Management of Anticoagulation Around Pacemaker and Defibrillator Surgery

David H. Birnie, MD; Jeff S. Healey, MD; Vidal Essebag, MD, PhD

Each year, an estimated 1.25 million pacemakers and 410,000 implantable cardioverter-defibrillators are implanted worldwide. Clinical trials suggest that ≈25% of pacemaker and 35% of implantable cardioverter-defibrillator patients receive long-term oral anticoagulation (OAC). The periprocedural management of their OAC presents a dilemma. This is particularly true in the subset of patients with moderate to high risk (eg, >5%/y) of arterial thromboembolic events (ATE).

Case 1
The first case is a 76-year-old man with atrial fibrillation, previous embolic stroke, diabetes mellitus, hypertension, and nonischemic cardiomyopathy. His ECG shows atrial fibrillation and left bundle-branch block with a QRS duration of 180 milliseconds, and his left ventricular ejection fraction is 25%. He is on long-term warfarin therapy with a CHADS2 score of 5 and an estimated annual risk of ATE of 12.5%. He is recommended for implantation of a cardiac resynchronization defibrillator.

How should his warfarin be managed around the device surgery?

Case 1 Discussion
Physicians responded to concerns about periprocedural ATE by treating moderate- to high-risk patients with heparin bridging, and guidelines recommended this as standard of care. However, a number of downsides to heparin bridging around device surgery were observed. First, there is a substantial risk of clinically significant device pocket hematoma related to heparin bridging. The risk of hematoma with bridging is between 17% and 31%. Importantly, device pocket hematomas can necessitate prolonged cessation of anticoagulation with the attendant risk of ATEs; they can significantly increase the duration and cost of hospitalization; and sometimes reoperation is required. In addition, there is an association between hematoma formation and subsequent device system infection. For example in the Implantable Cardiac Pulse Generator Replacement (REPLACE) registry, patients with infections were 20-fold more likely to have had postoperative hematomas. Device system infections are serious for patients because they usually require complete system removal, which has significant associated morbidity, mortality, and cost to the healthcare system.

In response to these issues, some centers started performing pacemaker and defibrillator surgery without interruption of warfarin anticoagulation. Physician surveys indicated clinical equipoise and supported the need for comparative studies. A large clinical trial, Bridge or Continue Warfarin for Device Surgery Randomized Controlled Trial (BRUISE CONTROL), was published in May 2013. Patients (n=681) with an annual risk of ATE of ≥5% were randomly assigned to continued warfarin or heparin bridging. The primary outcome was clinically significant hematoma, which was defined as prolonging hospitalization, necessitating interruption of anticoagulation, or requiring reoperation. Clinically
significant hematoma occurred in 12 of 343 patients (3.5%) in the continued-warfarin arm and 54 of 338 patients (16.0%) in the heparin-bridging arm (relative risk, 0.19; 95% confidence interval, 0.10–0.36; \( P < 0.001 \)). Major surgical and thromboembolic complications were rare and not significantly different between arms. They included 1 episode of cardiac tamponade and 1 myocardial infarction in the heparin-bridging arm, and 1 stroke and 1 transient ischemic attack in the continued-warfarin arm. These data were similar to those in a meta-analysis of the observational studies.\(^\text{10}\)

**Figure.** Algorithm for peri-device surgery anticoagulation for patients on warfarin (note that exceptions to operating without interruption of warfarin include subpectoral implants and lead extraction). INR indicates international normalized ratio; and VTE, venous thromboembolism. \*Based on Reference 13. **Per guidelines.\(^\text{14}\)

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**Table. Suggested Period of NOAC Interruption Before Device Surgery**

<table>
<thead>
<tr>
<th>Renal Function (CrCl), mL/min</th>
<th>Dabigatran, h</th>
<th>Apixaban, h</th>
<th>Rivaroxaban, h</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥80</td>
<td>&gt;24</td>
<td>&gt;24</td>
<td>&gt;24</td>
</tr>
<tr>
<td>≥50–&lt;80</td>
<td>&gt;36</td>
<td>&gt;24</td>
<td>&gt;24</td>
</tr>
<tr>
<td>≥30–&lt;50</td>
<td>&gt;48</td>
<td>&gt;24</td>
<td>&gt;24</td>
</tr>
</tbody>
</table>

CrCl indicates creatinine clearance; and NOAC, new oral anticoagulant.

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**Case 1 Suggested Management**

Hence, on the basis of these data, the patient should have device surgery without interruption of warfarin (see the Figure for the full algorithm).

**Case 2**

The patient in case 2 is similar to the patient in case 1 with the exception that he is on dabigatran 150 mg twice daily with a creatinine clearance of 46 mL/min.

**Case 2 Discussion**

There are 3 new OACs (NOACs) approved for use for the prevention of stroke and systemic embolism in patients with atrial fibrillation. Data on perioperative experience with dabigatran and rivaroxaban have been published. The key points from these 2 studies are the following\(^\text{15,16}\):

1. Temporary interruptions for procedures/surgery are common (between 10% and 15% of patients per year).
2. About 10% of the temporary interruptions are for pacemaker or defibrillator surgery.
3. Even brief temporary interruptions, carefully controlled in the environment of clinical trials, are associated with an ≈3-fold increase in stroke/systemic embolism.

Rowley et al\(^\text{17}\) recently published the first report on continuous anticoagulation with an NOAC during implantation of cardiac rhythm devices. Dabigatran was administered without interruption with no missed doses in 11 patients, and 1 patient developed a pocket hematoma. Jennings et al\(^\text{18}\) reported 48 patients having device surgery with uninterrupted dabigatran. Bleeding complications occurred in 1 of 48 patients (2.1%; a late pericardial effusion).

**Current Guidelines and Expert Opinion**

Warfarin and the NOACs are quite different drugs; hence, the results of \text{BRUISE CONTROL} cannot be applied to patients on the new agents.\(^\text{13}\) Physicians are concerned about the lack of a specific antidote...
for the NOACs. Whether it is better to operate without interrupting these new agents or with temporary cessation is currently unclear, and more data are required. Recently updated North American guidelines have not commented on perioperative management of the NOACs. A 2013 European document recommends interruption for device surgery, with the period of preoperative discontinuation based on the clinical trials. In addition, expert opinion has recommended temporary interruption around device surgery with the suggested period of interruption varying between 3 and 7 days.20–22

**Case 2 Suggested Management**

The patient’s dabigatran should be held for a period of >24 hours (see the Table for suggested period of NOAC interruption before device surgery). There are no data to guide when to restart the drug. In the clinical trials, the NOACs were restarted at the physician’s discretion when hemostasis was satisfactory. Physicians are concerned that early resumption of a NOAC, with its rapid onset of action, may have effects similar to those of postoperative bridging, that is, result in significant numbers of hematomas. Hence, in this patient, with an annual risk of ATE > 5%, we would suggest giving the first dose of dabigatran 24 hours after surgery. In patients with a lower risk of ATE (<5%), it would seem reasonable to wait for >48 hours after surgery. More data are required to refine all of these recommendations about NOAC management around surgery.

**Sources of Funding**

Drs Birnie and Healey are recipients of Heart and Stroke Foundation of Ontario Mid-Career Investigator awards. Dr Essebag is a recipient of a Clinician Scientist Award from the Canadian Institutes of Health Research.

**Disclosures**

Drs Birnie, Healey, and Essebag have received research support from Boehringer-Ingelheim.


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Circulation. 2014;129:2062-2065
doi: 10.1161/CIRCULATIONAHA.113.006027

The online version of this article, along with updated information and services, is located on the World Wide Web at:
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