Pocket Hematoma: A Call for Definition

FRANCESCO DE SENSI, M.D.,* GENNARO MIRACAPILLO, M.D.,* ALBERTO CRESTI, M.D.,* SILVA SEVERI, M.D.,* and KARI EINO JUHANI AIRAKSINEN, M.D., Ph.D.†

From the *Cardiology Unit, Misericordia Hospital, Grosseto, Italy; and †Heart Center, Turku University Hospital, Turku, Finland

Pocket hematoma is a common complication of cardiac implantable electronic device procedures and a potential risk factor for device infections, especially in patients on oral anticoagulation or antiplatelet treatment. There is a wide variability in the incidence of pocket hematoma and bleeding complications in the literature and the major cause for this seems to be the variability of the used definitions for hematomas. The lack of generally accepted definition for pocket hematoma renders the comparisons across the studies difficult. In this article, we briefly review the current literature on this issue and propose a uniform definition for pocket hematoma and criteria for grading the severity of hematoma in clinical practice and research. (PACE 2015; 00:1–5)

Pocket hematoma, oral anticoagulation, bleeding, antiplatelet therapy, heparin bridging, pacemaker infection

The number of cardiac implantable electronic device (CIED) procedures is in continuous rise worldwide.1 Pocket hematoma after CIED procedures is a common complication especially in patients on oral anticoagulation (OAC) or antithrombotic treatments.2,3 Perioperative anticoagulation management represents a dilemma for physicians, particularly in the subset of patients with moderate-to-high risk of thromboembolic events. Current guidelines recommend interruption of OAC and bridging with heparin.4 However, bridging strategy has been associated with a high risk of pocket hematoma (up to 20%),5 and numerous observational studies have later shown that continuing OAC during CIED implantation is safe and not associated with increased incidence of pocket hematoma.6–9 Recent multicenter randomized trials have confirmed the efficacy and safety of uninterrupted OAC strategy as compared with conventional heparin bridging.10,11

According to a recent meta-analysis, dual antiplatelet treatment also causes a fivefold increase in bleeding complications in CIED procedures, while aspirin carried a 1.5-fold risk compared to patients with no antithrombotic therapy.12 In the FinPAC trial, the risk of hematoma was similar in patients on aspirin (5.5%) and using OAC (5.6%), but higher than in those with no antithrombotic medications (0.9%).13

There is a wide variability in the incidence of pocket hematoma and bleeding complications in the numerous studies published between 2000 and 2014 on this issue. Differences in patient characteristics or operative techniques may not explain this variability and the major cause for the wide range in the reported incidence of pocket hematoma in these studies seems to be the variability of the used definitions for hematomas (Table I). Criteria have ranged from a simple ecchymosis through a palpable mass anterior to the pulse generator to a clinically significant hematoma requiring prolonged hospitalization, interruption of warfarin therapy, or evacuation/reoperation, or leading to a drop in hemoglobin >2 g/dL and/or blood product transfusion.6,8,10–12 In the randomized BRUISE Control trial, hematoma incidence in the uninterrupted warfarin group was 3.5% against 16.0% in the heparin bridging group,10 while in the randomized FinPAC study, the overall hematoma rates were as high as 33% both in patients with uninterrupted and interrupted OAC.13 The BRUISE Control study used hematoma requiring reoperation or prolonging hospitalization or interrupting OAC as the reported end point. This
Table I.
Recent Studies on Bleeding Complications after CIED Procedures

<table>
<thead>
<tr>
<th>Study</th>
<th>Type of Study</th>
<th>Type of Anticoagulation</th>
<th>Hematoma Definition</th>
<th>Hematoma Incidence</th>
</tr>
</thead>
</table>
| Wiegand et al.² | Prospective                    | UFH, LMWH               | Any palpable swelling of the pacemaker pocket exceeding the size of generator, severe if pain, prolonged hospitalization, necessity of reoperation                                      | Any pocket hematoma = 4.9%  
Severe hematoma = 2%  
Reoperation = 1% |
| Ahmed et al.⁷  | Retrospective                   | OAC uninterrupted, OAC withheld, bridging LMWH or UFH | A palpable tense swelling causing severe pain that required prolonged hospitalization (1 day longer than the scheduled hospitalization) and/or discontinuation of anticoagulation and/or surgical evacuation and/or blood transfusion. | OAC uninterrupted = 0.45%  
Bridging = 5.7%  
OAC withheld = 1.75% |
| Tompkins et al.³ | Retrospective                   | All kinds of antithrombotic therapy | Hematoma as a component of composite end point of bleeding complications (including pocket exploration, blood transfusion, medication discontinued, prolonged hospitalization) | Bleeding complications = 5.1% |
| Tolosana et al.⁶ | Prospective randomized single-center trial | Uninterrupted OAC versus interruption with bridging with LMWH | Palpable mass that protruded >2 cm anterior to the pulse generator. Evacuated if tense swelling with poor capillary perfusion, progressive enlargement, or severe pain | Pocket hematoma = 8% in both groups  
Reoperation = 2% |
| Li et al.⁸     | Retrospective                   | Interruption OAC versus no interruption versus interruption and bridging with LMWH | Palpable hematoma, and/or refractory pain, or threatened integrity of the incision as having a moderate or severe hematoma | Total study group = 5% |
| Ghanbari et al.⁹ | Retrospective                   | No interruption OAC versus interruption and bridging with LMWH | Palpable mass that protruded >2 cm anterior to the pulse generator. Considered significant if the hematoma required evacuation, reoperation, drop in hemoglobin >2 g/dL, blood product transfusion, or interruption of warfarin therapy | Warfarin = 5%  
LMWH = 20.7% |

(Continued)
Table I—Continued

<table>
<thead>
<tr>
<th>Study</th>
<th>Type of Study</th>
<th>Type of Anticoagulation</th>
<th>Hematoma Definition</th>
<th>Hematoma Incidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Airaksinen et al.</td>
<td>Randomized multicenter trial</td>
<td>Uninterrupted warfarin (UAC) versus 2 days interrupted warfarin (IAC)</td>
<td>Any palpable mass or ecchymosis in the pocket area; large hematoma: hematoma &lt; 100 cm²</td>
<td>Large hematoma: 33% in UAC versus 40% in IAC; any pocket hematoma: 6% in both groups; large hematoma: UAC = 3.5%; IAC = 16%</td>
</tr>
<tr>
<td>Birnie et al.</td>
<td>Randomized multicenter trial</td>
<td>Continued warfarin group versus heparin bridging group</td>
<td>Clinically significant device-pocket hematoma defined as hematoma requiring further surgery or resulting in prolongation of hospitalization or requiring interruption of OAC</td>
<td>Continued warfarin = 3.5%; Heparin-bridging = 16%</td>
</tr>
</tbody>
</table>

CIED = cardiac implantable electronic device; LMWH = low-molecular-weight heparin; OAC = oral anticoagulation; UFH = unfractionated heparin.

Table II.

Hematoma Grading based on Clinical Findings and Needed Interventions

<table>
<thead>
<tr>
<th>Hematoma Grade</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 1</td>
<td>Ecchymosis or mild effusion in the pocket, no swelling or pain to device-pocket (watchful waiting)</td>
</tr>
<tr>
<td>Grade 2</td>
<td>Large effusion in the pocket leading to swelling and causing functional impairment or pain to device-pocket</td>
</tr>
<tr>
<td>Grade 3</td>
<td>Any pocket hematoma requiring: Reoperation and/or resulting in prolongation of hospitalization (defined as extended hospitalization or rehospitalization for &gt; 24 hours, postindex surgery, primarily due to hematoma) and/or requiring interruption of OAC (defined as reversal or intentional withholding, in response to pocket hematoma, resulting in subtherapeutic anticoagulation for &gt; 24 hours)</td>
</tr>
</tbody>
</table>

OAC = oral anticoagulation.

definition is specific but the sensitivity for the whole clinical phenomenon may be inadequate. At the other end of the spectrum, the FinPAC study defined any hematoma as any palpable mass or ecchymosis in the pocket area and a hematoma > 100 cm² was considered as a large hematoma. Using these definitions, the incidence of any hematoma was 33% and that of large hematoma 6%, but more interestingly, no hematoma required reoperation or pocket reoperation. In the REPLACE registry, the complications associated with generator replacements and upgrade procedures were also classified as major and minor. Hematoma was considered as a major complication if it required evacuation, drainage, blood transfusion, hospitalization, or extension of hospital stay to treat it. Hematoma was defined as a minor complication if lasting more than 7 days and characterized by tenseness, or drainage, or minor dehiscence managed as an outpatient or if it was without tenseness but requiring additional outpatient evaluation. In a recent pilot study, we analyzed patients undergoing CIED procedures with uninterrupted OAC in order to define the best predictive SCORE for intrinsic bleeding risk. Reported hematomas (14.2%) were clinically described as any asymptomatic or minimally symptomatic effusions or
Figure 1. Large ecchymosis around the wound (Grade 1). No effusion and the pocket was not tight. This kind of clinical phenomenon does not require any therapeutic interventions, only watchful waiting.

Figure 2. Small effusion (Grade 1). A small effusion requiring no interventions.

echymosis in the pocket area, requiring frequent ambulatory follow-up and temporary reduction of OAC dosage. None of the hematomas required any interventions.

As shown above, the lack of generally accepted definition for pocket hematoma renders the comparisons across the literature difficult. Second, we feel that it is also important to report all clinical phenomena around the pocket and not only those leading to therapeutic interventions. At present, we do not know the incidence of these “minor” problems (ecchymosis, effusion, dehiscence) which may also increase the risk of pacemaker infections (Fig. 1).

Table II summarizes our suggestion for the definition and classification of pocket hematomas. Our proposed classification is suitable not only

Figure 3. Large effusion (Grade 2). This large effusion disappeared after 10 days and caused two outpatient visits and pain medication was needed.

Figure 4. Large effusion (Grade 3). This large effusion was very painful for the patient requiring reoperation and hematoma evacuation.
for OAC patients but also for all patients who develop pocket hematoma after CIED procedures. In this classification, hematoma size is not the only and the principal criterion in the grading of the bleeding complications. In this classification, a mild effusion or an ecchymosis not requiring any therapeutic intervention is classified as GRADE 1 (Figs. 1 and 2). When the effusion is larger and causes pain or functional impairment, requiring minor therapeutic interventions (e.g., not included in GRADE 3), the complication is classified as GRADE 2 (Fig. 3). GRADE 3 is defined according to the BRUISE Control trial as any hematoma requiring re-operation and/or resulting in prolongation of hospitalization and/or requiring interruption or reversal of OAC (Fig. 4).

In conclusion, pocket hematoma after CIED procedures is a common complication especially in patients on antithrombotic treatments. Uniform classification of this common complication is needed for the research of the magnitude of the problem and its clinical consequences. The number of device infections is also growing in spite of the progress in the management of the procedures and perioperative use of antibiotic prophylaxis. Pocket hematoma may be one of the various risk factors for CIED infections, but the association between hematoma and device infection is far from conclusive and uniform definitions for pocket hematoma may help to assess its role as a risk factor for this serious complication.

References