Laboratory Monitoring of Dabigatran

- Routine lab monitoring is NOT recommended
- In certain clinical situations, lab testing may be indicated including:
  1. Suspected drug failure (thrombosis while on dabigatran)
  2. Major/life-threatening bleeding while on dabigatran
  3. Urgent/emergent surgery or invasive procedure while on dabigatran
- Lab testing can be considered in patients of weight extreme or with renal insufficiency
- ALL coagulation tests must be interpreted with caution for patients on dabigatran
- Peak effect is 2-4 hours after administration

Laboratory Tests available at WVUH for documenting dabigatran effect

**Thrombin Time (TT)**
- Order in Merlin as “THROMBIN TIME”
- Consider obtaining 6-12 hours before elective surgery with a high risk of bleeding
- If TT is normal, no significant dabigatran is in patient.

**Activated partial thromboplastin time (PTT)**
- USE WITH CAUTION: The PTT is relatively insensitive to dabigatran effects
- If the PTT is within the reference range, there is unlikely to be significant dabigatran effect
- Patients with only a mildly elevated PTT CAN have significant bleeding (PTT level does not predict risk of bleeding)

**Prothrombin Time (PT/INR)**
- DO NOT USE to test for dabigatran effect: Patients with significant drug levels who are bleeding can have a normal PT/INR.

PT, PTT and thrombin time are available 24/7.

Perioperative Management - Holding for Procedures

Dabigatran package insert recommends the following based on renal function:
- CrCl > 50 mL/min: 1-2 days
- CrCl < 50 mL/min: 3-5 days

Dabigatran Discontinuation Prior to Elective Surgery - alternative strategy – see chart on next page
Dabigatran (Pradaxa®) Monitoring, Perioperative Management and Reversal
Last updated February 2012

<table>
<thead>
<tr>
<th>Renal function (CLCr, ml/min)</th>
<th>Half-life (hours)(^a)</th>
<th>Timing of discontinuation after last dose of dabigatran before surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt; 80</td>
<td>13 (11-22)</td>
<td>24 hours</td>
</tr>
<tr>
<td>&gt; 50 to ≤ 80</td>
<td>15 (12-34)</td>
<td>24 hours</td>
</tr>
<tr>
<td>&gt; 30 to ≤ 50</td>
<td>18 (13-23)</td>
<td>at least 2 days (48 hours)</td>
</tr>
<tr>
<td>≤ 30(^b)</td>
<td>27 (22-35)</td>
<td>2-5 days</td>
</tr>
</tbody>
</table>

\(^a\)Data from renal impairment study in healthy volunteers (11), geometric mean (range). \(^b\)Types of surgery associated with a high risk of bleeding (or in major surgery where complete hemostasis may be required) include but is not limited to cardiac surgery, neurosurgery, abdominal surgery or those involving a major organ. Other procedures such as spinal anesthesia may also require complete hemostatic function. Other important determinants of bleeding risk include advancing age, co-morbidities (e.g. major cardiac, respiratory or liver disease) and concomitant use of antiplatelet therapy. \(^c\)Dabigatran etexilate is contraindicated for use in these patients. CLCr = creatinine clearance.


**Acute Overdose of Dabigatran**
- Activated charcoal may be used in the event of an acute overdose of dabigatran if drug has been taken within 2 hours
- Two *in vitro* studies demonstrate that dabigatran can successfully be adsorbed by activated charcoal in the stomach fluid as well as the plasma
- Recommendation: Give activated charcoal 1-2 hours post-overdose before intestinal absorption occurs

**Bleeding Management: Reversal Options (If patient has significant bleeding or requires urgent procedure.)**
**Treatment options**
- Fresh frozen plasma (FFP) 5-10 mL/kg: There are conflicting opinions on the efficacy of FFP in dabigatran overdose.
- Dialysis - Approximately 60% is removed over 2-3 hours
  - A small study of 6 patients with end-stage renal failure underwent dialysis and a mean of 62% and 68% of the drug was removed at 2 hours and 4 hours, respectively.
- Recombinant activated factor VII (rFVIIa) (NovoSeven®) - dosing unclear
  - Consider 40 mcg/kg. May repeat dose. Higher dose of 90 mcg/kg can be considered.
- Prothrombin complex concentrate (PCC) - Bebulin® - 25-50 units/kg is available at WVUH.

**References**

PNT Approved 2/12