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Continued Warfarin Better Than Bridging Therapy for Pacemaker or Defibrillator Surgery

Clinical Question

For patients who are currently taking warfarin (Coumadin) and undergoing the insertion of a pacemaker or defibrillator, should warfarin be continued or should patients be bridged with heparin?

Bottom Line

This is the best and largest single trial comparing continued warfarin with a bridging strategy. Patients with an annual risk of thromboembolic events of 5% or more undergoing pacemaker or defibrillator surgery who continued to use warfarin had fewer device-pocket hematomas than patients who received bridging therapy with heparin. This result is consistent with the results of previous observational studies [*Circulation*. 2012;126(13):1630-1639] that found that bridging actually worsens outcomes. One theory is that the surgeons performing the implantation in a patient receiving anti-coagulants were better able to identify potential bleeding complications intraoperatively—what the authors call an “anticoagulant stress test.” It’s refreshing that the simpler, less expensive, and far less complex strategy is also the better one. (Level of Evidence = 1b)

Synopsis

There have been few clinical trials to guide decisions about anticoagulation management during surgical procedures. This is one of the first to rigorously address this issue. The researchers identified 681 patients with at least a 5% annual risk of thromboembolism who were taking warfarin and who were scheduled to have a pacemaker or defibrillator implanted. Their mean age was 71 years,

73% were male, and most had atrial fibrillation or flutter as the indication for anticoagulation. The patients were randomized, with appropriate concealment of allocation, to continue their usual management with warfarin or to receive bridging heparin. Patients in the bridging group received their final dose of warfarin at least five days before the procedure, and received full-dose low-molecular-weight heparin (Lovenox) or unfractionated heparin from that point until 24 hours before the procedure (for the low-molecular-weight heparin) or four hours before the procedure (for the unfractionated heparin). The heparin and warfarin were restarted 24 hours after the procedure, and heparin was discontinued once a therapeutic international normalized ratio (INR) was achieved.

The patients were not masked, but the members of the care team evaluating each patient for hematoma were masked to group assignment. Groups were balanced at the beginning of the study, analysis was by intention to treat, and follow-up was excellent. The primary outcome was occurrence of a device-pocket hematoma that necessitated further surgery, a longer hospitalization, or interruption of anticoagulation. The study was terminated prematurely because this outcome occurred in 3.5% of patients in the continued warfarin group and in 16% of patients in the heparin-bridging group (relative risk = 0.19; 95% confidence interval, 0.1 to 0.36; absolute risk increase = 12.5%; number needed to treat to harm = 8). Two patients in the continued warfarin group had embolic events, but both had unintentionally subtherapeutic INR values of 1.0 and 1.2.

Reference

Birnie DH, Healey JS, Wells GA, et al.; BRUISE CONTROL Investigators. Pacemaker or defibrillator surgery without interruption of anticoagulation. *N Engl J Med*. 2013;368(22):2084-2093.

Study design: Randomized controlled trial (single-blinded)

Funding source: Government

Allocation: Concealed

Setting: Inpatient (any location) with outpatient follow-up

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