Ablation and Cardiac Electronic Implantable Devices, What to do with my patient on Oral Anticoagulation??

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April 14 2017
Disclosures:

• None relevant to this talk
Learning Goals:

• Understand how to perform individual patient risk/benefit analysis when considering discontinuation of OAC
• Be aware that different surgeries/Procedures have different thrombosis and bleeding risk
• Know which procedures can be performed on full or partial oral anticoagulation
• Most cardiac implantable electronic devices (CIED) are treated the same
• All Ablations are different!
Anti-coagulation and procedures/surgery

• A Moving Target!
• Roll in data as new medications and studies come out
• Lack of consistency between all sub-specialities-GI, surgeons, cardiologists
• What to tell your patients???
Case 1:

70 year old female with Htn, DM, NICM, EF 30%, Class 3 CHF, LBBB >150 msec s/p single chamber ICD in 2012, is now referred for upgrade to CRT-D therapy. She is on chronic warfarin therapy for pAF. Prior to surgery she should:

a. DC warfarin 5 days prior to surgery and be admitted as an inpatient for heparin bridging

b. DC warfarin 5 days prior to surgery and be given enoxaparin shots to take at home until the day before the procedure

c. DC warfarin 5 days prior to procedure with no bridge

d. Continue full dose warfarin
Case 1a

- 70 year old female with Htn, DM, NICM, EF 30%, Class 3 CHF, LBBB >150 msec s/p single chamber ICD in 2012, is now referred for upgrade to CRT-D therapy. She is on chronic warfarin therapy for pAF AND a Mechanical Mitral Valve. Prior to surgery she should:

a. DC warfarin 5 days prior to surgery and be admitted as an inpatient for heparin bridging

b. DC warfarin 5 days prior to surgery and be given enoxaparin shots to take at home until the day before the procedure

c. DC warfarin 5 days prior to procedure with no bridge

d. Continue full dose warfarin
Case 2

62 year old man with history of paroxysmal atrial fibrillation that has recently become persistent, is referred for atrial fibrillation ablation. CHADS2-VaSC is 1. He takes rivaroxaban. Which of the following is appropriate:

a. DC rivaroxaban and change to warfarin for the procedure
b. Hold rivaroxiban 24 hours prior to procedure
c. DC rivaroxaban 1 week prior to procedure
d. DC rivaroxaban 1 week prior to the procedure and give enoxaparin shots at home
Case 3

68 year old man with Htn, DM, ischemic cardiomyopathy, s/p ICD, on warfarin for recurrent DVTs, prior CVA, and atrial fibrillation, referred for VT ablation. What do you advise prior to the procedure?

a. Hold warfarin 5 days prior to the procedure and bridge with enoxaparin
b. Transition to dabigatran and hold 24 hours prior to procedure

c. Continue full dose warfarin

d. Hold warfarin 5 days prior to the procedure and admit for IV heparin bridge
Case 4

82 year old woman with atrial fibrillation, CHF, EF 15%, with CVA 3 weeks ago, on apixaban is referred for primary prevention ICD. You advise:

a. Defer procedure for a minimum of 3 months
b. Continue apixaban through the procedure
c. Discontinue apixaban 48 hours prior to procedure
d. Transition to warfarin for the procedure
e. Discontinue apixaban 5 days prior to procedure and bridge with IV heparin inpatient
GLORIA-AF (Global Registry on Long-Term Oral Antithrombotic Treatment in Patients with Atrial Fibrillation)

**CENTRAL ILLUSTRATION:** Stroke Prevention in AF: Antithrombotic Treatment per Region

NOACS

- All of the FDA-approved NOACs are associated with a reduced rate of intracranial bleeding compared with warfarin in the treatment of atrial fibrillation.
- Of the NOACs, only dabigatran 150 mg twice daily significantly reduced the risk for ischemic stroke compared with warfarin (0.92% risk vs 1.2% for warfarin; \(P = .002\)). (RELY trial)
- Rivaroxaban 20 mg daily was noninferior to warfarin in stroke reduction.
- Apixaban 5 mg was associated with an annual ischemic stroke risk similar to that with warfarin.
- Recent trial comparing Dabigatran, Rivaroxaban, Apixaban to each other showed no difference in efficacy, but slightly reduced risk of bleeding with Apixaban.

warfarin

• Unpredictability
• Monitoring
• Diet
• Drug interactions
• T1/2 about 40 hours
enoxaparin/HEPARIN

• enoxaparin: T1/2 about 12 hours
  – Discontinue 12-24 hours prior to procedure

• Heparin: dose based, 30-150 minutes
  – Discontinue 2-6 hours before procedures
WHO gets bridged?

• Bridging therapy with UFH or LMWH is recommended for patients with AF and a mechanical heart valve undergoing procedures that require interruption of warfarin. Decisions on bridging therapy should balance the risks of stroke and bleeding.

• For patients with AF without mechanical heart valves who require interruption of warfarin or new anticoagulants for procedures, decisions about bridging therapy (LMWH or UFH) should balance the risks of stroke and bleeding and the duration of time a patient will not be anticoagulated.
2017 Guidelines

• 2017 American College of Cardiology Expert Consensus Decision Pathway for Peri-procedural Management of Anticoagulation in Patients with Nonvalvular Atrial Fibrillation (JACC 2017)

• “Decision Pathways” to “assist”
Data to review:

- Procedural bleeding risk
- Patient’s bleeding risk
- Type of OAC
- “additional clinical information”
HAS- BLEDScore

- Hypertension,
- Abnormal Renal Function
- Abnormal Liver Function,
- Stroke,
- **Bleeding** History or Predisposition,
- Labile INR,
- Elderly,
- Drugs
- Alcohol

- >160, uncontrolled
- Dialysis, transplant, Cr >2.26 mg/dL or >200 µmol/L
- Cirrhosis or bilirubin >2x normal with AST/ALT/AP >3x normal
- <60% therapeutic window
- >65
- NSAIDS, Antiplatelets
- >8 drinks per week
Bleeding risk (approximate)

• 0 = 0.9%
• 1 = 3.4%
• 2 = 4.1%
• 3 = 5.8%
• 4 = 8.9%
• 5 = 9.1%
• 6+ “likely >10%”
CHADS2-VASC Score

- Congestive Heart Failure
- Hypertension
- AGE
- Diabetes
- Stroke/TIA/TE
- Vascular disease
- Sex

- Low EF or clinical
- History of htn
- >64 =1, >74 =2
- Clinical diagnosis of
- History of
- Coronary, or peripheral
- Female**
CHADS2VASC risk (stroke/TIA/TE)

- 0 = 0.3%
- 1 = 0.9%
- 2 = 2.9%
- 3 = 4.6%
- 4 = 6.7%
- 5 = 10%
- 6 = 13.6%
- 7 = 15.7%
- 8 = 15.2%
- 9 = 17.4%

- Vs bleed:
  - 0 = 0.9%
  - 1 = 3.4%
  - 2 = 4.1%
  - 3 = 5.8%
  - 4 = 8.9%
  - 5 = 9.1%
  - 6+ “likely >10%”

65 yo Woman Htn ASA
CV:3 (4.6%) vs. HB:3 (5.8%)
2017 AHA Scientific Statement

**Peri-Procedural Bleeding Risk**

<table>
<thead>
<tr>
<th>Low</th>
<th>Moderate</th>
<th>High</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minor Dental</td>
<td>SVT ablation</td>
<td>Cardiovascular/Thoracic Surgery</td>
</tr>
<tr>
<td>Minor Dermatologic</td>
<td>ICD implant</td>
<td>Intra-abdominal/Pelvic surgery</td>
</tr>
<tr>
<td>Ophthalmologic</td>
<td>Endoscopy with Biopsy</td>
<td>Major Orthopedic Surgery</td>
</tr>
<tr>
<td>Endoscopy without Biopsy</td>
<td>Prostate Biopsy</td>
<td>Neurosurgery</td>
</tr>
<tr>
<td></td>
<td>Cardiac catheterization</td>
<td>Cardiac catheterization via femoral artery</td>
</tr>
<tr>
<td></td>
<td>via radial artery</td>
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**Peri-Procedural Thromboembolic Risk**

<table>
<thead>
<tr>
<th>Low</th>
<th>Moderate to High</th>
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</thead>
<tbody>
<tr>
<td>CHA₂DS₂VASc ≤ 1</td>
<td>CHA₂DS₂VASc &gt; 2</td>
</tr>
<tr>
<td>No Stroke/TIA, VTE within 3 months</td>
<td>Stroke/TIA, VTE within 3 months</td>
</tr>
<tr>
<td>Heterozygous Factor V Leiden Heterozygous PT gene mutation</td>
<td>Protein C or S Deficiency Antithrombin Deficiency Antiphospholipid Syndrome</td>
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**PROCEDURE**

Note: Pre-op NOAC interruption of >48 hours is generally not necessary and may increase thrombosis risk in MOST procedures in patients with normal CrCl.
Moderate and High Risk Guidance

- **Moderate risk (5% to 10%/year)**
  - CHA2DS2-VASc score of 5 to 6
  - History of prior ischemic stroke, TIA, or peripheral arterial embolism
  - Determine the patient’s bleed risk to determine the appropriateness of bridging therapy.

- **High risk (>10% per year)**
  - CHA2DS2-VASc score of 7+
  - Recent (within 3 months) ischemic stroke, TIA, or SE,
  - Hypercoagulable state: Prot C, S, AT3, recurrent VTEs
  - parenteral bridging anticoagulation should be considered.
<table>
<thead>
<tr>
<th></th>
<th>Dabigatran</th>
<th>Apixaban</th>
<th>Rivaroxaban</th>
<th>Edoxaban</th>
</tr>
</thead>
<tbody>
<tr>
<td>CrCl &gt; 80</td>
<td>24 hours</td>
<td>24 hours</td>
<td>24 hours</td>
<td>no data yet</td>
</tr>
<tr>
<td>CrCl &lt; 50</td>
<td>48-96 hours</td>
<td>36-48 hours</td>
<td>36-48 hours</td>
<td>no data yet</td>
</tr>
</tbody>
</table>
When to restart?

• For procedures associated with immobilization, it is considered appropriate to initiate a reduced venous thrombo-prophylactic or intermediate, dose of low molecular weight heparins (LMWH) 6–8 h after surgery

• Therapeutic anticoagulation by restarting NOACs is deferred 48–72 h after the invasive procedure.

• warfarin often started night of surgery
CIED: ESS- PREDI

- Prospective European study
- Implant or revision of a cardiac implantable electronic device (CIED) on chronic antithrombotic therapy
- 723 patients (66.7% men, 76.9% aged ≥66 years).
- Antithrombotic treatment was continued during surgery in 489 (67.6%) patients;
- Non-vitamin K oral anticoagulant (NOAC) treatment was interrupted in 88.7% of patients
- No intracranial hemorrhage or embolic events were observed.
- Chronic NOAC treatment before surgery was associated with lower rates of minor pocket haematoma (1.4%; P= 0.042) vs. dual antiplatelet therapy (13.0%), VKA (11.4%), VKA + antiplatelet (9.2%), or NOAC + antiplatelet (7.7%).
- Similar results were observed for bleeding complications (P= 0.028).
- Hemorrhagic complications were significantly less frequent in patients treated with NOACs.
What do we really do?
Canada 2014

• Data survey on CIED management in Canada
• Twenty-two centers, 14,971 device implants;
• 1150 (8%) of these implants were in patients who were prescribed a NOAC.
• 82% discontinue NOAC, 73% do not bridge with heparin.
• If CHADS2 ≥ 2, 72% of the restart NOAC within 48 hours of the procedure.
• For patients with abnormal renal function (glomerular filtration rate < 80 mL/min), the timing of NOAC discontinuation is variable.
• Hematoma rates vary from 0 to 30%.
Catheter Ablation of Atrial Fibrillation

NOAC vs. continuous warfarin

• Nineteen studies 7996 patients
• -subgroups included interrupted and continuous NOAC vs. interrupted and continuous Warfarin

• Conclusions:
  – NOAC treatment was associated with fewer overall bleeding events than continuous warfarin treatment (RR = 0.78, 95% CI = 0.64-0.95, P = 0.01);
  – NOAC treatment also had fewer bleeding events than interrupted warfarin treatment (RR = 0.58, 95% CI = 0.44-0.77, P = 0.0002).
  – NOAC treatment did not increase the risk of thromboembolic complications compared with warfarin treatment (P > 0.05).

Cryoablation of Atrial fibrillation

- Transseptal with a 14 french sheath
- Large foreign body in the atrium
- Historically warfarin
- NOACS now more common

VT ablation: Retrograde Aorta
Watchman vs. NOACS

- Meta-analysis of Watchman vs. NOACS with afib (NOT PROCEDURE BASED)

RESULTS:
- 14 studies with 246,005 patients, 124,823 were treated with warfarin, 120,450 were treated with NOACs and 732 had Watchman implanted.
- Mean age was 72 ± 9 years, 53% were male, and mean CHADS2 score was 2.1 ± 1.6.
- Both NOACs and Watchman were superior to warfarin in hemorrhagic stroke prevention (OR = 0.46 [0.30-0.82] and OR = 0.21 [0.05-0.99],
- NOACs significantly reduced total stroke (OR = 0.78 [0.58-0.96]) and major bleeding (OR = 0.78 [0.65-0.91]) compared with warfarin.
- Indirect comparison between NOAC and Watchman revealed no significant differences in outcomes

CONCLUSIONS:
- NOAC therapy was superior to warfarin for multiple outcomes while Watchman reduced hemorrhagic stroke.
- Further studies are needed to assess Watchman versus NOAC to optimize therapy for stroke prevention in AF patients.
Watchman:
FDA Approval Date: March 13, 2015

The WATCHMAN should not be used in patients who:

- currently have a blood clot in their heart.
- have had surgical repair of the wall between the upper chambers of the heart (atrial septum) or have a device placed in the atrial septum, or have a LAA that is too large or too small to fit the WATCHMAN.
- cannot tolerate blood thinning medicines (warfarin, clopidogrel, and aspirin).
- have sensitivity to nickel or titanium (Nitinol) or any other material that is part of the device.

picture from: https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm440621.htm
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c. DC warfarin 5 days prior to procedure with no bridge
d. Continue full dose warfarin
e. 1A: fake out; same answer
Case 2

62 year old man with history of paroxysmal atrial fibrillation that has recently become persistent, is referred for atrial fibrillation ablation. CHADS2-VaSC is 1. He takes rivaroxaban. Which of the following is appropriate:

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68 year old man with Htn, DM, ischemic cardiomyopathy, s/p ICD, on warfarin for recurrent DVTs, prior CVA, and atrial fibrillation, referred for VT ablation. What do you advise prior to the procedure?

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b. Transition to dabigatran and hold 24 hours prior to procedure
c. Continue full dose warfarin
d. Hold warfarin 5 days prior to the procedure and admit for IV heparin bridge
e. A, C or D are possible, consult with EP doc
Case 4

82 year old woman with atrial fibrillation, CHF, EF 15%, with CVA 3 weeks ago, on apixaban is referred for primary prevention ICD. You advise:

a. Defer procedure for a minimum of 3 months
b. Continue apixaban through the procedure
c. Discontinue apixaban 48 hours prior to procedure
d. Transition to warfarin for the procedure
e. Discontinue apixaban 5 days prior to procedure and bridge with IV heparin inpatient
Summary:

• Different EP procedures have different requirements for AC discontinuation
• Over time, people get more aggressive in performing procedures on full OAC
• Every patient who needs to hold anticoagulation an independent risk benefit analysis to determine if “bridging” is necessary; most often it is not.
References


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