



Β' ΠΑΝΕΠΙΣΤΗΜΙΑΚΗ
ΚΑΡΔΙΟΛΟΓΙΚΗ ΚΛΙΝΙΚΗ -
Γ.Ν.Θ. «ΙΠΠΟΚΡΑΤΕΙΟ»

ΕΤΑΙΡΕΙΑ
ΑΘΗΡΟΣΚΛΗΡΩΣΗΣ
ΒΟΡΕΙΟΥ ΕΛΛΑΔΟΣ



ΙΠΠΟΚΡΑΤΕΙΕΣ ΗΜΕΡΕΣ ΚΑΡΔΙΟΛΟΓΙΑΣ

ΛΗΨΗ ΚΛΙΝΙΚΩΝ ΑΠΟΦΑΣΕΩΝ ΜΕΣΑ ΑΠΟ ΤΗΝ
ΠΑΡΟΥΣΙΑΣΗ ΠΕΡΙΣΤΑΤΙΚΩΝ
ΜΕ ΔΙΕΘΝΗ ΣΥΜΜΕΤΟΧΗ

12-13 ΜΑΪΟΥ 2023

ELECTRA PALACE / ΘΕΣΣΑΛΟΝΙΚΗ

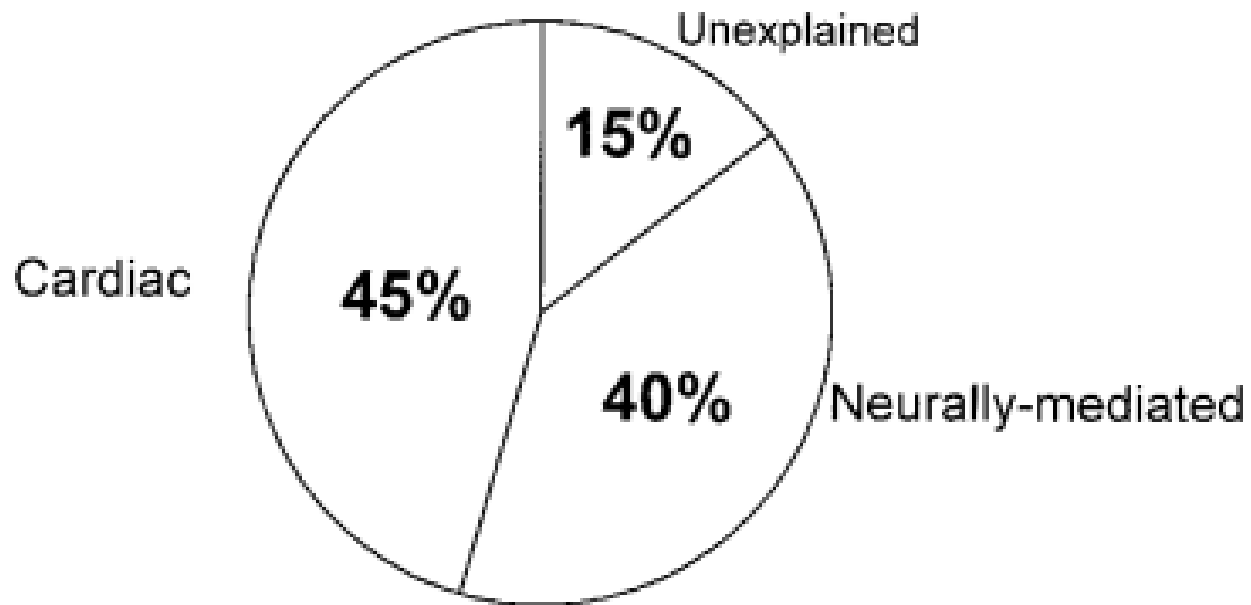


Συγκοπή και διδесμικός αποκλεισμός. ΗΦΕ, ILR ή βηματοδότης;

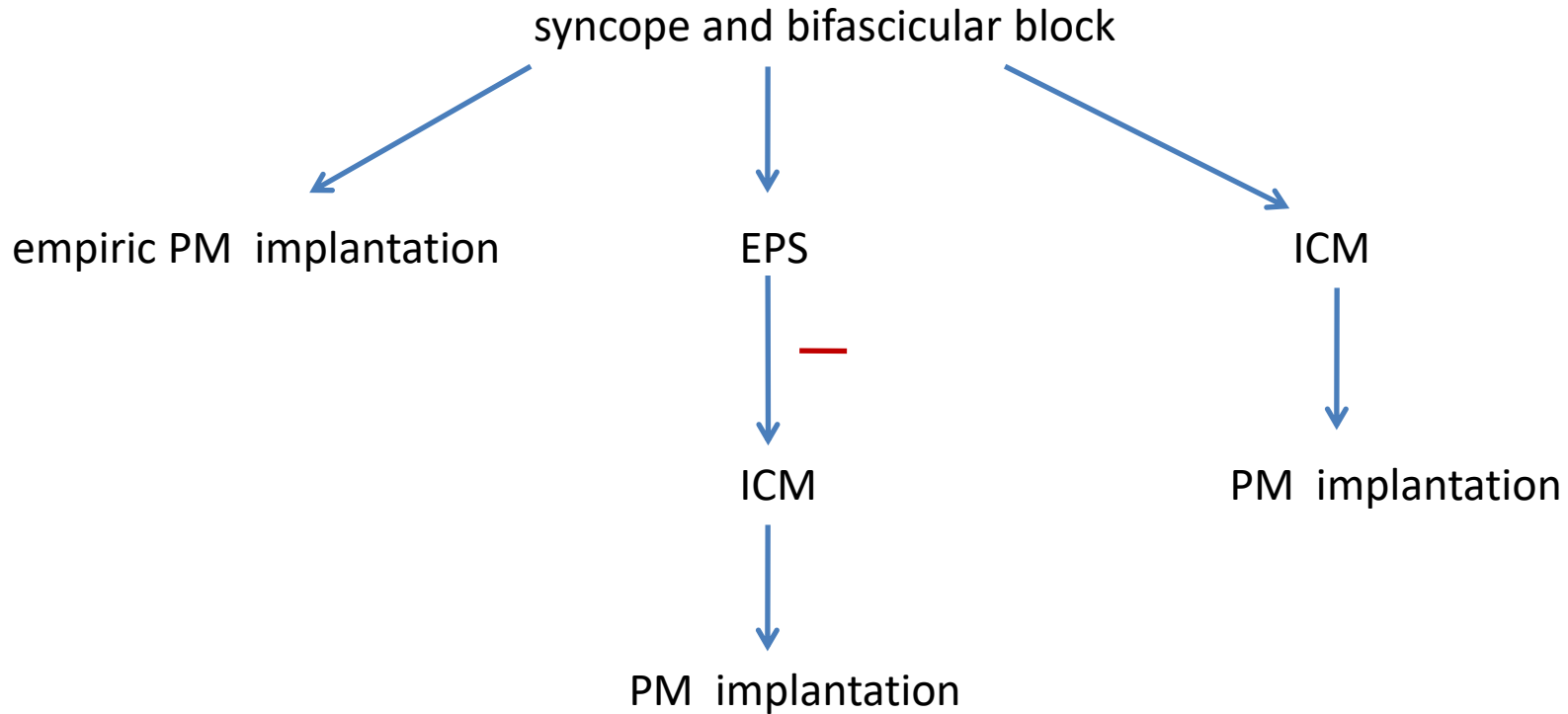
Dr. Ηλίας Θ. Ζάρβαλης
Διευθυντής ΕΣΥ
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Γ.Ν. "Παπαγεωργίου"
Θεσσαλονίκη

- **Bifascicular block** :left bundle branch block or right bundle branch block with anterior or posterior fascicular block
 - **prevalence** of 1–1.5% in an adult population
 - Up to **25%** of patients with BFB have a history of **syncope**
 - conservatively estimated **74 of 100 000 emergency visits per year** for patients with syncope and bifascicular block
 - **common cause** of syncope in this population is transient high-degree **AVB**
 - **median interval** of 11 months between the index syncopal episode and the documented high-degree AV block
 - the **intermittent nature** of this arrhythmia sometimes makes it difficult to document
- the progression to a **pacing indication was 44% in 2 years** (ISSUE study)

A standardized conventional evaluation of the mechanism of syncope in patients with bundle branch block



Uncertain optimal strategy

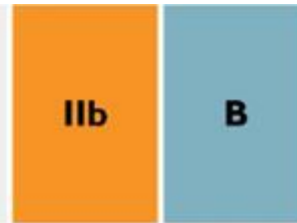


empiric PM implantation



ACC/AHA/ HRS Syncope Guideline 2017: PPM receives a **Class IIa** recommendation for syncope and bifascicular block in the absence of advanced AV block when other causes have been excluded

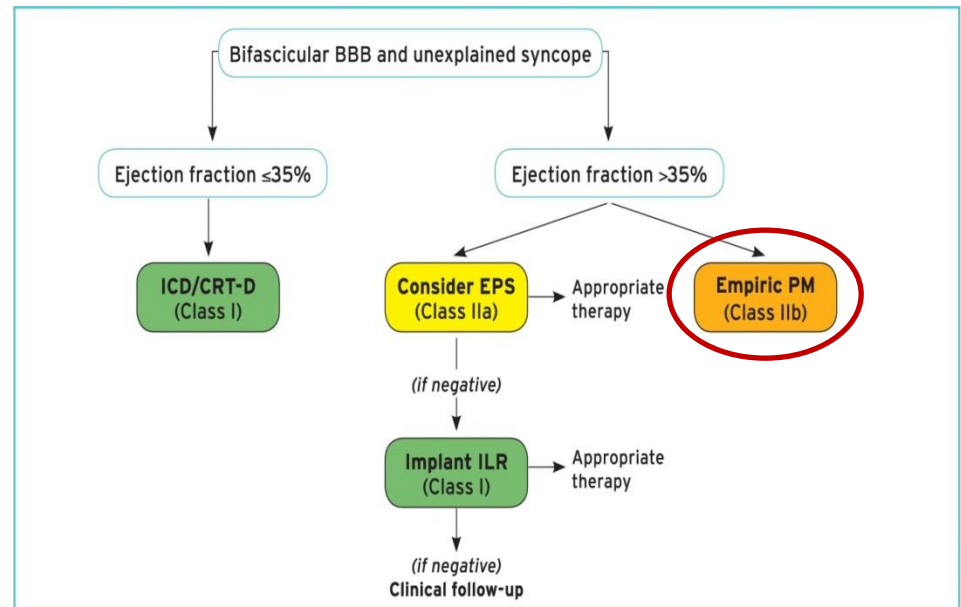
Pacing may be considered in selected patients with unexplained syncope and bifascicular block without EPS (elderly, frail patients, high-risk and/or recurrent syncope).²¹³



2021 ESC Guidelines on cardiac pacing

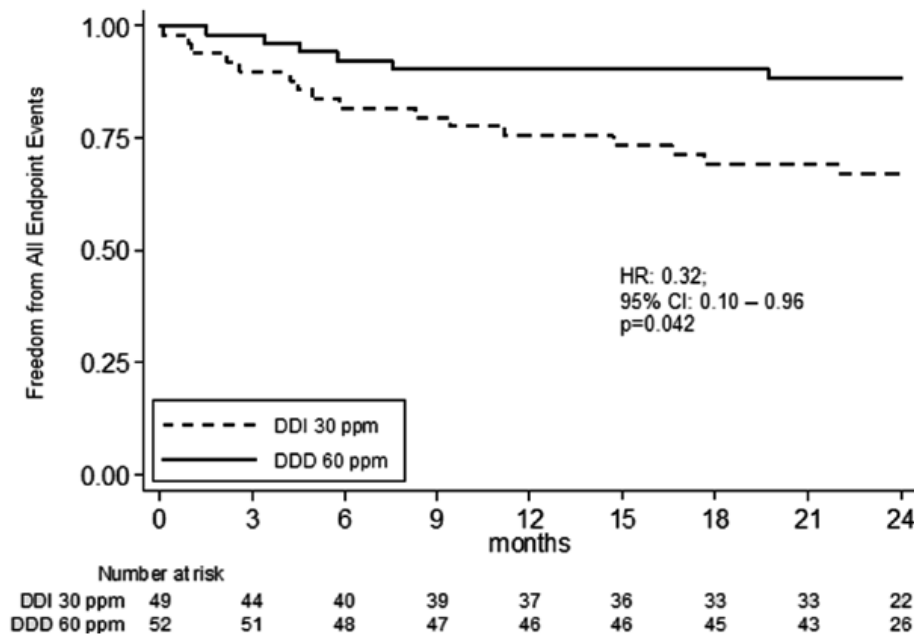


Eur Heart J, Volume 39, Issue 21, 01 June 2018



Prevention of Syncope Through Permanent Cardiac Pacing in Patients With Bifascicular Block and Syncope of Unexplained Origin

The PRESS Study



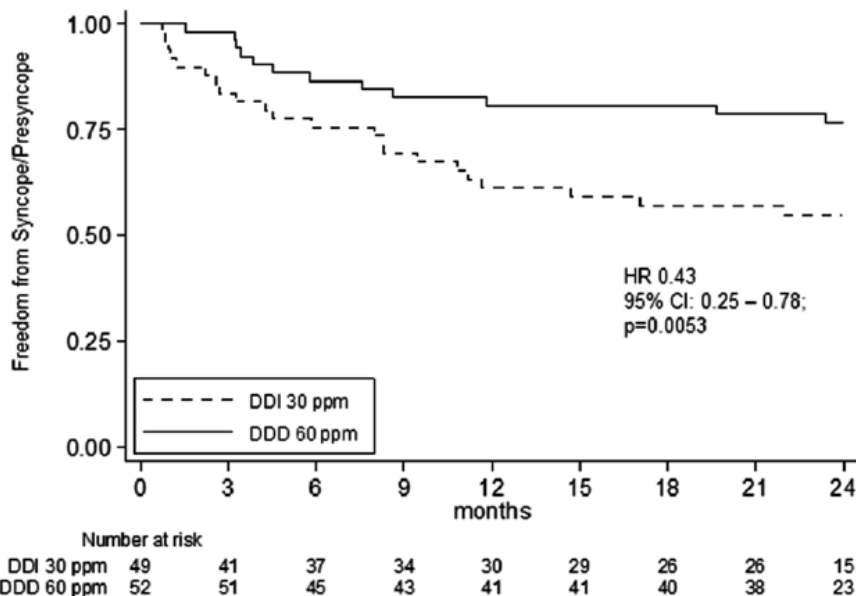
- 101 patients men age 77±8 y
- diagnostic criteria** used for the patients selection ECG, Holter, tilt table testing, and EPS
- The **end point** consisted of (1) syncope, (2) symptomatic presyncopal episodes associated with a device intervention (ventricular pacing), and (3) symptomatic episodes associated with intermittent or permanent atrioventricular block (any degree).

at 2 years

- The **composite primary end point** occurred in 23 22.8% patients
- 32.6% in the DDI30 group and 3.5% in DDD60 group (hazard ratio, 0.32 [0.10–0.96]; $P=0.042$).
- median time to event of 5.4 months
- [NNT]=5.23

Prevention of Syncope Through Permanent Cardiac Pacing in Patients With Bifascicular Block and Syncope of Unexplained Origin

The PRESS Study



- significant absolute 20% reduction of syncope recurrence (57% relative reduction rate) with cardiac pacing

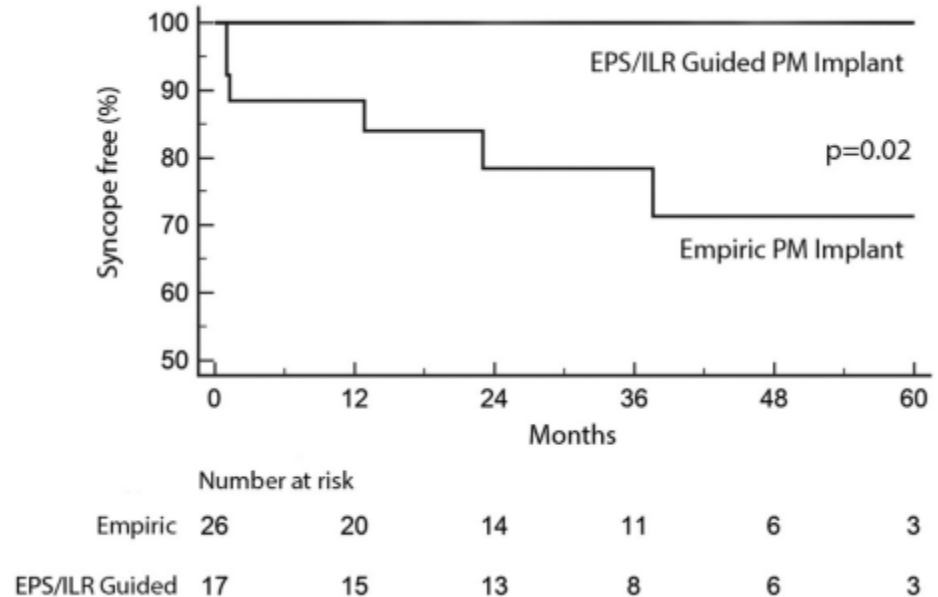
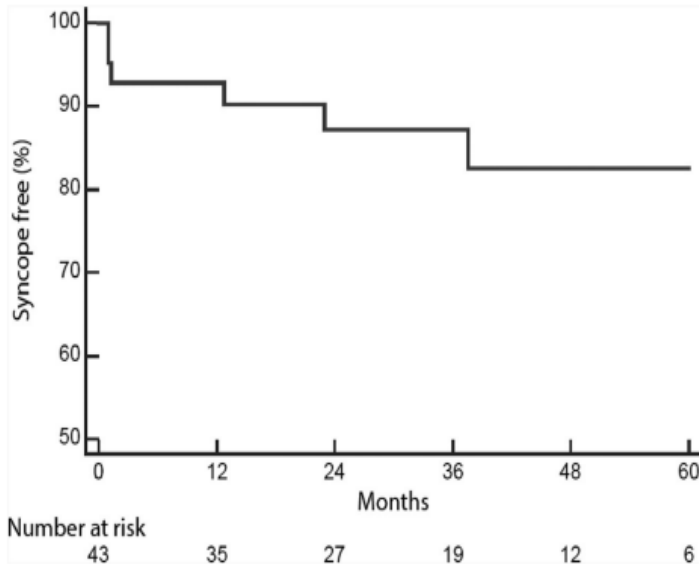
- **25% of patients were still at risk for recurrence**

- annual incidence of rhythm disease development was 7.4%.

- **a majority of patients did not have syncopal/pre-syncopal events or documented AV block during the 2 years of follow-up**

EPS : positive predictive value 80%

Long-Term Outcome of Patients with Bifascicular Block and Unexplained Syncope Following Cardiac Pacing



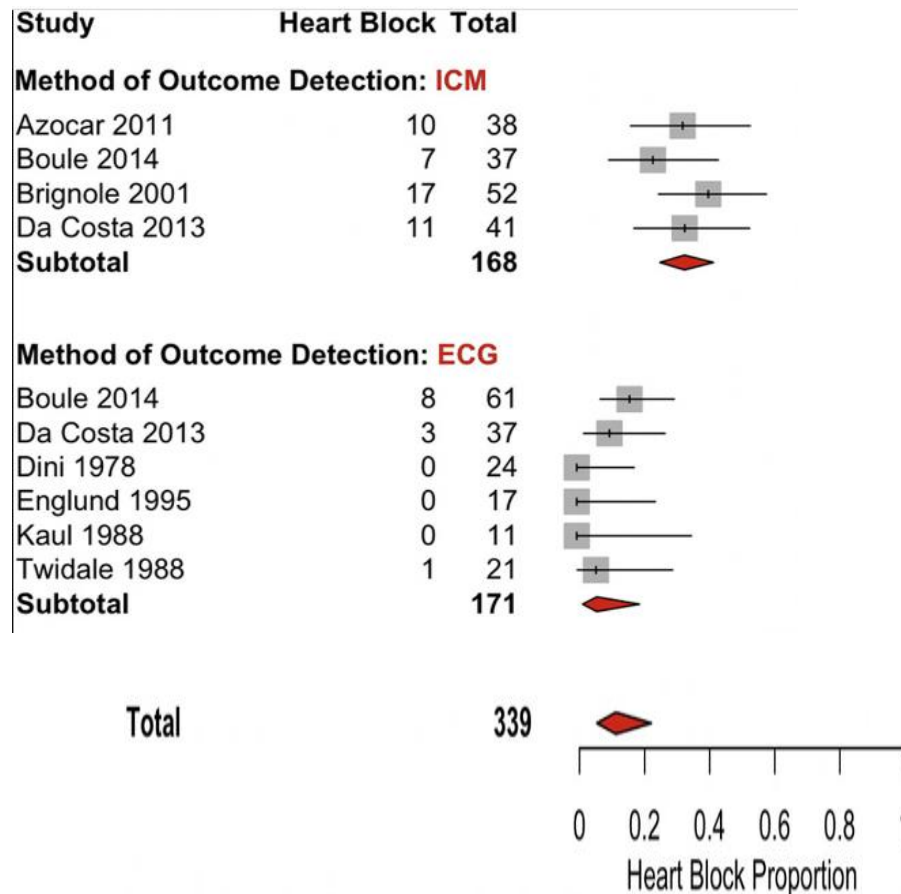
- recurrence rate of 27% over a mean follow-up of 31 months in patients who received empiric pacing

- Syncope recurrence was limited to patients who received empiric cardiac pacing

- To the contrary, pacing was highly effective in preventing syncope recurrence in patients who received a PM following a positive EPS or documentation of AVB during ILR monitoring

Electrophysiology studies for predicting atrioventricular block in patients with syncope: A systematic review and meta-analysis

R. Sheldon et al. August 2021 [Heart Rhythm](#)



- The **negative predictive value** of EPS in patients with syncope and bundle branch block is 0.71
 - The mean prespecified His-to-ventricle interval criterion was ≥ 70 ms.
- sufficiently low to question its use**
- ISSUE** : negative predictive value for EPS 58%

Electrophysiological study

In patients with syncope and bifascicular block, EPS should be considered when syncope remains unexplained after non-invasive evaluation or when an immediate decision about pacing is needed due to severity, unless empirical pacemaker implantation is preferred (especially in elderly and frail patients).

IIa

B



2021 ESC Guidelines on cardiac pacing

IIa

**B-
NR**

In patients with symptoms suggestive of intermittent bradycardia (e.g., lightheadedness, syncope), with conduction system disease identified by ECG and no demonstrated atrioventricular block, an EPS is reasonable

2018 ACC/AHA/HRS Guideline on the Evaluation and Management of Patients With Bradycardia and Cardiac Conduction Delay



Recommendations	Class ^a	Level ^b
In patients with unexplained syncope and bifascicular block, a pacemaker is indicated in the presence of either a baseline HV of ≥ 70 ms, second- or third-degree intra- or infra-Hisian block during incremental atrial pacing, or an abnormal response to pharmacological challenge. ^{119,120}	I	B



2021 ESC Guidelines on cardiac pacing

COR	LOE	Recommendations
I	C-LD	1. In patients with syncope and bundle branch block who are found to have an HV interval 70 ms or greater or evidence of infranodal block at EPS, permanent pacing is recommended

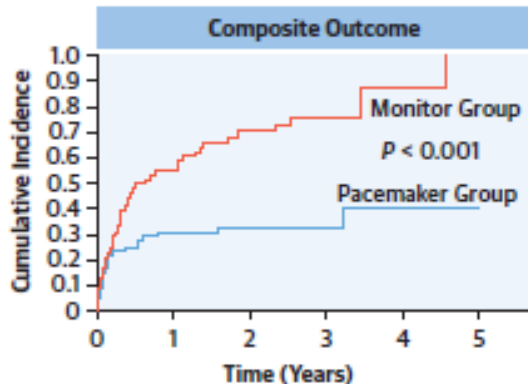
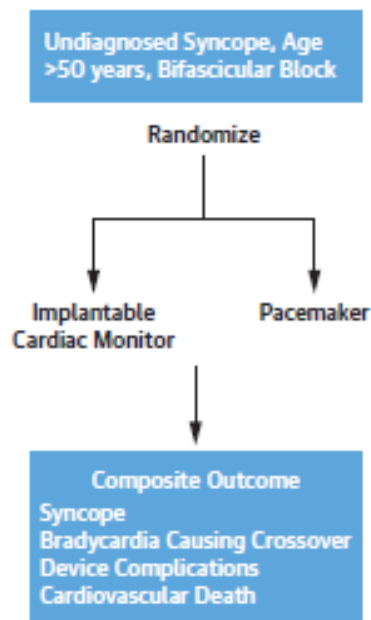
2018 ACC/AHA/HRS Guideline on the Evaluation and Management of Patients With Bradycardia and Cardiac Conduction Delay



Randomized Pragmatic Trial of Pacemaker Versus Implantable Cardiac Monitor in Syncope and Bifascicular Block

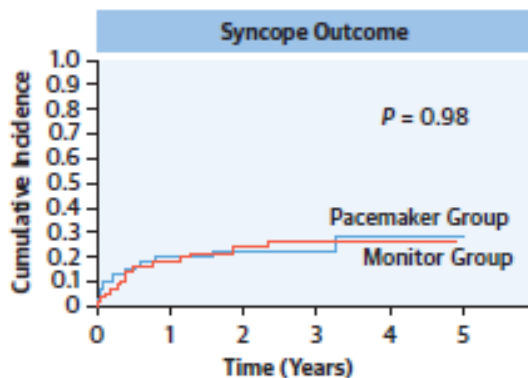
CENTRAL ILLUSTRATION Summary of Study Structure and Important Study Outcomes

Randomized Pragmatic Trial of Pacemaker Versus Implantable Cardiac Monitor in Syncope and Bifascicular Block



Number at risk

— Pacemaker	57	38	31	15	5	2
— Monitor	58	26	15	4	2	1



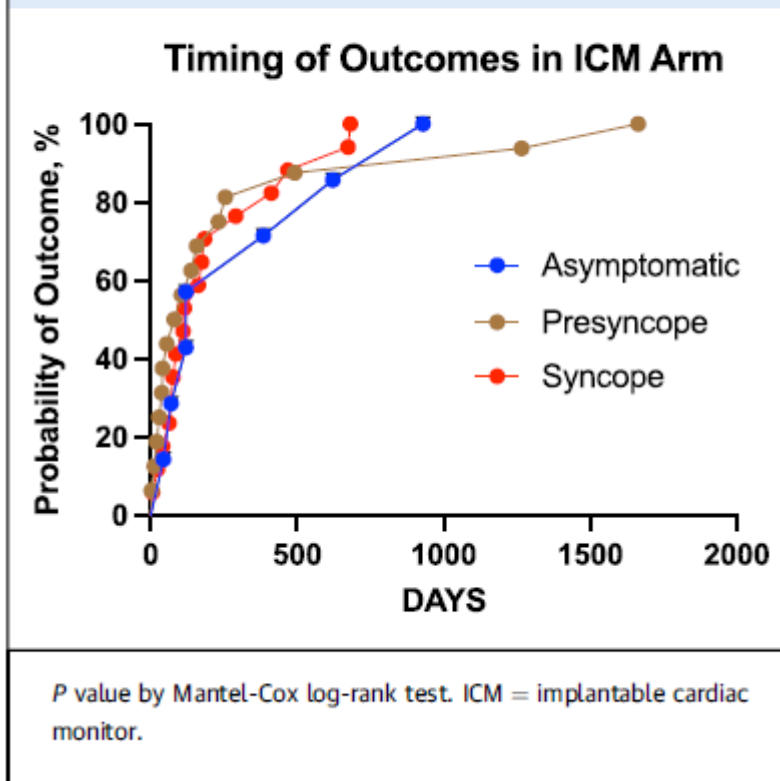
Number at risk

— Pacemaker	57	43	36	18	5	2
— Monitor	68	46	36	19	8	1

Summary

- All patients in ICM arm exited or crossed over to pacemaker
- Both strategies resulted in similar syncope outcomes
- Primary pacemaker implant reduces procedures at no cost to outcome rate

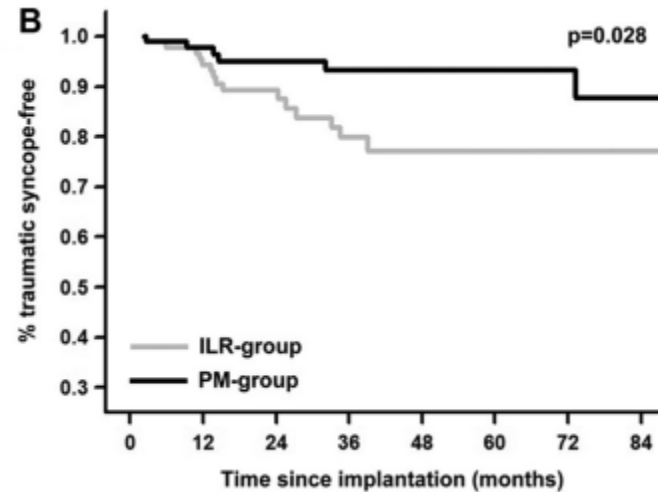
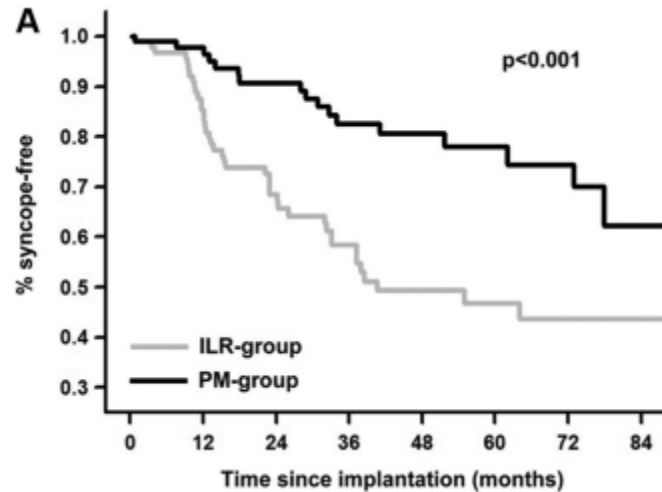
FIGURE 3 Cumulative Incidence of Composite Primary Outcomes in the ICM Arm According to the Nature of Symptoms



42 of 58 patients in the ICM subsequently received a pacemaker, and after accounting for exit events such as death and dementia, **all ICM patients received a pacemaker**

Management of older patients with unexplained, recurrent, traumatic syncope and bifascicular block: Implantable loop recorder versus empiric pacemaker implantation—Results of a propensity-matched analysis

TRAUMA registry



prospective, multicenter, observational study , median follow-up of **33 months**

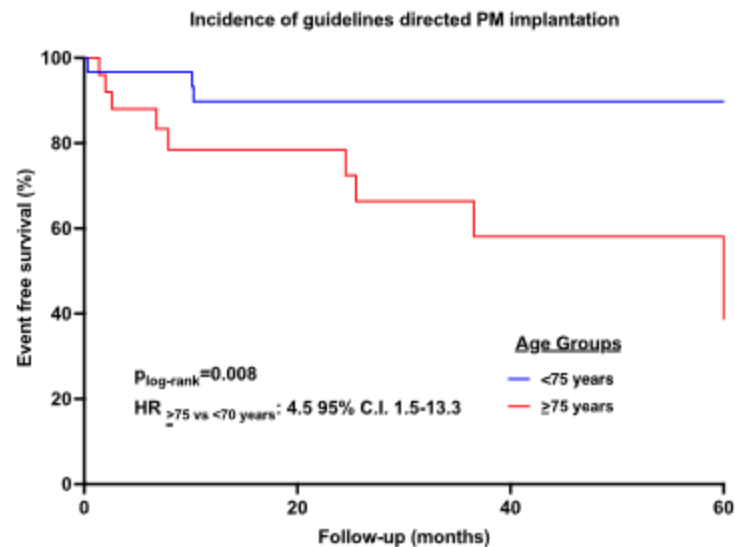
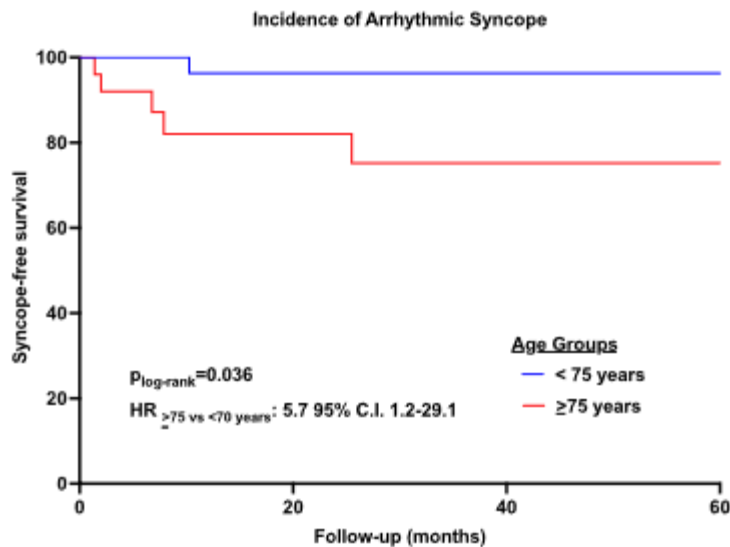
- **empiric PM implantation** was associated with a significantly **lower risk of syncope** recurrence than ILR monitoring (19.1 vs 46.1%; $P, .001$)

- A total of 35 patients (**39.3%**) who underwent ILR monitoring developed **bradyarrhythmias requiring PM implantation**

 - (68.6% paroxysmal AV block)

Low incidence of arrhythmic syncope and pacemaker implantation in older patients with bifascicular block and implantable cardiac monitor

Carlo Fumagalli ^{a,*}, Martina Rafanelli ^{a,1}, Michele Brignole ^{a,b}, Caterina Guarducci ^a, Niccolò Bettoni ^a, Giulia Rivasi ^a, Paolo Pieragnoli ^c, Giuseppe Ricciardi ^c, Luca Checchi ^c, Marco Gambardella ^c, Flavia Casolaro ^d, Giuseppe Paolisso ^{d,e}, Raffaele Marfella ^{d,e}, Giuseppe Signoriello ^f, Niccolò Marchionni ^a, Andrea Ungar ^a, Celestino Sardu ^d



- **syncope 36.3%**, 16.3%/year of patients

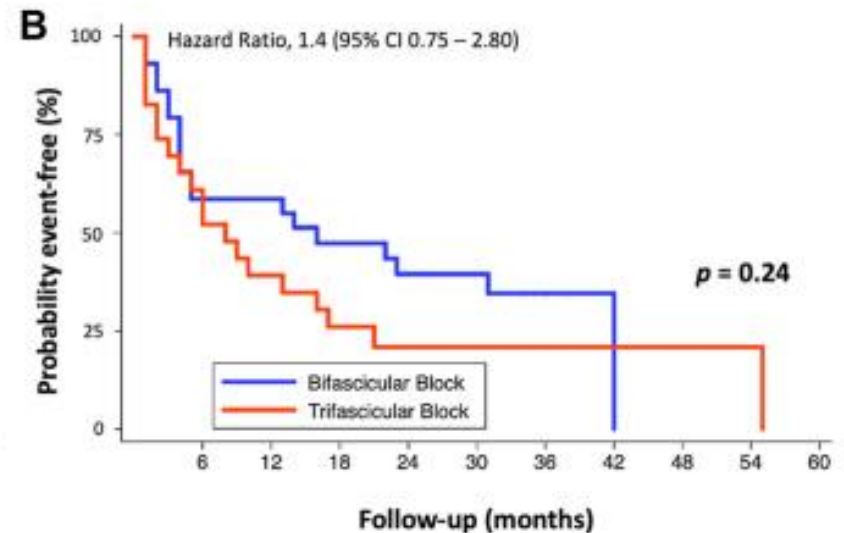
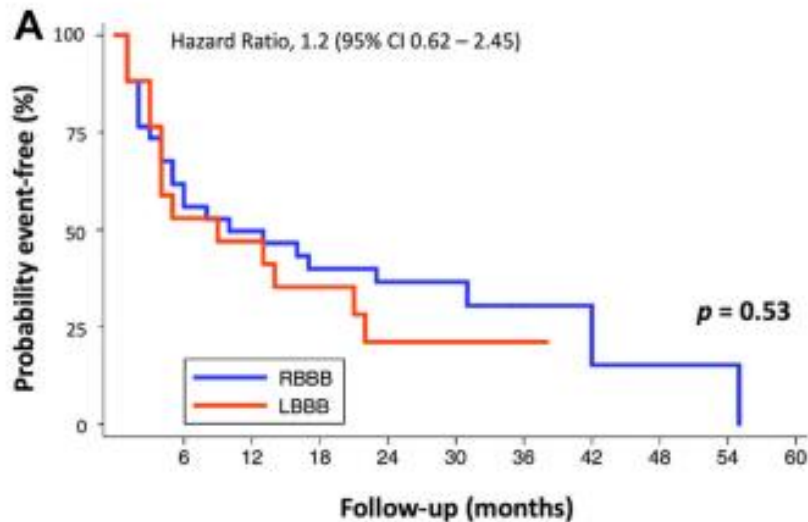
- **PM implantation 25.5%** of patients

- **age** was the strongest risk factor for **PM implantation, which was almost 5-times higher in patients ≥75 years**

- The mechanism of syncope in older patients with BFB is heterogeneous, non-arrhythmic in most of them.

- Early direct PM implantation, before ECG documentation of the mechanism, should be discouraged because of the high risk of ineffectiveness and, hence, of clinical futility.

Impact of bundle branch block morphology on outcomes of patients with syncope and bifascicular block: A SPRITELY (POST 3) substudy



A Cost-Utility Analysis of the Syncope: Pacing or Recording in The Later Years (SPRITELY) Trial

Summary of outcomes

Analysis	Cost: PM	Cost: ICM	QALYs: PM	QALYs: ICM	ICER
Trial evaluation (2-y time horizon)	\$9806	\$13,483	-0.021	-0.046	PM dominates
Decision analytic model (3-y time horizon)	\$9934	\$15,500	-0.031	-0.134	PM dominates

Costs are given in Canadian dollars.

Mark Hofmeister et al. CJC Open (2022)

ICM strategy resulted in a greater mean cost per participant

CONCLUSIONS

- **neither strategy is fully satisfactory**
- treatment of patients with syncope and bifascicular block will always be **individualized**.
- **shared decision-making and informed consent**

- **Empiric pacemaker**
 - often **fails to prevent syncope recurrence**, probably because the cause of syncope is a vasodepressor reflex and
 - **may be unnecessary**

- **EPS : low negative predictive value**

- The alternative approach **to wait and treat the results of an ICM** is also not satisfactory because
 - **most patients develop bradycardic episodes that leads to pacemaker insertion.**
 - may result in an **otherwise preventable syncopal spell**
 - it may be **costly**

- the diagnostic chain to exclude current class IA pacemaker indication **including EPS** is often **burdensome** to perform in current practice

CONCLUSIONS

- **Elderly, frail** patients with bifascicular block and unexplained syncope
- especially in **unpredictable and recurrent syncope** that exposes the patient to a **high risk of traumatic** recurrences might benefit from an **empirical pacemaker**
- **Younger patients** may benefit from **more targeted PM implantation (ICM ± EPS)** in terms of reducing recurrent syncopal episodes

