A pacemaker reduced the recurrence of syncope in patients with severe vasovagal syncope


Question
In patients with severe recurrent vasovagal syncope, can a dual-chamber pacemaker with rate-drop response reduce the rate of recurrent syncope?

Design
Randomized, unblinded, controlled trial with planned interim analyses.

Setting
16 clinical centers in North America.

Patients
Patients with > 6 syncopal episodes and a positive tilt-table test result with syncope or presyncope and relative bradycardia. Exclusion criteria were other causes of loss of consciousness (ventricular tachycardia, complete heart block, postural hypertension, hypersensitive carotid sinus syndrome, or seizures); important valvular, coronary, myocardial, or conduction abnormality; previous pacemaker therapy; contraindications to a permanent pacemaker; or a major chronic noncardiovascular disease. 54 (mean age 43 y, 72% women) of the planned 284 patients were studied. Follow-up was 85%.

Intervention
27 patients were allocated to a permanent pacemaker (Medtronic Thera DR dual-chamber pacemaker with rate-drop response) that was to be implanted within 1 week of randomization. 27 patients were allocated to no pacemaker. All other treatment in both groups was done at the discretion of the treating physicians.

Main outcome measures
First recurrence of syncope. Secondary outcomes were presyncope and adverse events.

Main results
The study was stopped early when a clinical benefit was found. 1 patient refused the pacemaker; all patients were included in the intention-to-treat analysis. Patients in the pacemaker group had a lower rate of recurrence of syncope (P = 0.001) (Table) and a greater time to syncope (112 vs 54 d, P = 0.001) than those in the control group. The groups did not differ for the proportion of patients with > 1 presyncope event (74% in the pacemaker group vs 63% in the control group, P = 0.6) or any other measure of presyncope events. There were 7 adverse events in the pacemaker group and none in the control group.

Conclusion
A permanent dual-chamber pacemaker reduced the recurrence of syncope, but not presyncope events, in patients with severe recurrent vasovagal syncope.

Abstract and Commentary also published in ACP Journal Club. 1999;131:43.

Permanent pacemaker vs usual care for severe vasovagal syncope*

<table>
<thead>
<tr>
<th>Outcome at 2 y</th>
<th>Pacemaker</th>
<th>Usual care</th>
<th>RRR (95% CI)</th>
<th>NNT (CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recurrence</td>
<td>22.2%</td>
<td>70.4%</td>
<td>68% (38 to 85)</td>
<td>3 (1 to 2)</td>
</tr>
</tbody>
</table>

*Abbreviations defined in Glossary; RRR, NNT, and CI calculated from data in article.
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