

dysfunction with RV pacing is patient specific and therapy needs to be individualized.

## Implanted Pacemakers With DDD60 Pacing Superior to DDI30 Pacing for BFB

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For patients with the conduction disturbance bifascicular block (BFB) and syncope of unexplained origin, an implanted pacemaker programmed at DDD60 pacing is superior to DDI30 pacing in reducing syncopal episodes and other symptomatic events regardless of their cause.

Massimo Santini, MD, S. Filippo Neri Hospital, Rome, Italy, presented the results of the prospective multicenter Prevention of Syncope by Cardiac Pacing in Patients With Bifascicular Block trial [PRESS; Santini M et al. *Circ Arrhythm Electrophysiol* 2013]. This randomized clinical trial evaluated the efficacy of antibradycardic pacing on symptoms in patients with BFB and syncope of unexplained origin.

The study included 101 patients with BFB and ≥1 episode of syncope within the 6 months before study enrollment. Patients with a dual-chamber permanent pacemaker were randomly assigned to treatment (DDD pacing mode with a lower rate limit of 60 ppm [DDD60]; n=52) or control (backup DDI pacing mode with a lower rate limit of 30 ppm [DDI30]; n=49).

All patients in the study had an ejection fraction  $\ge 40\%$  and a mean nocturnal heart rate  $\ge 35$  bpm. Preenrollment screening excluded patients with brady-tachy syndrome, vasovagal syncope, carotid sinus syndrome, atrial fibrillation, and inducible atrioventricular (AV) block. Patients were followed for 2 years, with follow-up at 1 month and then ambulatory follow-up every 3 months to collect clinical and device data.

The primary end point was the first occurrence of the composite of syncope of any origin, presyncopal episode with documented cardioinhibitory origin, or AV block of any degree associated with patient symptoms.

A primary endpoint occurred in 23 patients (22.8%) of the total population at 2 years. In the DDD60 group, 7 (13.5%) patients had a primary end point event compared with 16 (32.6%) in the DDI30 group (HR, 0.32; 95% CI, 0.10 to 0.96; p=0.042). Evaluation of the individual components of the endpoint was notable for significant reductions in presyncope and symptomatic AV block but not in syncope (Table 1). According to Prof. Santini, the lack of a significant difference in episodes of syncope could be due to the vasodepressor syncope, hypotension

from a noncardiac etiology (eg, excessive medications, postural orthostasis), or a neurologic issue not detected at preenrollment testing. He said that it is reasonable to hypothesize that patients with cardioinhibitory episodes experience most of the presyncope symptoms.

Table 1. Incidence of the Primary End Points Components With DDD60 and DDI30 Pacing, n (%)

	Total	DDI30	DDD60	p Value
Syncope	14 (13.9)	7 (14.3)	7 (13.5)	0.89
Presyncope	22 (21.8)	16 (32.6)	6 (11.5)	<0.001
Symptomatic AV block	10 (9.9)	8 (16.3)	2 (3.8)	<0.001

AV=atrioventricular.

The secondary end points were first occurrence of a symptomatic episode of syncope or presyncope of any origin, symptoms associated with rhythm disease progression, and AF. At 2 years, 14.8% of the total study population had developed symptoms associated with new-onset heart rhythm disease (Table 2).

Table 2. Secondary Outcomes in the PRESS Study

	Population, n (%)					
Outcome	Total	DDD60	DDI30	HR	CI	p Value
First symptomatic syncope/ presyncope event	35 (34.6)	13 (25)	22 (44.9)	0.43	0.25- 0.78	0.0053
First symptoms of rhythm disease progression	15 (14.8)	3 (5.8)	12 (24.5)	0.21	0.09- 0.50	0.0004
First occurrence of atrial fibrillation	27 (26.7)	18 (34.6)	9 (18.4)	2.25	0.81- 6.23	0.117

Among the limitations of the study are the inability of the implanted pacemakers to detect all events with a cardioinhibitory origin and its being single-blinded. Strengths include the inclusion of a highly selected, screened patient population and the frequent assessments throughout the study.

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