

CARDIAC PACING & ICD UPDATE

Pacemaker and/or Defibrillator Implantation: Continued Warfarin Outperforms Bridging with Heparin

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oral anticoagulation; warfarin; heparin*

ABBREVIATIONS

ICD = implantable cardioverter
defibrillator

OAC = oral anticoagulants

Among patients undergoing pacemaker or implantable cardioverter-defibrillator (ICD) implantation, approximately 14–45% are on anticoagulation therapy.¹ Recently updated guidelines from the American College of Chest Physicians have recommended use of bridging anticoagulation with therapeutic dose of subcutaneous low-molecular-weight heparin or intravenous heparin in patients with mechanical heart valves, atrial fibrillation, or venous thromboembolism who are at moderate or high risk for thromboembolic events (estimated annual stroke risk >5%). While this strategy may be appropriate in cases involving major surgery, this may not be applicable to device-based procedures where implantations typically occur above the pectoral fascia. In fact, significant hematomas have been shown to occur in approximately 30% of patients managed with heparin bridging in this setting.²

It has recently been suggested that device implantation without discontinuation of oral anticoagulation (OAC) is a safe and efficient approach, with reduced thromboembolic risk, bleeding risks, and reduced hospital inpatient stay. In a 2012 meta-analysis that included 5978 patients from 13 studies (which included only one prospective randomized trial of 101 patients), the overall rate of bleeding complications (hematoma at device pocket, transfusion, or prolonged hospital stay) was 3.7%, ranging from 2.2% in those receiving no anticoagulation to 14.6% in persons whose chronic OAC was stopped and bridging therapy with heparin administered. While the odds of bleeding were significantly higher in those patients with heparin bridging strategy (adjusted odds ratio-OR 8.3; 95% confidence intervals-CI 5.5–12.9) or dual antiplatelet therapy (adjusted OR 5.0; 95% CI 3.0–8.3) compared with those receiving no anticoagulation, those patients who continued oral anticoagulation (adjusted OR 1.6; 95% CI 0.9–2.6) or were taking aspirin alone (adjusted OR 1.5; 95% CI 0.9–2.3) showed only a non-significant trend toward higher bleeding.³

Subsequent to the 2012 meta-analysis, the BRUISE CONTROL investigators performed the largest randomized trial of antithrombotic treatment strategies in patients undergoing cardiac devices implantation. Among 681 patients with an annualized risk of thromboembolic events of 5% or greater and taking long-term warfarin, those randomized to device insertion while on continued warfarin therapy had a significantly lower incidence of the primary outcome (clinically significant pocket hematoma requiring prolonged hospital stay, interruption of anticoagulation therapy, or surgery for evacuation) compared with those whose warfarin was stopped and heparin-bridging therapy was used (3.5% versus 16%; relative risk 0.19; 95% CI 0.10–0.36).⁴

There are several explanations for why continuing warfarin may be safe. Most of these procedures involve implantation of the device above the pectoral fascia and thus avoid the more vascular areas of the chest. Second, electrocautery is often used

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to improve hemostasis. Patients who are fully anticoagulated and develop oozing at the time of the procedure will likely have that cauterized before the incision is closed. Individuals who are not anticoagulated at the time of the procedure may have subclinical bleeding that is only later unmasked when anticoagulation is reinitiated. Third, the amount of the time during which the patient is not anticoagulated is minimized and even eliminated. Fourth, and perhaps most important, continuing warfarin avoids the need for heparin and the increased risk of bleeding associated with post-procedural administration. This is particularly beneficial because heparin administration requires extended hospital stays, frequent monitoring and hematologic complications including periods of sub-therapeutic anticoagulation and heparin-induced thrombocytopenia.

Three new oral anticoagulant agents, dabigatran (a direct thrombin inhibitor), rivaroxaban and apixaban (Xa elective inhibitors), have been approved within the past few years for the prevention of stroke in patients with nonvalvular atrial fibrillation. These agents have short half-lives, with maximal anticoagulant effects observed soon after oral intake and reduction of the effects soon after cessation. A retrospective study published by Rowley et al in May 2013 compared uninterrupted dabigatran with uninterrupted warfarin in patients undergoing cardiac device implantation. The study concluded that there is a similar risk of bleeding complications in either group. However, it is important to note that the study was retrospective, comparing two separate cohorts.⁵

Based on available data, for patients requiring cardiac device implantation, who have the highest risk of thromboembolic events (greater than 5% per year), in whom the risk of discontinuing antithrombotic therapy is thought to exceed the risks of post-procedural bleedings, continuation of chronic OAC therapy is recommended rather than a bridging strategy using heparin.

For patients with a lower risk of thromboembolic events (5% per year or less), there are no outcomes data to guide the decision to continue or temporarily suspend antithrombotic therapy at the time of the procedure. Based on individualized assessment of risks and benefits, field experts feel that it is reasonable to discontinue antithrombotic therapy two days prior to the procedure and, in the absence of any post-procedure bleeding, to resume antithrombotic therapy on the day following the procedure. This approach should be taken without any bridging anticoagulation. However, it is also reasonable to continue antithrombotic therapy without interruption in selected patients.⁶

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