



COLUMBIA UNIVERSITY MEDICAL CENTER

DIVISION OF GENERAL MEDICINE

Senior Medicine Rotation: Evidence-Based Medicine Project

Sub-Intern Name: Magni Hamso **Block:** June **Date:** June 26, 2009

Case SIGNOUT:

86yo woman with HTN, hyperlipidemia, progressive dementia, and a long history of falls, admitted with syncope. She was in her USOH, defined as independent in her ADLs and living alone w/ a 6h/day HHA, until the DOA when she was visiting her sister at a NH and suddenly lost consciousness. When she regained consciousness she found herself on the ground surrounded by medical staff. She denied hitting her head, tongue bite or confusion, but did lose urine. She denied HA, CP, palpitations, N/V, or poor appetite. Prodromal symptoms included lightheadedness and blurry vision. When EMS arrived, she had an SBP in the 80s, which increased to the 110s with IVFs. Admission exam was unremarkable, with a normal CXR and unchanged EKG. On parallel history from her niece, the pt has a 15-yr history of falls and syncopal events that have been extensively worked up at an OSH and were ultimately labeled vasovagal.

Clinical Question: *Can pacemaker implantation reduce the risk of syncope and falls among elderly patients with neurocardiogenic syncope?*

Search Strategy

Database: Ovid Medline <1950 to June Week 2 2009>

- P: 1: exp Syncope, Vasovagal/
2: carotid sinus hypersensitivity.mp.
3: neurocardiogenic syncope.mp
4: 1 or 2 or 3 (1,413)
- I: 5: exp Pacemaker, Artificial/ or exp Cardiac Pacing, Artificial/ (33,369)
- C:
- O: 6: exp Recurrence/ or recurrence of syncope.mp.
7: exp Accidental Falls/ or falls.mp.
8: 6 or 7 (152,597)
9: 4 and 5 (229)
10: 4 and 5 and 8 (67)
11: limit 10 to randomized controlled trial (17)
12: limit 11 to core clinical journals (aim) (5)

Of the five articles that were then reviewed, one was a commentary. Of the four that described randomized clinical trials, VPS II was not only the most recent trial but also the only one that was randomized and double-blinded.

Authors Connolly SJ, Sheldon R, Thorpe KE, Roberts RS, Ellenbogen KA, Wilkoff BL, Morillo C, Gent M.
**Pacemaker therapy for prevention of syncope in patients with recurrent vasovagal syncope:
Second Vasovagal Pacemaker Study (VPS II): a randomized trial.**

Source JAMA. 289(17): 2224-9, 2003 May 7.

Authors Kenny RA. Richardson DA. Steen NA. Bexton RS. Shaw FE. Bond J.

Carotid sinus syndrome: a modifiable risk factor for nonaccidental falls in older adults (SAFE PACE).

Source Journal of the American College of Cardiology. 38(5): 1491-6, 2001 Nov. 1

Authors Sutton R. Brignole M. Menozzi C. Raviele A. Alboni P. Giani P. Moya A.

Dual-chamber pacing in the treatment of neurally mediated tilt-positive cardioinhibitory syncope: pacemaker versus no therapy: a multicenter randomized study. The Vasovagal Syncope International Study (VASIS) Investigators.

Source Circulation. 102(3): 294-9, 2000 Jul 18.

Authors Connolly SJ. Sheldon R. Roberts RS. Gent M.

The North American Vasovagal Pacemaker Study (VPS). A randomized trial of permanent cardiac pacing for the prevention of vasovagal syncope.

Source Journal of the American College of Cardiology. 33(1): 16-20, 1999 Jan.



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Authors Connolly SJ, Sheldon R, Thorpe KE, Roberts RS, Ellenbogen KA, Wilkoff BL, Morillo C, Gent M.

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Group	Criteria or definition	n
Population screened	Patients at 15 centers in Canada, Australia, the United States and Colombia between Sept 1998 and April 2002	Unknown
Inclusion criteria	Included if >19yo w/ typical h/o recurrent vasovagal syncope w/ at least 6 episodes of syncope ever or at least 3 in the 2 yrs prior to enrollment, and w/ positive head-up tilt table test result	137
Exclusion criteria	Excluded if any other cause of syncope, if important valvular, coronary artery, or myocardial disease, if ECG abnormality, or other major noncardiovascular disease.	100
Treatment group	Dual-chamber pacemaker with pacing (DDD)	52
No treatment group	Dual-chamber pacemaker with sensing but no pacing (ODO)	48

Primary endpoints: Time to first recurrence of syncope, defined as a transient loss of consciousness with prompt spontaneous recovery.

Secondary endpoints: None.

- Are the Results of the Trial Valid?
 - Randomized? Yes
 - All patients accounted for at end? Yes
 - Intention to treat? Yes
 - Blinding? Yes
 - Groups similar at start of trial? Yes
 - Equal treatment of groups? Yes
 - Did randomization work? Yes
- Are the Results of the Trial important?
 - Size of treatment effect? Yes
 - Precision of the estimate of the effect? No

Endpoint	Result	Significance	ARR	NNT
Cumulative risk of syncope at 6 months	ODO 40% (25%-52%) DDD 31% (17%-43%) RRR 30% (-33%-63%)	1-sided p=0.14		
Morbidity	Result	Significance	ARI	NNH
Major complications	ODO 1 DDD 1			
Minor complications	ODO 8 DDD 9			

- Can I apply these results to my patient?
 - Comparison of my patient to trial patients
 - My patient could have qualified for the trial by inclusion and exclusion criteria. Although she was significantly older than the median trial participant, she shared many of their characteristics, including multiple syncopal and pre-syncopal events in the past year and co-morbid conditions such as cardiac disease and hypertension.
 - All clinically important outcomes considered.
 - Time to recurrence of syncope is a patient important outcome; decreasing recurrence of syncope can significantly affect the quality of life of patients.
 - It could also have been interesting to evaluate the effect of pacing on frequency of falls. However, this was a small, relatively short-term trial for which one primary outcome was appropriate.
 - Likely benefits outweigh potential harms and cost?
 - Benefits do not outweigh the harms and costs in this case. Artificial pacing did not yield a significant relative rate reduction in the time to recurrence of syncope among these patients.
 - The evidence suggests that patients with vasovagal syncope should not undergo pacemaker implantation.