Consequences of an Outpatient Treatment Protocol on Thromboembolic Disease Management in a Community Emergency Department

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Decision Support Consultant: Cheri Beckman
Deep Vein Thrombosis

- An Estimated 45 000 Canadians are affected by DVT each year
  - 1-2/1000 cases annually
  - Up to 50% unprovoked

- 1/3 will develop PE
- 1/3 will develop post-thrombotic syndrome
- 1/3 will have recurrence VTE within 10 years
Deep Vein Thrombosis

- According to Thrombosis Canada Guidelines for DVT Treatment (2015), Outpatient management preferred
  - Lower costs
  - Higher patient satisfaction
  - Lower exposure to hospital acquired infections

- What do we fear?
  - Patient noncompliance, lack of appropriate follow up, difficulty coordinating treatments, complications
DVT Research Question

• **Primary Question:**
  – In patients managed for DVT after the launch of a new outpatient treatment protocol in June 2013, were admission rates decreased when compared to patients diagnosed prior to the protocol?

• **Secondary Question:**
  – In patients managed for DVT after the protocol, was there an increase in revisits within 7 and 30 days for any reason and for the same diagnosis?
**Suggested Outpatient DVT Treatment Protocol**

For diagnosed DVT requiring treatment
And when outpatient treatment is appropriate

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### STEP 1: Workup

- Order CBC, INR/PTT, Chem, LFT
- Stop NSAIDS & IM injection
- Discuss RTED & F/U Plan with patient
- Consider admission in complicated case, patient factors, bleeding risk or history of bleeding
- Discuss options with patient especially financial implications

**Cost:**

- **Enoxaparin** covered by CCAC if no other coverage.
- **Warfarin** is inexpensive and covered by all plans.
- **Xarelto**: Third Party and ODB LU 444. Cash cost Costco: $134 per 3wks then $96 per month. Shoppers: $151 per 3wks then $112 per month.

### Step 2: Choose an Option

1. **Rivaroxaban (Xarelto)**: primary option for treatment
   - Contraindicated in: Hepatic Disease (active hepatitis, ALT > 3x normal), CrCl < 30, or on Dilantin, Carbamazepine, Systemic Ketoconazole, or Anti-retroviral drugs.
   - Consider alternative if: Increased bleeding risk, or history of bleeding (esp. GI)

2. **Enoxaparin (Lovenox)**: Use alone in active malignancy, pregnancy, Breast feeding.

3. **Enoxaparin/Warfarin Combo**: use in patients other than above e.g. renal failure or financially prohibitive

### A. Enoxaparin/Warfarin Option

**A1. Enoxaparin/Warfarin**

- **Give first dose** Enoxaparin S.C. in ED, by CrCl
  - CrCl > 30 - 1.5mg/kg (max 180mg) _______ mg
  - CrCl < 30 - 1 mg/kg (max 180mg) _______ mg

- **Give prescription**, by CrCl
  - 1. Enoxaparin _______ mg OD x 5/7 repeat x3
  - LU 186 (Prefilled in 30, 40, 60, 80, 100, 120, 150mg)
  - 2. Warfarin 1mg tabs x 100,
    - begin warfarin 10mg PO OD 1d prior to f/u appointment with Hematology Clinic

**A2. Further Care**

- Complete CCAC req
- FAX to Thrombo Clinic for further care, follow up and investigation

### B. Rivaroxaban (Xarelto) Option

**B1. Rivaroxaban**

- **Give first dose in ED**
  - Rivaroxaban (Xarelto) 15mg PO NOW

- **Give prescription**:
  - Rivaroxaban (Xarelto) 15mg PO BID x 3/52 LU 444

**B2. Further Care**

- FAX to Thrombo Clinic for further care, follow up and investigation
You have been diagnosed with a blood clot in the vein (DVT) that requires treatment. The treatment is “blood thinners” (known as anticoagulants). Most patients require treatment for 3 to 9 months, but some will need it longer.

It is very important that you:

1. See the Specialist at the Hematology Clinic located at 219 Queenston St, St Catharines for follow up and further care within a few days. A referral has already been made.
2. CALL THE CLINIC (905) 685-8082 yourself within the next 24hrs to get an appointment. Leave a detailed message with your contact information.
3. Take your medications regularly and read the instructions and information given to you by your pharmacist.
4. Return to the Emergency Department (or Call 911) if you develop signs of:
   a. bleeding that could be caused by blood thinners. These could be bleeding in your urine or stool, bleeding from the nose, acute severe headache, sudden loss of vision, or extensive bruising.
   b. a clot traveling to the lung. These could include acute chest pain, acute shortness of breath, coughing up blood, or loss of consciousness.
5. Avoid:
   a. having intramuscular injections
   b. taking Anti-inflammatories (Like Aleve or Advil) because of the increased risk of bleeding.
   c. Doing activities that increase your risk of injury or bleeding.
6. Ask your doctor, pharmacist or nurse any questions that you might have. One helpful article you might choose to read is from the Mayo Clinic. Use this internet address: www.bit.ly/dvtinfo

Blood thinners can be used in one of two ways. Know yours and what you need to do:

<table>
<thead>
<tr>
<th>Enoxaparin (Lovenox)/Warfarin Option</th>
<th>Rivaroxaban (Xarelto) Option</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. You will have to get daily injections of Lovenox until your blood is thin enough on Warfarin (INR between 2 and 3)</td>
<td></td>
</tr>
<tr>
<td>2. Injections are arranged through CCAC nurses. We faxed the forms and CCAC will contact you. They can be reached at (905) 684-9441 and their clinic is at 149 Hartzel Rd in St Catharines.</td>
<td></td>
</tr>
<tr>
<td>3. If prescribed, start taking your warfarin the evening before your appointment with the Hematologist. Take 10mg that evening and then follow your doctor’s instructions.</td>
<td></td>
</tr>
<tr>
<td>4. You will be getting blood work regularly through your doctor, usually every 2-3 days for the first 2 weeks then every 2-3 weeks for the length of treatment</td>
<td></td>
</tr>
<tr>
<td>1. Take your medications</td>
<td></td>
</tr>
<tr>
<td>2. CALL THE HEMATOLOGY CLINIC (905) 685-8082</td>
<td></td>
</tr>
</tbody>
</table>

If you do not have a family doctor, call Health Care Connect Ontario at 1-800-445-1822 for help getting one.
Methods for DVT Group

- Using the database at SCGH and our Decision Support Consultant, we searched OHIP Diagnostic Code 451 for visits between January 2011-May 2013 (before protocol) and June 2013-October 2015 (after protocol)
  
  Collected data on admission numbers on initial visits, return visits (total and same dx) within 7 days and return visits (total and same dx) within 30 days

<table>
<thead>
<tr>
<th>Most Responsible Diagnosis</th>
<th>Total ED Visits</th>
<th>Admits via ED</th>
<th>Admit Rate</th>
<th>Male</th>
<th>Female</th>
<th>Avg Age</th>
<th>Return Visits within 7 days</th>
<th>Return Visits within 30 days</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total</td>
<td>Admits</td>
<td>Same MRDx</td>
<td>Total</td>
<td>Admits</td>
<td>Same MRDx</td>
<td>Total</td>
<td>Admits</td>
</tr>
<tr>
<td>Phlebitis &amp; Thrombophlebitis of Femoral Vein &amp; Other Deep Vessels of Lower Extremities</td>
<td>868</td>
<td>61</td>
<td>412</td>
<td>456</td>
<td>61</td>
<td>397</td>
<td>19</td>
<td>112</td>
</tr>
<tr>
<td>Phlebitis &amp; Thrombophlebitis of Femoral Vein &amp; Other Deep Vessels of Lower Extremities</td>
<td>1,182</td>
<td>59</td>
<td>538</td>
<td>644</td>
<td>59</td>
<td>488</td>
<td>15</td>
<td>108</td>
</tr>
</tbody>
</table>
Results

Admission and Revisit Rates at 7 and 30 days before and after introduction of an outpatient DVT treatment protocol.
# Results

<table>
<thead>
<tr>
<th>Comparison Measures Before and After Protocol</th>
<th>Trend Direction</th>
<th>Chi-Square Conclusion (p&lt;0.05)</th>
<th>Chi Square P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial Admission Rate</td>
<td>Decrease</td>
<td>Not significant</td>
<td>P=0.052</td>
</tr>
<tr>
<td>Return Visits 7 days- Any reason</td>
<td>Decrease</td>
<td><strong>Significant</strong></td>
<td>P=0.044</td>
</tr>
<tr>
<td>Return Visits 7 days- Same Diagnosis</td>
<td>Decrease</td>
<td><strong>Significant</strong></td>
<td>P=0.007</td>
</tr>
<tr>
<td>Return Visits 30 days- Any reason</td>
<td>Decrease</td>
<td>Not Significant</td>
<td>P=0.0869</td>
</tr>
<tr>
<td>Return Visits 30 days- Same Diagnosis</td>
<td>Decrease</td>
<td><strong>Significant</strong></td>
<td>P=0.0193</td>
</tr>
</tbody>
</table>
Summary

• Trend towards a decrease in admissions, not significant
  - Likely admissions were for complex patient care issues, as DVT itself not immediately life threatening

• Significant decrease in revisits, any reason, at 7 days and revisits at 7 and 30 days for same diagnosis

• Trend towards decrease in revisits, any reason, 30 days but not significant
Pulmonary Embolism

- Thrombosis Canada 2015 guidelines recommend patients with new diagnosis of PE be risk stratified with PESI score
  - Outpatient and Inpatient management reasonable based on clinical picture
- September 2013 PE treatment protocol introduced at St. Catharines General Hospital, guiding decision making and facilitating outpatient management in appropriate patients
- Follow up arranged with thrombosis clinic as outpatient
PE Research Question

• Primary Question:
  – In patients managed for PE after the launch of a new outpatient treatment protocol in September 2013, were admission rates decreased when compared to patients diagnosed prior to the protocol?

• Secondary Question:
  – In patients managed for PE after the protocol, was there an increase in revisits within 7 and 30 days for any reason and for the same diagnosis?
### Suggested Outpatient PE Treatment Protocol

For diagnosed PE requiring treatment
And when outpatient treatment is appropriate

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**STEP 1: Workup/Stratify Risk**

- ☐ Order CBC, INR/PTT, Chem, LFT
- ☐ Apply PESI Score (add up)

<table>
<thead>
<tr>
<th>Patient Age</th>
<th>Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>History of Cancer?</td>
<td>+10</td>
</tr>
<tr>
<td>Male Patient?</td>
<td>+30</td>
</tr>
<tr>
<td>History of CHF?</td>
<td>+10</td>
</tr>
<tr>
<td>History of Chronic Lung Disease?</td>
<td>+10</td>
</tr>
<tr>
<td>Heart Rate &gt;110 bpm?</td>
<td>+20</td>
</tr>
<tr>
<td>SBP &lt;100 mmHg?</td>
<td>+30</td>
</tr>
<tr>
<td>Respiratory Rate &gt;30?</td>
<td>+20</td>
</tr>
<tr>
<td>Temperature &lt;36°C?</td>
<td>+20</td>
</tr>
<tr>
<td>Altered Mental Status?</td>
<td>+60</td>
</tr>
<tr>
<td>O₂ Saturation &lt;90% on room air?</td>
<td>+20</td>
</tr>
</tbody>
</table>

**TOTAL**

Patient is eligible for O/P Rx if all of the following:
- ☐ Score is 85 or less (Mortality  3.5%)
- ☐ Clinically well and able to care for self
- ☐ Reliable for follow-up with Thrombo

*Consider admission in complicated case, patient factors, bleeding risk or history of bleeding*

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### Enoxaparin/Warfarin Option

**A1. Enoxaparin/Warfarin**

Give first dose Enoxaparin now, by CrCl
- ☐ CrCl > 30 - 1.5mg/kg (max 180mg) ______ mg
- ☐ CrCl < 30 - 1 mg/kg (max 180mg) ______ mg

Give prescription, by CrCl

1. Enoxaparin ______ mg OD x 5/7 repeat x3
2. Enoxaparin 1mg tabs x 100,
   - begin warfarin 10mg PO OD 1d prior to f/u appointment with Thrombo

**A2. Further Care**

- ☐ Complete CCAC req
- ☐ Give PE patient information sheets

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### Rivaroxaban (Xarelto) Option

**B1. Rivaroxaban**

Give prescription:
- ☐ Rivaroxaban (Xarelto) 15mg PO BID x 3/52 LU 444
- ☐ Give first dose in ED

**B2. Further Care**

- ☐ Enforce importance of follow up within 2-3 days
- ☐ Give PE patient information sheets

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**STEP 2: Pick an Option**

1. **Xarelto (Rivaroxaban)** is Primary Option
   - **Contraindicated in:** Hepatic Disease (active hepatitis, ALT > 3x normal), CrCl < 30 or patient on Dilantin, Carbamazepine, Systemic Ketoconazole, or Anti-retroviral drugs.
   - Consider alternative if: Increased bleeding risk, or history of bleeding (esp. GI)

2. **Enoxaparin (Lovenox)** alone in active malignancy, pregnancy, Breast feeding

3. **Enoxaparin/Warfarin Combo:** use in patients other than above e.g. renal failure or financially prohibitive

- ☐ Stop NSAIDS & IM injection
- ☐ Discuss Diagnosis, options, RTED and F/U plan with patient
- ☐ Discuss RTED & F/U Plan

**Cost:**

- Enoxaparin covered by CCAC if no other coverage. Warfarin is inexpensive and covered by all plans
  - Shoppers: $144.40 per month
  - Shoppers: $585 per 3 weeks

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**FAX this form and ED chart to THROMBO Clinic**

Fax Number (905) 988-5776
You have been diagnosed with a blood clot in the lung (PE) that requires treatment. The treatment is “blood thinners” (known as anticoagulants). Most patients require treatment for 3 to 9 months, but some will need it longer.

**It is very important that you:**

1. See the Specialist at the Hematology Clinic located at 219 Queenston St, St Catharines for follow up and further care within a few days. A referral has already been made.
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4. Return to the Emergency Department (or Call 911) if you develop signs of:
   a. bleeding that could be caused by blood thinners. *These could be bleeding in your urine or stool, bleeding from the nose, acute severe headache, sudden loss of vision, or extensive bruising.*
   b. **worsening lung function.** *These could include increasing chest pain, increasing shortness of breath, coughing up blood, or loss of consciousness.*
5. Avoid:
   a. having intramuscular injections
   b. taking Anti-inflammatories (Like Aleve or Advil) because of the increased risk of bleeding.
   c. Doing activities that increase your risk of injury or bleeding.
6. Ask your doctor, pharmacist or nurse any questions that you might have. **One helpful article you might choose to read is from the Mayo Clinic. Use this internet address:** [www.bit.ly/peinfo](http://www.bit.ly/peinfo)

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**Blood thinners can be used in one of two ways. Know yours and what you need to do:**

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**Rivaroxaban (Xarelto) Option**

1. Take your medications
2. **CALL THE HEMATOLOGY CLINIC (905) 685-8082**

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If you do not have a family doctor, call Health Care Connect Ontario at 1-800-445-1822 for help getting one.
Research Methods

- Using the database at SCGH and our Decision Support Consultant, we searched OHIP Diagnostic Code 415 for visits between July 2011-August 2013 (before protocol) and September 2013-October 2015 (after protocol)
  - Collected data on admission numbers on initial visits, return visits (total and same dx) within 7 days and return visits (total and same dx) within 30 days
Results
Admission and Revisit Rates at 7 and 30 days before and after introduction of an outpatient PE treatment protocol
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<td><strong>Significant</strong></td>
<td>P=0.0002</td>
</tr>
<tr>
<td>Return Visits 7 days- Any reason</td>
<td>Decrease</td>
<td>Not Significant</td>
<td>P=0.5671</td>
</tr>
<tr>
<td>Return Visits 7 days- Same Diagnosis</td>
<td>Increase</td>
<td>Not Significant</td>
<td>P=0.3209</td>
</tr>
<tr>
<td>Return Visits 30 days- Any reason</td>
<td>Decrease</td>
<td>Not Significant</td>
<td>P=0.5926</td>
</tr>
<tr>
<td>Return Visits 30 days- Same Diagnosis</td>
<td>Increase</td>
<td>Not Significant</td>
<td>P=0.0945</td>
</tr>
</tbody>
</table>
Summary

- Statistically significant decrease in admission rates without significant increase in revisits at 7 and 30 days for same or new diagnoses
- Successfully guided physicians in identifying appropriate patients for outpatient treatment
Discussion and Outcomes

• Both the DVT and PE protocols showed positive outcomes in the dispositioning of patients, and so it is anticipated that there will be continued use of the protocols within our ED.

• Further studies could address degree of physician uptake of the protocols, patient oriented factors such as symptoms at various intervals, negative side effects encountered and satisfaction levels etc.
References
