Gruppo Italiano Multidisciplinare per lo Studio della Sincope

Università degli Studi della Campania *Luigi Vanvitelli*

UNIVERSITÀ DEGLI STUDI FIRENZE

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

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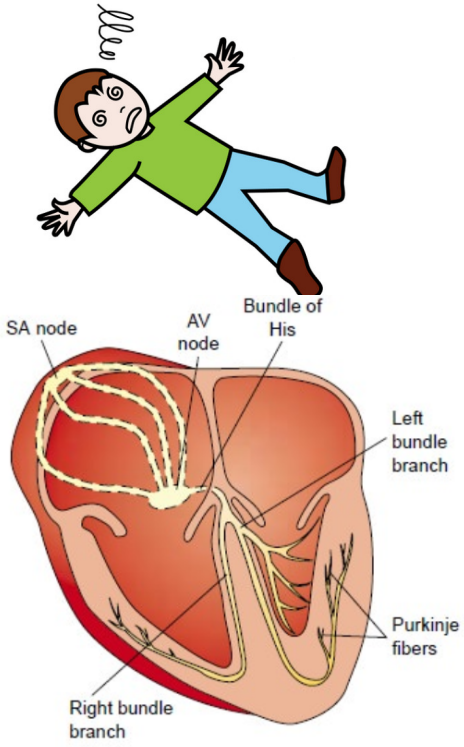
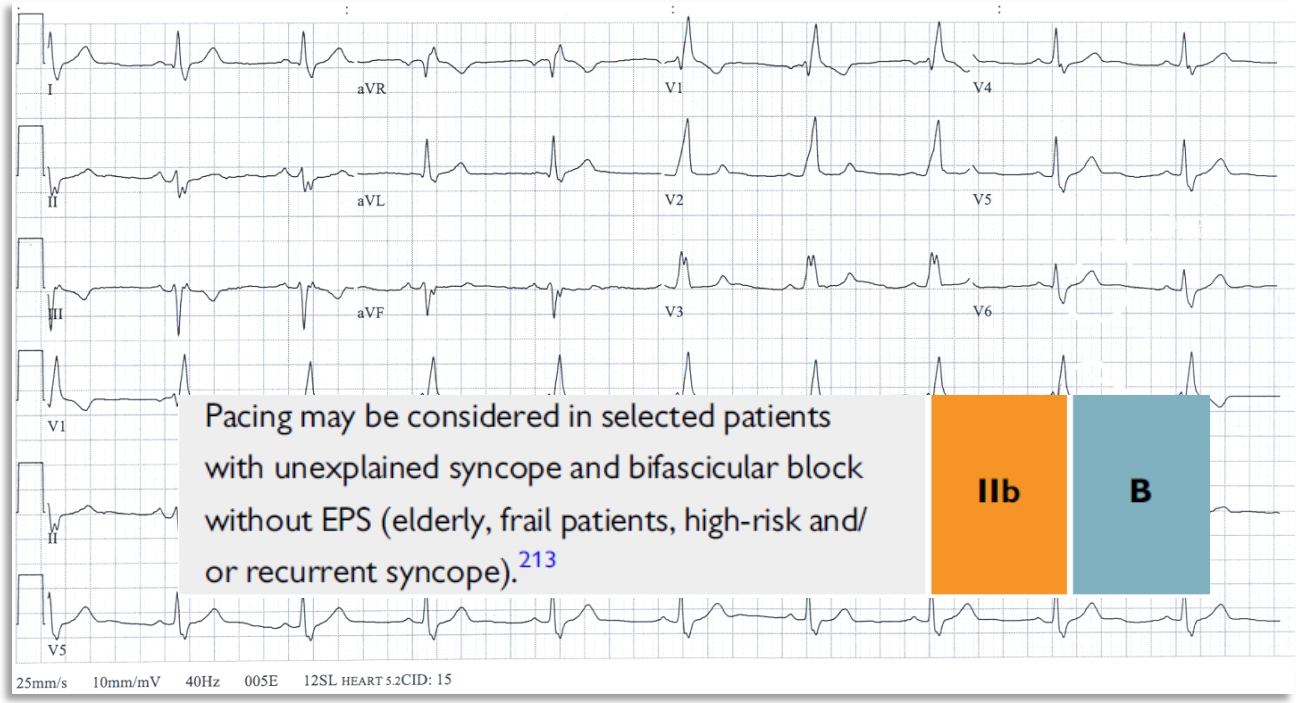
Il blocco bifascicolare e la sincope

Prevalenza del blocco bifascicolare: 1-1.5% degli individui adulti

1 individuo su 4 riferisce un episodio sincopale





1. Siegman-Igra, Y et al, *Am. Heart J.* **96**, 669–679 (1978).

2. Santini, M. *et al. Circ. Arrhythm. Electrophysiol.* **6**, 101–107 (2013).

Il blocco bifascicolare e la sincope

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

Robert Sheldon, MD, PhD,[a] Mario Talajic, MD,[b] Anthony Tang, MD,[c] Giuliano Becker, MD,[d] Vidal Essebag, MD, PhD,[e] Omar Sultan, MD,[f] Adrian Baranchuk, MD,[g] Debbie Ritchie, MN,[a] Carlos Morillo, MD,[a] Andrew Krahn, MD,[h] Michele Brignole, MD,[i] Braden Manns, MD, MSc,[a] Connor Maxey, BSc,[a] Satish R. Raj, MD, MSCI,[a] on behalf of the SPRITELY Investigators

CONCLUSIONS Empiric permanent pacing compared with ICM reduced major adverse events but not syncope in older patients with bifascicular block and recent syncope. There remains a substantial likelihood of syncope recurrence in patients who receive a permanent pacemaker likely caused by vasodepressor syncope. (Syncope: Pacing or Recording in the Later Years [SPRITELY]; NCT01423994) (J Am Coll Cardiol EP 2022;8:239–248) © 2022 by the American College of Cardiology Foundation.

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

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Conclusions: *We have shown that syncope recurs not infrequently in patients with BF-B who received pacing for syncope. Nearly one in four patients who had empiric pacing suffered syncope recurrence compared to no recurrences in patients who received a PM following a positive EPS or documentation of transient AVB. (PACE 2016; 39:1126–1131)*

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

RESULTS A total of 309 consecutive patients (age 77.2 ± 12.2 years; 60.8% male) were enrolled. Propensity matching yielded 89 matched pairs. After 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 (68.6% paroxysmal AV block) requiring PM implantation during follow-up. Excluding bradyarrhythmic syncope, the most frequent causes of syncope recurrence in both study groups were reflex syncope and orthostatic hypotension.

CONCLUSION In patients with unexplained, recurrent, traumatic syncope and BFB, empiric PM implantation significantly reduced the risk of syncope recurrence in comparison with ILR monitoring. A high rate of patients who underwent ILR monitoring developed bradyarrhythmias requiring PM implantation.

Palmisano et al, Heart Rhythm 2022

Study Purpose and Methods

Purpose

The real impact of aging on syncope recurrence in patients with BFB is still debated. Therefore, we evaluated the association of age with PM indication in patients with BFB referred for implantable cardiac monitoring (ICM).

Methods

Study design: Multicenter, retrospective, observational cohort study performed in two referral centers for syncope and ICM implantation.

We reviewed the clinical records of consecutive patients with BFB referred for ICM at Careggi University Hospital, Florence, Italy and Department of Advanced Medical and Surgical Sciences, University of Campania Luigi Vanvitelli, Naples, Italy, from January 2012 to December 2020.

Inclusion Criteria:

- ≥2 clinical visits,
- an ICM monitoring with >1-year follow-up and
- age ≥18 years.

Exclusion Criteria:

Patients with left ventricular ejection fraction <35%, indication for PM/ICD implantation, incomplete follow-up and with moderate-to-severe cognitive impairment at baseline, were excluded.

Study Endpoints

Outcomes

The primary study outcome was the incidence of a Class I indication to PM implantation:

- spontaneous documented symptomatic asystolic pause >3s
- or asymptomatic pause >6s due to sinus arrest or AVB;
- symptomatic patients with bradycardia-tachycardia form of sinus node dysfunction;
- patients with atrial arrhythmia and third- or high-degree AVB

Definition of BFB

BFB was defined as QRS duration >120ms and left bundle branch block (LBBB), or right bundle branch block (RBBB) and a left fascicular anterior block (LFAB) or left posterior hemiblock (LPB), or any two of three single fascicular blocks documented at different times.

Definition of syncope

- Arrhythmic: due to sinus arrest or sinoatrial block with asystole, bradycardia, alternating bundle branch block, complete AV block AV block, 2:1 AV block AV block, slow ventricular response atrial fibrillation, ventricular tachycardia
- Non-arrhythmic: none of the above - episode were classified as presumed reflex or hypotensive.

Devices

Medtronic

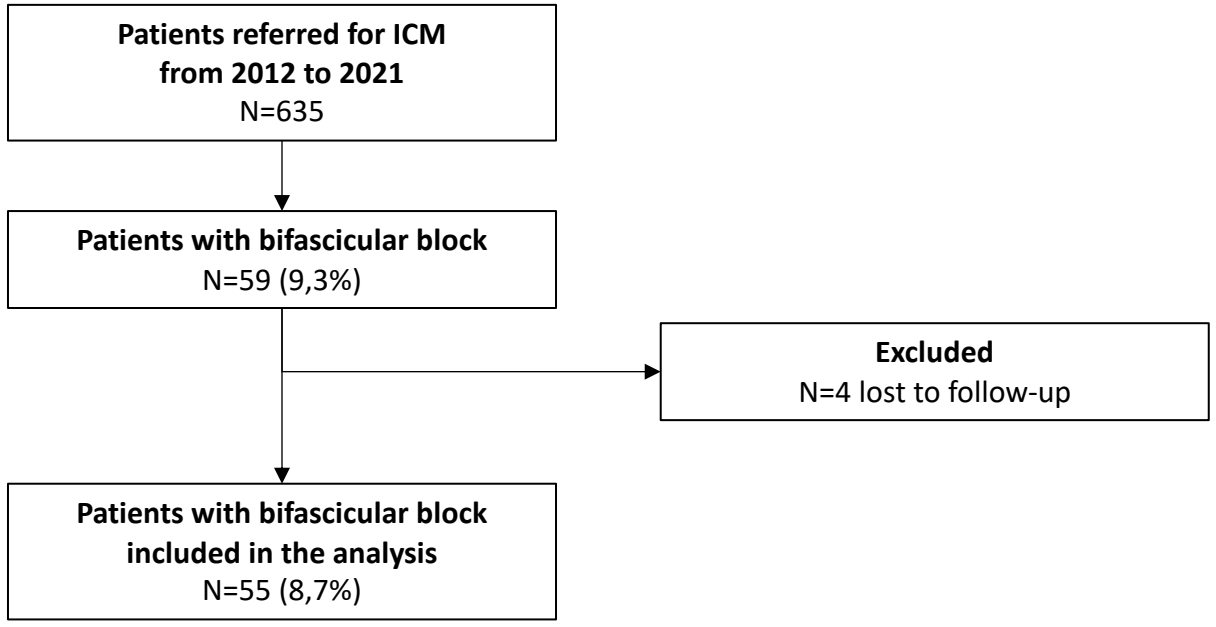
Reveal LINQ

Reveal XT

BIOTRONIK
excellence for life

ST. JUDE MEDICAL

Study Results

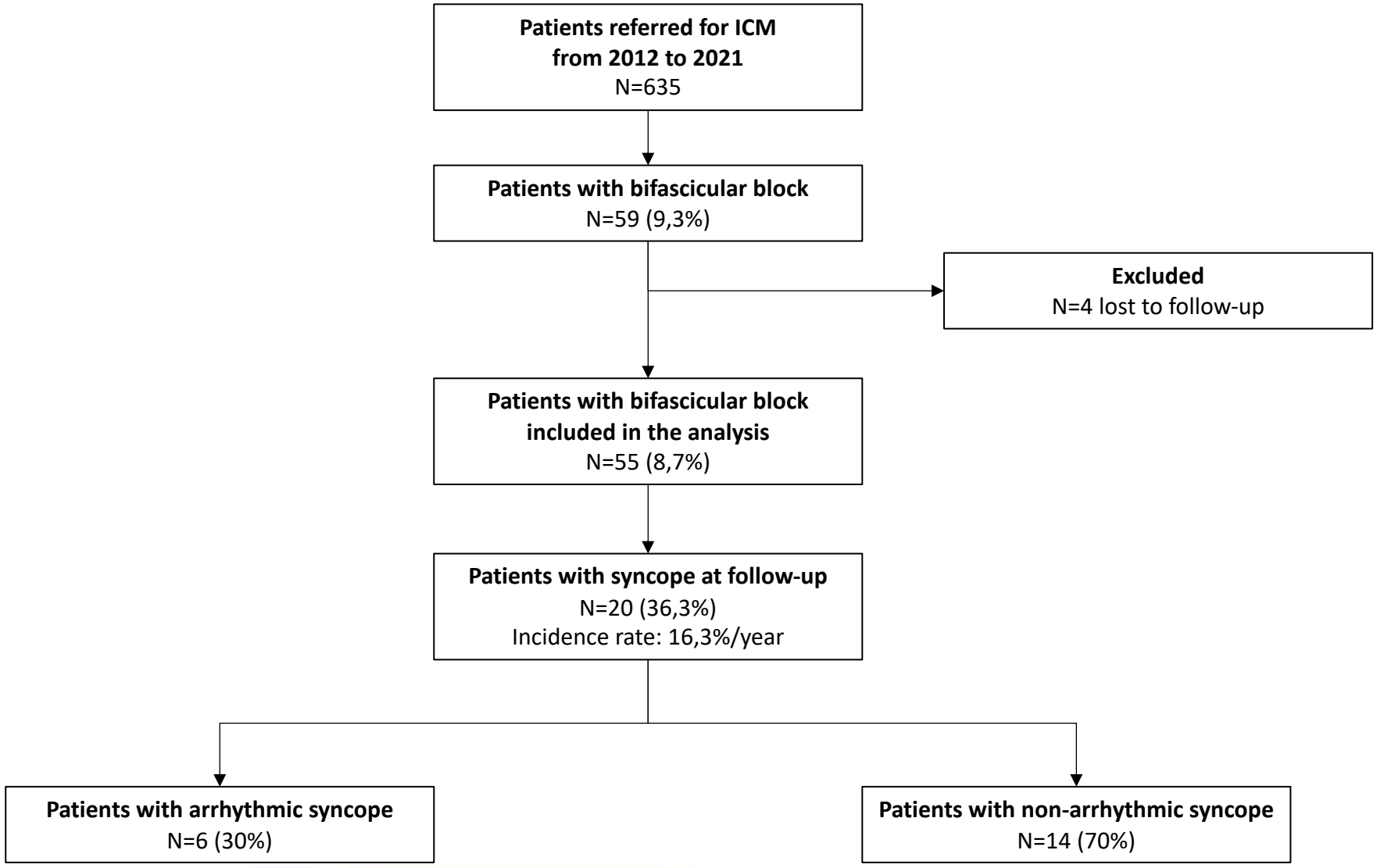


Study Results

	Total group (N=55)	Age subgroups <75 years (N=30)	Age subgroups ≥75 years (N=25)	P
Age, median [IQR], years	75 [64-81]	66 [49-72]	81 [79-85]	<0.001
Women, N (%)	27 (49.1)	2 (28.6)	14 (50.0)	0.876
Number of syncope episodes	2 [1-4]	3 [1-4]	2 [1-2]	0.744
Comorbidities, N (%)				
Hypertension	31 (56.4)	12 (40.0)	19 (76.0)	0.007
Atrial Fibrillation	16 (29.1)	6 (20.0)	10 (40.0)	0.104
Cancer (non-active)	13 (23.6)	5 (16.7)	8 (32.0)	0.183
Stroke/Transient Ischemic Attack	11 (20.0)	5 (16.7)	6 (24.0)	0.498
Diabetes Mellitus	8 (14.5)	5 (16.7)	3 (12.0)	0.625
Ischemic Heart Disease	7 (12.7)	2 (6.7)	5 (20.0)	0.373
LVEF<50%	7 (12.7)	3 (10.0)	4 (16.0)	0.678
Pharmacological therapy, N (%)				
ACEi/ARBs	32 (58.2)	12 (40.0)	20 (80.0)	<0.001
Calcium Channel Blockers	6 (10.9)	1 (3.3)	5 (20.0)	0.048
Beta-blockers	12 (21.8)	6 (20.0)	6 (24.0)	0.721
Alpha-1 antagonists	8 (14.5)	5 (16.7)	3 (12.0)	0.625
Diuretics	12 (21.8)	5 (16.7)	7 (28.0)	0.311
Nitrates	1 (1.8)	0 (0.0)	1 (4.0)	0.269
Antiarrhythmic Drugs	5 (9.1)	3 (10.0)	2 (8.0)	0.493
Oral Anticoagulants	5 (9.1)	2 (6.7)	3 (12.0)	0.650
Antiplatelet	29 (52.7)	13 (43.3)	16 (64.0)	0.127
Selective serotonin reuptake inhibitors	10 (18.2)	2 (6.7)	8 (32.0)	0.015
Serotonin and norepinephrine reuptake inhibitors	4 (7.3)	1 (3.3)	3 (12.0)	0.320
Benzodiazepines	8 (14.5)	2 (6.7)	6 (24.0)	0.069

	Total group (N=55)	Age subgroups <75 years (N=30)	Age subgroups ≥75 years (N=25)	P
Clinical evaluation upon 1st visit				
Systolic blood pressure, mmHg (median [IQR])	131 [121-150]	134 [122-150]	130 [116-139]	0.157
Diastolic blood pressure, mmHg (median [IQR])	75 [69-82]	79 [75-86]	70 [62-81]	0.211
Orthostatic Hypotension, N (%)	13 (23.6)	4 (13.3)	9 (36.0)	0.049
Right Bundle Branch Block + Left Anterior Hemiblock, N (%)	33 (60.0)	18 (60.0)	15 (60.0)	0.999
Left Bundle Branch Block, N (%)	22 (40.0%)	12 (40)	10 (40.0)	
Events at follow up				
Overall follow-up, median [IQR]), months	26 [12-41]	30 [12-47]	25 [7-39]	0.091

Study Results



Events at follow-up

	Total group (N=55)	Age subgroups <75 years (N=30)	Age subgroups ≥75 years (N=25)	P
Death, N (%)	2 (3.6)	0 (0.0)	2 (8.0)	0.115
Syncope, N (%)	20 (36.1)	10 (33.3)	10 (40.0)	0.690

Events at follow-up

	Total group (N=55)	Age subgroups <75 years (N=30)	Age subgroups ≥75 years (N=25)	P
Death, N (%)	2 (3.6)	0 (0.0)	2 (8.0)	0.115
Syncope, N (%)	20 (36.1)	10 (33.3)	10 (40.0)	0.690
Associated with an arrhythmic episode N (%)	6 (10.9)	1 (3.3)	5 (20.0)	0.048
Not associated with an arrhythmic episode, N (%)	14 (25.5)	9 (30.0)	5 (20.0)	0.397

Events at follow-up

	Total group (N=55)	Age subgroups <75 years (N=30)	Age subgroups ≥75 years (N=25)	P
Death, N (%)	2 (3.6)	0 (0.0)	2 (8.0)	0.115
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Not associated with an arrhythmic episode, N (%)	14 (25.5)	9 (30.0)	5 (20.0)	0.397
Presumed Vasovagal or Reflex Syncope*, N (%)	14 (25.5)	8 (26.7)	6 (24.0)	0.916
Associated with an arrhythmic episode N (%)	3 (5.5)	1 (3.3)	2 (8.0)	
Not associated with an arrhythmic episode, N (%)	11 (20.0)	7 (23.3)	4 (16.0)	

Events at follow-up

	Total group (N=55)	Age subgroups <75 years (N=30)	Age subgroups ≥75 years (N=25)	P
Death, N (%)	2 (3.6)	0 (0.0)	2 (8.0)	0.115
Syncope, N (%)	20 (36.1)	10 (33.3)	10 (40.0)	0.690
Associated with an arrhythmic episode N (%)	6 (10.9)	1 (3.3)	5 (20.0)	0.048
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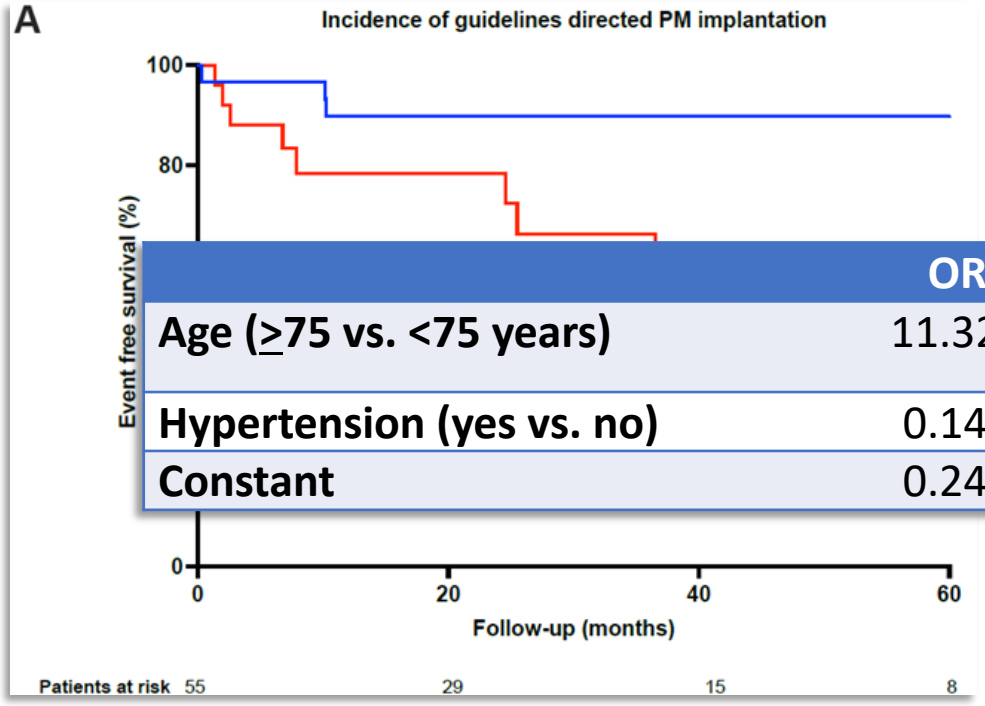
Presumed Vasovagal or Reflex Syncope*, N (%)	14 (25.5)	8 (26.7)	6 (24.0)	0.916
Associated with an arrhythmic episode N (%)	3 (5.5)	1 (3.3)	2 (8.0)	
Not associated with an arrhythmic episode, N (%)	11 (20.0)	7 (23.3)	4 (16.0)	
Pacemaker implantation, N (%)	14 (25.5)	4 (13.3)	10 (40.0)	0.024
Due to arrhythmia associated with syncope, N (%)	6 (10.9)	2 (6.7)	4 (16.0)	
Due to arrhythmia associated with pre-syncope or in asymptomatic patients, N (%)	8 (14.5)	2 (6.7)	6 (24.0)	

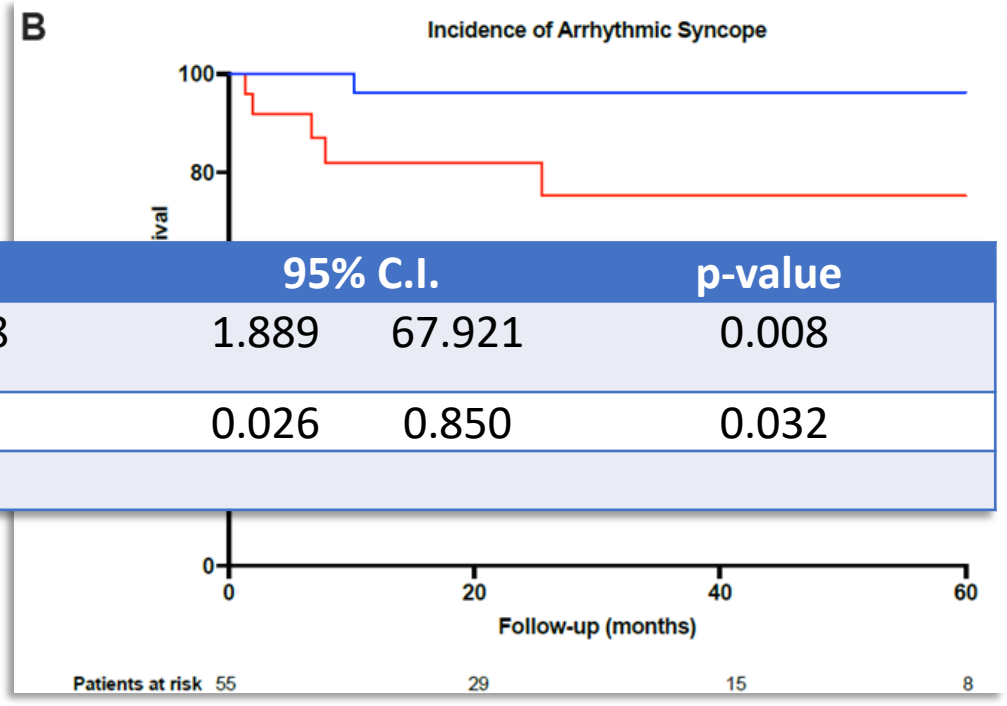
ACEi: angiotensin converting enzyme inhibitors; ARBs: angiotensin receptor blockers; LVEF: left ventricular ejection fraction; N: number. *: p<0.05 (as statistically significant) vs. <75 years old.

Arrhythmic events recorded during long-term monitoring

	Patients without syncope (N=35)	Patients with brady-arrhythmic syncope (N=6)	Patients with presumed vasovagal or reflex syncope (N=14)
Sinus arrest and bradycardias, N (%)	7 (20.0)	5 (83.3)	3 (21.4)
Complete AV block, N (%)	3 (8.6)	2 (33.3)	0
Alternating bundle branch block, N (%)	4 (11.4)	0	0
Ventricular Tachycardia, N (%)	1 (2.9)	1 (16.7)	0
2:1 atrioventricular block, N (%)	1 (2.9)	0	0
Slow atrial fibrillation, N (%) (Heart rate < 60 beats/minute)	0 (0.0)	1 (16.7)	0
Note: events are not mutually exclusive.			

Arrhythmic events recorded during long-term monitoring





	OR	95% C.I.		p-value
Age (≥75 vs. <75 years)	11.328	1.889	67.921	0.008
Hypertension (yes vs. no)	0.148	0.026	0.850	0.032
Constant	0.248			

Conclusions

- In our study, **36% of patients with BFB experienced syncope** but only **11% were referred for PM** implantation; a further 15% of patients were referred for PM implantation for pre-syncopal or asymptomatic arrhythmic episodes.

- Overall, **25%** of patients presented with **brady-arrhythmic episodes** without **any correlation with syncope or pre-syncope**.

- **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**, being non-arrhythmic in most of them. Our findings support that **older patients should be managed through a multiparametric approach**, which includes prolonged cardiac monitoring and a careful assessment of non-cardiac causes of syncope.

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