Abstract

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Pacemaker or defibrillator surgery without interruption of anticoagulation.

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Abstract

BACKGROUND: Many patients requiring pacemaker or implantable cardioverter-defibrillator (ICD) surgery are taking warfarin. For patients at high risk for thromboembolic events, guidelines recommend bridging therapy with heparin; however, case series suggest that it may be safe to perform surgery without interrupting warfarin treatment. There have been few results from clinical trials to support the safety and efficacy of this approach.

METHODS: We randomly assigned patients with an annual risk of thromboembolic events of 5% or more to continued warfarin treatment or to bridging therapy with heparin. The primary outcome was clinically significant device-pocket hematoma, which was defined as device-pocket hematoma that necessitated prolonged hospitalization, interruption of anticoagulation therapy, or further surgery (e.g., hematoma evacuation).

RESULTS: The data and safety monitoring board recommended termination of the trial after the second prespecified interim analysis. Clinically significant device-pocket hematoma occurred in 12 of 343 patients (3.5%) in the continued-warfarin group, as compared with 54 of 338 (16.0%) in

the heparin-bridging group (relative risk, 0.19; 95% confidence interval, 0.10 to 0.36; P<0.001). Major surgical and thromboembolic complications were rare and did not differ significantly between the study groups. They included one episode of cardiac tamponade and one myocardial infarction in the heparin-bridging group and one stroke and one transient ischemic attack in the continued-warfarin group.

CONCLUSIONS: As compared with bridging therapy with heparin, a strategy of continued warfarin treatment at the time of pacemaker or ICD surgery markedly reduced the incidence of clinically significant device-pocket hematoma. (Funded by the Canadian Institutes of Health Research and the Ministry of Health and Long-Term Care of Ontario; BRUISE CONTROL ClinicalTrials.gov number, NCT00800137.).

Comment in

Device surgery without interruption of anticoagulation. [N Engl J Med. 2013]
Device surgery without interruption of anticoagulation. [N Engl J Med. 2013]
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Device surgery without interruption of anticoagulation. [N Engl J Med. 2013]

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