Impact of dual-chamber pacing with closed loop stimulation on quality of life in patients with recurrent reflex vasovagal syncope: results from the SPAIN study

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On behalf: Spanish Syncope Study Group

Topic(s):
Pacemaker Therapy

Citation:
Background: Reflex vasovagal syncope (VVS) is one of the most common causes of syncope and, when recurrent, can have devastating consequences on the quality of life of patients despite pharmacological interventions. The closed loop stimulation (CLS) pacing algorithm converts, during an incipient VVS, variations in right intracardiac impedance into heart rate adaptation. The study SPAIN was the first randomized, double-blind trial robustly showing a strong reduction in syncopal recurrence in patients paced with dual-chamber (DDD)-CLS. (NCT01621464).

Purpose:To evaluate whether the differences observed in the SPAIN study regarding syncope burden and time to recurrence translate into improvements on quality of life.

Methods:This study analysed quality of life data from the SPAIN study: a randomized, prospective, double-blind, multicenter trial conducted in 10 Spanish and 1 Canadian centers. Ethics Committee approval was obtained at each participating center. Patients aged ≥40 years, with ≥5 VVS episodes and cardioinhibitory response to head-up tilt testing were included. After implant, patients were randomized 1:1 to active DDD-CLS mode for 12 months followed by sham DDI mode for the remaining 12 months or vice-versa. Quality of life was assessed via the Short Form-36 (SF-36) health survey before randomization (baseline), and at 12- and 24-month follow-up. The change in quality of life during the entire follow-up relative to baseline was compared between each pacing mode (DDD-CLS vs. DDI).

Results:Fifty-four patients were enrolled with a mean age of 56.3 ±10.6 years and a median of 12 syncopal episodes before randomization. Median SF-36 scores greatly increased from baseline in the DDD-CLS group across the 8 domains, whereas the response was variable in the DDI group. Comparing both pacing algorithms, median SF-36 scores were higher in the DDD-CLS group, with differences reaching statistical significance for ‘physical role’ and ‘vitality’ domains (p-value =0.006 and 0.014, respectively). Pacing sequence or treatment period did not significantly influence the response (p-value >0.05 for all the domains).

Conclusions:We demonstrated the beneficial effect of this physiological pacing algorithm on the quality of life of patients, as evidenced by the improvement in all the domains of the SF-36 when stimulated in DDD-CLS as compared to the sham DDI mode.