± 3.2	-3.9 ± 3.4
Calgary Syncope Symptom Score, Range	-11, 1	-14, 5
No prodromal symptoms	40	36
Syncope started over age of 35y	49	48
Baseline ECG		
LBBB	21	20
RBBB and LAFB	33	36
RBBB and LPFB	3	2

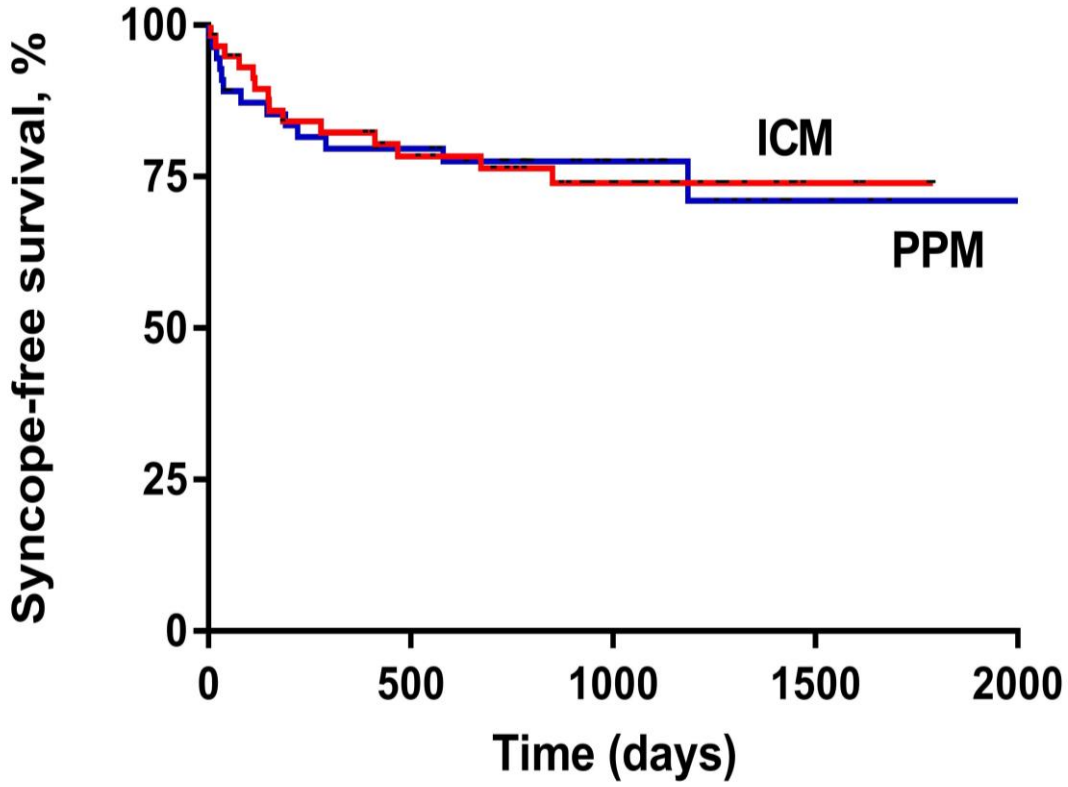
SPRITELY (POST 3)

Results: Primary Outcome



SPRITELY (POST 3)

Results: Syncope-Free



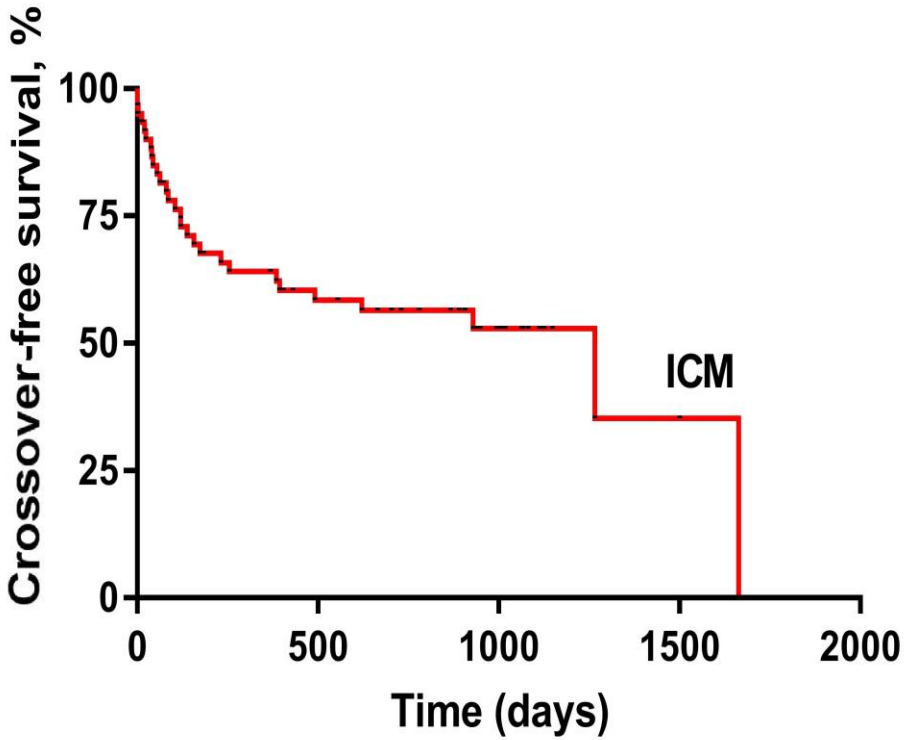
SPRITELY (POST 3)

Results: Outcomes by Patient

Outcomes	PM (n=57)	ICM (n=58)	P Value
Patients with primary outcomes	19	44	0.0001
CV Death	1	2	0.98
Syncope	13	14	0.87
Syncope causing X-over	0	11	<0.001
Bradycardia crossovers	0	32	<0.001
Asymptomatic brady causing X-over	0	8	0.006
Symptomatic brady causing X-over	0	20	<0.001
Delayed crossover after syncope	0	4	0.12
Device comp requiring intervention	5	0	0.03

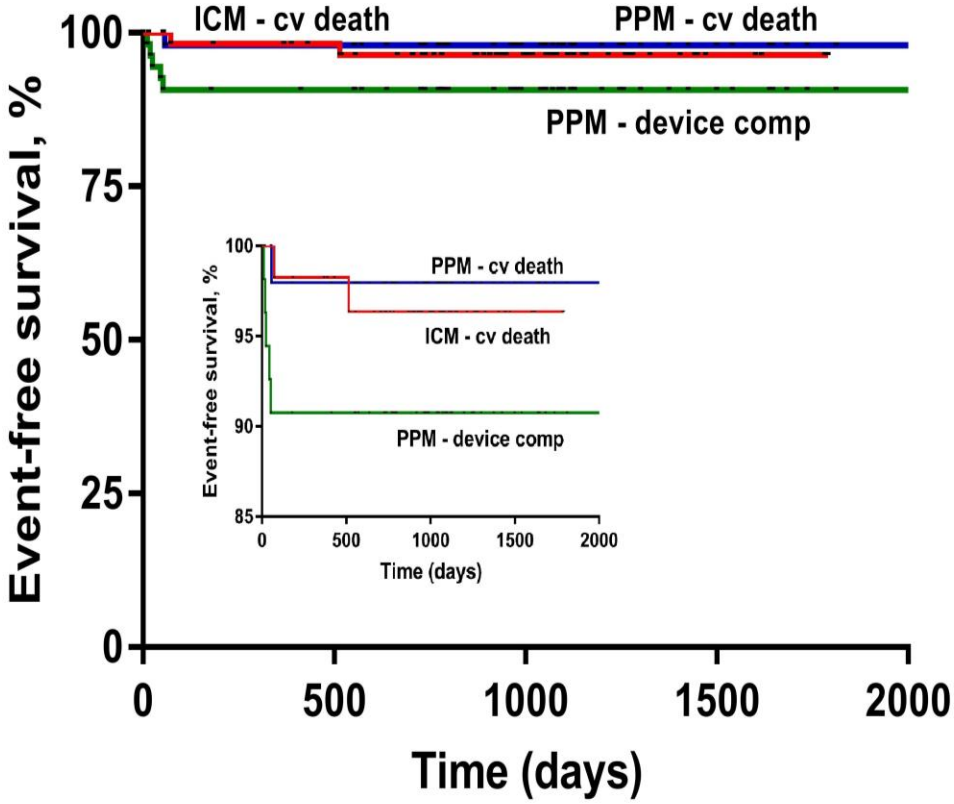
SPRITELY (POST 3)

Results: Crossover-Free



SPRITELY (POST 3)

Results: CV Death or Device Complications



SPRITELY (POST 3)

Conclusions 1

- In elderly patients with bifascicular block, Pacemaker compared to ILR:
  - Reduced major adverse events
    - High rate of crossover from ILR to PM
  - Did not decrease syncope recurrence
- Syncope recurrence 25-30% in PM group
  - Due to vasodepression
- Crossovers may have been due to non-severe bradycardia
  - ILR group did not have more syncope

SPRITELY (POST 3)

Conclusions 2

- Low Risk Group (LVEF>35%, syncope, bifascicular block)
  - No early deaths or tachyarrhythmia
  - May not require admission
  - May be able to arrange for early O/P pacemakers

SPRITELY (POST 3)

Acknowledgements

- POST3 Investigators
- POST3 Patients
- POST Office
  - University of Calgary Syncope Coordinating Center
  - PI: Robert S Sheldon MD PhD
- Canadian Institute of Health Research

CIHR IRSC
Canadian Institutes of Health Research
Instituts de recherche en santé du Canada