Perioperative anticoagulation management in CIED implantation
Consider....

Pocket hematoma
- pain, ↓ QoL
- infection(> 7 times)

Thromboembolism

Bleeding

Thrombosis

J Am Coll Cardiol. 2016;67(11):1300-8
• Estimating thromboembolic risk
• Estimate bleeding risk

  – Anticoagulant interruption
  – Without cessation or reduction of oral anticoagulation (INR, therapeutic range)
  – Use bridging anticoagulation
# Suggested risk stratification for perioperative TE

## Table 1. Suggested risk stratification for perioperative thromboembolism

<table>
<thead>
<tr>
<th>Risk category</th>
<th>MHV</th>
<th>Atrial fibrillation</th>
<th>VTE</th>
</tr>
</thead>
<tbody>
<tr>
<td>High (&gt; 10%/y risk of ATE or &gt; 10%/mo risk of VTE)</td>
<td>Any mechanical mitral valve</td>
<td>CHADS&lt;sub&gt;2&lt;/sub&gt; score of 5 or 6</td>
<td>Recent (&lt; 3 mo) VTE</td>
</tr>
<tr>
<td></td>
<td>Caged-ball or tilting disc valve in mitral/aortic position</td>
<td>CHA&lt;sub&gt;2&lt;/sub&gt;DS&lt;sub&gt;2&lt;/sub&gt;-VASc ≥ 6</td>
<td>Severe thrombophilia</td>
</tr>
<tr>
<td>Recent (&lt; 6 mo) stroke or TIA</td>
<td>Recent (&lt; 3 mo) stroke or TIA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intermediate (4%-10%/y risk of ATE or 4%-10%/mo risk of VTE)</td>
<td>Bileaflet AVR with major risk factors for stroke</td>
<td>CHADS&lt;sub&gt;2&lt;/sub&gt; score of 3 or 4</td>
<td>VTE within past 3-12 mo</td>
</tr>
<tr>
<td></td>
<td>AF, CHADS (&gt;1)</td>
<td>CHA&lt;sub&gt;2&lt;/sub&gt;DS&lt;sub&gt;2&lt;/sub&gt;-VASc 4 or 5</td>
<td></td>
</tr>
<tr>
<td>Low (&lt; 4%/y risk of ATE or &lt; 2%/mo risk of VTE)</td>
<td>Bileaflet AVR without major risk factors for stroke</td>
<td>CHADS&lt;sub&gt;2&lt;/sub&gt; score of 0-2 (and no prior stroke or TIA)</td>
<td>VTE &gt; 12 mo ago</td>
</tr>
</tbody>
</table>

TIA indicates transient ischemic attack; AVR, aortic valve replacement; ATE, arterial thromboembolism; VTE, venous thromboembolism; and MHV, mechanical heart valve.
## Procedural bleeding risks

<table>
<thead>
<tr>
<th>High (2-day risk of major bleed 2%-4%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart valve replacement</td>
</tr>
<tr>
<td>Coronary artery bypass</td>
</tr>
<tr>
<td>Abdominal aortic aneurysm repair</td>
</tr>
<tr>
<td>Neurosurgical/urologic/head and neck/abdominal/breast cancer surgery</td>
</tr>
<tr>
<td>Bilateral knee replacement</td>
</tr>
<tr>
<td>Laminectomy</td>
</tr>
<tr>
<td>Transurethral prostate resection</td>
</tr>
<tr>
<td>Kidney biopsy</td>
</tr>
<tr>
<td>Polypectomy, variceal treatment, biliary sphincterectomy, pneumatic dilatation</td>
</tr>
<tr>
<td>PEG placement</td>
</tr>
<tr>
<td>Endoscopically guided fine-needle aspiration</td>
</tr>
<tr>
<td>Multiple tooth extractions</td>
</tr>
<tr>
<td>Vascular and general surgery</td>
</tr>
<tr>
<td>Any major operation (procedure duration &gt; 45 minutes)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Low (2-day risk of major bleed 0%-2%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cholecystectomy</td>
</tr>
<tr>
<td>Abdominal hysterectomy</td>
</tr>
<tr>
<td>Gastrointestinal endoscopy ± biopsy, enteroscopy, biliary/pancreatic stent without sphincterotomy, endonosonography without fine-needle aspiration</td>
</tr>
<tr>
<td>Pacemaker and cardiac defibrillator insertion and electrophysiologic testing</td>
</tr>
<tr>
<td>Simple dental extractions</td>
</tr>
<tr>
<td>Carpal tunnel repair</td>
</tr>
<tr>
<td>Knee/hip replacement and shoulder/foot/hand surgery and arthroscopy</td>
</tr>
<tr>
<td>Dilatation and curettage</td>
</tr>
<tr>
<td>Skin cancer excision</td>
</tr>
<tr>
<td>Abdominal hernia repair</td>
</tr>
<tr>
<td>Hemorrhoidal surgery</td>
</tr>
<tr>
<td>Axillary node dissection</td>
</tr>
<tr>
<td>Hydrocele repair</td>
</tr>
<tr>
<td>Cataract and non-cataract eye surgery</td>
</tr>
<tr>
<td>Noncoronary angiography</td>
</tr>
<tr>
<td>Bronchoscopy ± biopsy</td>
</tr>
<tr>
<td>Central venous catheter removal</td>
</tr>
<tr>
<td>Cutaneous and bladder/prostate/thyroid/breast/lymph node biopsies</td>
</tr>
</tbody>
</table>

**Major bleeding**
- **Fatal**
- **Intracranial**
- **Require surgery**
- Hgb ≥ 2g/dL
- Tf ≥ 2 units
CASE

• 75세 남자
• Old CVA, HT, DM
• AF(CH2ADS-VASc score 6)
• 대장내시경을 위해 warfarin 3일간 중단
• 4 시간 전 발생한 dysarthria로 응급실 방문
• INR 1.20
DWI showed high signal in the right frontal lobe, suggestive of acute infarction
Unadjusted, pooled rates of bleeding complications. Bleeding event rates were (33/1500, 2.2%) for No Therapy, (26/1044, 2.5%) for AC held, (34/1200, 2.8%) for AC Continued, (45/1165, 3.9%) for SAPT: Single antiplatelet therapy, (37/392, 9.4%) for DAPT: Dual antiplatelet therapy and (99/677, 14.6%) for HBS: Heparin Bridging Strategy.
Continued warfarin treatment at the time of CIED surgery reduced the incidence of device-pocket hematoma.

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>No./Total No.</th>
<th>Risk Ratio (95% CI)</th>
<th>P Value for Interaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;70 yr</td>
<td>26/249</td>
<td></td>
<td>0.26</td>
</tr>
<tr>
<td>≥70 yr</td>
<td>40/432</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>49/495</td>
<td></td>
<td>0.40</td>
</tr>
<tr>
<td>Female</td>
<td>17/186</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Antiplatelet-agent use</td>
<td></td>
<td></td>
<td>0.96</td>
</tr>
<tr>
<td>Yes</td>
<td>36/279</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>30/402</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device surgery</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>New ICD</td>
<td>19/193</td>
<td></td>
<td>0.61</td>
</tr>
<tr>
<td>New pacemaker</td>
<td>13/115</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pulse-generator change only</td>
<td>15/211</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pulse-generator change with additional</td>
<td>19/142</td>
<td></td>
<td></td>
</tr>
<tr>
<td>procedure</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fellow or resident participation in</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>procedure</td>
<td>28/319</td>
<td></td>
<td>0.86</td>
</tr>
<tr>
<td>No</td>
<td>38/342</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Procedure duration</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;50 min</td>
<td>19/305</td>
<td></td>
<td>0.44</td>
</tr>
<tr>
<td>≥50 min</td>
<td>46/353</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mechanical-valve replacement</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>26/203</td>
<td></td>
<td>0.12</td>
</tr>
<tr>
<td>No</td>
<td>40/478</td>
<td></td>
<td></td>
</tr>
<tr>
<td>All patients</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1' outcome occurred in 12/343 patients (3.5%) in the continued-warfarin group as compared with 54/338 (16.0%) in the heparin-bridging group (RR, 0.19; 95% CI, 0.10 to 0.36; P<0.001).
Incidence of pocket hematoma in different ranges of INR

766, -WARF 243, +WARF 324, +HPR 199 pts

PACE 2011; 34:868–874
Anticoagulation strategies in patients undergoing device implantation

TABLE 2  Unadjusted outcomes 30 days after cardiac implantable electronic device implantation by oral anticoagulation strategy

<table>
<thead>
<tr>
<th></th>
<th>Warfarin</th>
<th>NOAC</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Overall</td>
<td>Uninterrupted</td>
</tr>
<tr>
<td>No.</td>
<td>284</td>
<td>101</td>
</tr>
<tr>
<td>Major bleeding</td>
<td>1 (0.4%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Stroke/TIA</td>
<td>3 (1.1%)</td>
<td>1 (1.0%)</td>
</tr>
<tr>
<td>All-cause hospitalization</td>
<td>18 (6.3%)</td>
<td>4 (4.0%)</td>
</tr>
<tr>
<td>Cardiovascular hospitalization</td>
<td>12 (4.2%)</td>
<td>2 (2.0%)</td>
</tr>
<tr>
<td>Bleeding hospitalization</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
</tr>
</tbody>
</table>

Abbreviations: NOAC, non-vitamin K antagonist oral anticoagulants; TIA, transient ischemic attack.
Values are reported as number with percentage of total patients experiencing adverse event in parenthesis.
Peri-device surgery warfarin management

Patient on coumadin scheduled for PM/ICD Implantation

High risk for thromboembolism >=5%

Continue warfarin; perform procedure if INR <3
If above 3, hold one dose of and perform when <3

Low risk for thromboembolism <5%

Stop warfarin 3-4 days prior to procedure (without bridging)
Perform once INR <1.8
OR
Continue warfarin

Continued use of warfarin post procedure (if no significant bleeding)

Resume 12-24 hours after procedure (if no significant bleeding)

Journal of Arrhythmia. 2016;63–169
Peri-device surgery DOAC management

**Patient on DOAC scheduled for PM/ICD insertion**

- **CrCl ≥ 50**
  - Hold 1 day before the surgery

- **CrCl 30-50**
  - Hold 2 days before surgery (for Dabigatran)
  - Hold 1 day before surgery (for Rivaroxaban/Apixaban/Edoxaban*)

- **CrCl ≤30**
  - Patient should not be on DOAC but if on Apixaban/Rivaroxaban/Edoxaban* then hold for at least 36 hours

- Resume DOAC 24-48 hours postoperatively (if no significant bleeding)
### 2015 Updated EHRA Practical guide on NOAC in AF

#### EHRA 2015 guidance on last intake of drug before elective surgical intervention

<table>
<thead>
<tr>
<th></th>
<th>Dabigatran</th>
<th>Apixaban–edoxaban–rivaroxaban</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>No important bleeding risk and/or adequate local haemostasis possible:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>perform at trough level (i.e. ≥12 or 24 h after last intake)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Low risk</strong></td>
<td><strong>High risk</strong></td>
<td><strong>Low risk</strong></td>
</tr>
<tr>
<td>CrCl ≥ 80 mL/min</td>
<td>≥24 h</td>
<td>≥48 h</td>
</tr>
<tr>
<td>CrCl 50–80 mL/min</td>
<td>≥36 h</td>
<td>≥72 h</td>
</tr>
<tr>
<td>CrCl 30–50 mL/min&lt;sup&gt;a&lt;/sup&gt;</td>
<td>≥48 h</td>
<td>≥96 h</td>
</tr>
<tr>
<td>CrCl 15–30 mL/min&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Not indicated</td>
<td>Not indicated</td>
</tr>
<tr>
<td>CrCl &lt; 15 mL/min</td>
<td>Not indicated</td>
<td>No official indication for use</td>
</tr>
<tr>
<td>There is no need for bridging with LMWH/UFH</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Bold values deviate from the common stopping rule of ≥24 h low risk, ≥48 h high risk.

Low risk: with a low frequency of bleeding and/or minor impact of a bleeding; high risk with a high frequency of bleeding and/or important clinical impact. See also Table 11.

CrCl, creatinine clearance.

<sup>a</sup>Many of these patients may be on the lower dose of dabigatran (i.e. 110 mg BID) or apixaban (i.e. 2.5 mg BID), or have to be on the lower dose of rivaroxaban (i.e. 15 mg OD) or edoxaban (i.e. 30 mg OD).
Peri-device surgery management of antiplatelets

- Aspirin only
- Clopidogrel only
- Aspirin and clopidogrel (DAPT)
- Continue aspirin peri-procedurally
- Continue clopidogrel
- Recent implantation of BMS/DES with last 4 weeks/6 months respectively
- No recent stents
- Continued DAPT use
  - Clopidogrel -> aspirin 5 d before
  - > 28 d stent – clopidogrel D/C
- Stop clopidogrel 5 days before and resume soon after

**Table 1**
Peri-procedural (PM/ICD) management of antiplatelets—guideline recommendations.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Aspirin</td>
<td>Continue aspirin given low-risk procedure</td>
<td>Continue aspirin given low-risk procedure</td>
<td>Continue aspirin given low-risk procedure</td>
<td>Continue aspirin</td>
</tr>
<tr>
<td>DAPT- BMS</td>
<td>Continue DAPT if &lt; 6 weeks post-insertion</td>
<td>Continue DAPT if &lt; 30 days post-insertion</td>
<td>Minimum of 1-month duration of DAPT</td>
<td>Minimum of 1-month duration of DAPT</td>
</tr>
<tr>
<td>DAPT- DES</td>
<td>Continue DAPT if &lt; 6 months post-insertion</td>
<td>Continue DAPT if &lt; 12 months post-insertion</td>
<td>Minimum 3-month duration of DAPT</td>
<td>Minimum 6-month duration of DAPT (3 months if new-generation DES)</td>
</tr>
</tbody>
</table>

Abbreviations: ACCP, American College of Chest Physicians; ACC/AHA, American College of Cardiology/American Heart Association; CCS, Canadian Cardiovascular Society; ESC/ESA, European Society of Cardiology; DAPT, Dual Antiplatelet Therapy; BMS, Bare Metal Stent; DES, Drug Eluting Stent; N/A, Not Available.

<sup>a</sup> All guidelines recommend a delay in procedure if possible.
<sup>b</sup> ESC/ESA recommends at least 12 months of DAPT after ACS.
What to do during implant

- Meticulous attention to hemostasis
- Prefer cephalic venous cut-down approach, especially in patient with high venous pressure
- Avoid single puncture/retained wire approach
- Consider subfascial pocket rather than submuscular pocket
- Use fibrin sealants/thrombin in high risk patients
Topical tranexamic acid during CIED implantation was associated with reduced pocket hematoma in patients with high bleeding risk

Table 6: Univariate and multivariate predictors of pocket hematoma

<table>
<thead>
<tr>
<th>Variables</th>
<th>Univariate</th>
<th></th>
<th></th>
<th></th>
<th>Multivariate</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>1.043</td>
<td>1.002–1.085</td>
<td>0.040</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Presence of LV thrombus</td>
<td>3.782</td>
<td>0.939–15.228</td>
<td>0.061</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>History of recent stent implantation</td>
<td>13.225</td>
<td>3.734–46.839</td>
<td>&lt;0.001</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spironolactone use</td>
<td>3.449</td>
<td>1.340–8.879</td>
<td>0.010</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Periprocedural warfarin use</td>
<td>0.110</td>
<td>0.035–0.341</td>
<td>&lt;0.001</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Periprocedural warfarin plus DAPT use</td>
<td>12.149</td>
<td>4.483–32.920</td>
<td>&lt;0.001</td>
<td></td>
<td>10.874</td>
<td>2.496–47.365</td>
<td>0.001</td>
</tr>
<tr>
<td>ICD device</td>
<td>6.686</td>
<td>0.860–51.991</td>
<td>0.069</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Three lead implantation</td>
<td>2.406</td>
<td>1.006–5.757</td>
<td>0.049</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Topical TXA use during CIED implantation</td>
<td>0.231</td>
<td>0.075–0.716</td>
<td>0.011</td>
<td>0.059</td>
<td>0.012–0.300</td>
<td>0.001</td>
<td></td>
</tr>
</tbody>
</table>

CI confidence interval, CIED cardiac electronic device implantation, DAPT dual antiplatelet therapy, ICD implantable cardioverter defibrillator, LV left ventricular, MBC major bleeding complications, PH pocket hematoma, TXA tranexamic acid
Venogram
Micropuncture Kit

- 21 G puncture needle
- 0.08 inch guidewire
- 4-5 Fr sheath
Micropuncture (1)
Micropuncture (2)
CASE

• 68세 남자
• HT
• Persistent AF (CH2ADS-VASC score 2)
  Dabigatran 150mg bid
  Flecainide 100mg bid
• Dizziness
• eGFR 69 mL/min
• Dabigatran 1일 중단
• 항응고제 사용하는 환자에서 CIED 삽입시 출혈위험도와 전신색전증 위험도를 따져 보아야 한다

• 전신색전증 위험도가 높은 경우 항응고제를 복용하는 채로 시술하는 것이 안전하다

• 시술 중에 출혈이 되지 않게 주의하여야 하며 필요한 경우 지혈제를 사용할 수 있다.
감사합니다