Understanding Risks of DVT/PE in Foot and Ankle Surgery

Alan Banks, DPM
Tucker, GA
• Balancing the risk between the prevention of DVT / PE and increased bleeding.
American College of Chest Physicians

– 2012 Chest

“We suggest no prophylaxis ... in patients with isolated lower-leg injuries requiring leg immobilization.”
American Orthopedic Foot and Ankle Society, 2013

“...There is currently insufficient data ... to recommend for or against routine VTED prophylaxis...."
• International consensus panel
  – 2013 Int Angiol

“Current available data...suggest that routine LMWH prophylaxis should be considered for isolated limb trauma in the absence of contraindications.”

Duration of prophylaxis – “...until the patient is weight bearing.”
American College of Foot and Ankle Surgeons, 2015

“Current evidence argues against the routine use of chemical prophylaxis for VTED in foot and ankle surgery or in injuries requiring immobilization.”
Confounded by numerous study factors

- Definition of VTE – symptomatic or not
- Anatomic location – leg vs. thigh
- Diagnostic modalities
- Time elapsed from event to evaluation
• Meta-analysis of 6 RCT with leg immobilization
• 1490 patients, 750 receiving LMWH
• Incidence of DVT 4.3 – 40% in the control group
• Symptomatic DVT 2.5%
• Proximal DVT was rare
• Use of LMWH significantly reduces VTE when immobilization is required.
• 216 patients
• 130 patients BK cast for minimum 4 weeks
• 88 patients with HAV surgery weight bearing postop
• Ultrasound evaluation between 2-6 weeks
• Incidence of thrombosis
  – Weight bearing 0%
  – Cast 8.46%

• DVT usually developed after 30 days

Recommended prophylaxis until weight bearing
Meta-analysis

All randomized trials using LMWH with transient reduced mobility in non major orthopedic surgery

14 studies - 4,726 patients

Weighted rate of VTE – 2.9%

68% reduction of major VTE with LMWH
• 70+ year old male
• ORIF calcaneal fracture
• 2 weeks Lovenox
• Cast / NWB 12 weeks
• DVT/PE at 13 weeks
• 18 year old obese female
• Gastroc recession / NC fusion
• Placed on birth control pills by GYN periop
• 2 weeks postop – Pulmonary embolism
• 26 year old active male
• Delayed primary repair lateral ankle ligaments
• Pain in calf at 3 weeks
• DVT
American Orthopedic Foot and Ankle Society, 2013

- “We do recommend, however, that patients be assessed preoperatively for VTED risk.”

- “Exactly what constitutes sufficient risk, ... remains undetermined.”
American College of Foot and Ankle Surgeons, 2015

- “...foot and ankle surgeons should attempt to stratify patients and develop a prophylaxis plan for those at high risk of VTED.”

- “Exactly what constitutes sufficient risk to warrant chemical prophylaxis is not clear.”
• Caprini survey
• L-Trip Cast score
• ACFAS clinical model
Are You at Risk for DVT?

FOR PATIENTS

Complete this risk assessment tool to find out.

Name

- Male
- Female

Today's Date

Directions:
1. Check all statements that apply to you.
2. Enter the number of points for each of your checked statements in the space at right.
3. Add up all points to reach your total DVT Risk Score.
   Then, share your completed form with your doctor.

Add 2 points for each of the following statements that apply:

- Age 65–74 years
- Current or past malignancies (excluding skin cancer, but not melanoma)
- Planned major surgery lasting greater than 45 minutes (excluding laparoscopic and arthroscopic)
- Non-removable plaster cast or mold that has kept you from moving your leg within the last month
- Tube in blood vessel in neck or chest that delivers blood or medicine directly to heart within the last month (also called central venous access, PICC, line, or port)
- Confined to a bed for 72 hours or more

Add 3 points for each of the following statements that apply:

- Age 75 or over
- History of blood clots, either Deep Vein Thrombosis (DVT) or Pulmonary Embolism (PE)
- Family history of blood clots (thrombosis)
- Personal or family history of positive blood test indicating an increased risk of blood clots

Add 1 point for each of the following statements that apply now or within the past month:

- Age 41–60 years
- Minor surgery (less than 45 minutes) is planned
- Past major surgery (more than 45 minutes) within the last month
- Visible varicose veins
- A history of Inflammatory Bowel Disease (IBD) (for example, Crohn’s disease or ulcerative colitis)
- Swollen legs (current)
- Overweight or obese (Body Mass Index above 25)
- Heart attack
- Congestive heart failure
• Age 41-60 years
• BMI > 25
• Edema
• Varicose veins
• Oral contraceptive
• Hormonal therapy
• Bed rest < 72 hours
• Inflammatory bowel disease
• Past major surgery in the month
• MI / CHF
• Lung disease
• Pregnancy / post partum
- Age 61 – 74 years
- Cast < 1 month
- Bed rest > 72 hours

- Arthroscopy
- Laparoscopy
- General surgery > 45 minutes
- Current / past malignancies
- PICC / Central line
• Age 75 or more
• Prior history DVT / PE
• Family history of DVT / PE

• Clotting factor aberrations
• Lupus anticoagulants
• Anticardiolipin antibodies
• Fracture of hip, pelvis, leg
• Elective arthroplasty – hip / knee
• Polytrauma

• Stroke in previous month
• Acute spinal cord injury in previous month
Score 0-1: Low risk
Score 2: Moderate risk
Score 3-4: High risk
Score 5 or more: Highest risk
• Goal: to develop a clinical prediction tool for DVT in patients with casts

• Comparison of patients with DVT and controls
### L-TriP(cast) Score Based On The Clinical Risk Prediction Model

<table>
<thead>
<tr>
<th>Environmental Predictor Variable</th>
<th>Point Variable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age ≥ 35 and &lt; 55 y</td>
<td>2</td>
</tr>
<tr>
<td>Age ≥ 55 y</td>
<td>3</td>
</tr>
<tr>
<td>Male sex</td>
<td>1</td>
</tr>
<tr>
<td>Current use of oral contraceptives</td>
<td>4</td>
</tr>
<tr>
<td>Cancer within the past 5 y</td>
<td>3</td>
</tr>
<tr>
<td>Pregnancy or puerperium</td>
<td>3</td>
</tr>
<tr>
<td>BMI ≥ 25 and &lt; 35 kg/m²</td>
<td>1</td>
</tr>
<tr>
<td>BMI ≥ kg/m²</td>
<td>2</td>
</tr>
<tr>
<td>Pneumonia</td>
<td>3</td>
</tr>
<tr>
<td>Family history of VTE (first-degree relative)</td>
<td>2</td>
</tr>
<tr>
<td>Comorbidity (rheumatoid arthritis, chronic kidney disease, COPD, multiple sclerosis)</td>
<td>1</td>
</tr>
<tr>
<td>Hospital admission within the past 3 mo</td>
<td>2</td>
</tr>
<tr>
<td>Bedridden within the past 3 mo</td>
<td>2</td>
</tr>
<tr>
<td>Surgery within the past 3 mo</td>
<td>2</td>
</tr>
<tr>
<td>Superficial vein thrombosis</td>
<td>3</td>
</tr>
<tr>
<td>Plaster cast: lower leg</td>
<td>4</td>
</tr>
</tbody>
</table>

### CASE 1

<table>
<thead>
<tr>
<th>Description</th>
<th>Caprini</th>
<th>L-TriP</th>
</tr>
</thead>
<tbody>
<tr>
<td>45 year old</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Obese patient</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Lapidus bunionectomy (cast)</td>
<td>2</td>
<td>4</td>
</tr>
</tbody>
</table>

*4 - high risk*  
7 (9)
### Case 2

<table>
<thead>
<tr>
<th></th>
<th>Caprini</th>
<th>L-TriP</th>
</tr>
</thead>
<tbody>
<tr>
<td>24 year old female</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Ankle reconstruction (cast)</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Birth control pills</td>
<td>1</td>
<td>4</td>
</tr>
</tbody>
</table>

**Total**

3 – High risk  8 (9)

7/21/2016
### Case 3

<table>
<thead>
<tr>
<th>Caprini</th>
<th>L-TriP</th>
</tr>
</thead>
<tbody>
<tr>
<td>65 year old male</td>
<td>2</td>
</tr>
<tr>
<td>Repair TPD (cast)</td>
<td>2</td>
</tr>
<tr>
<td>Varicose veins</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
ACFAS risk assessment

- 1 or more primary risk factors
- Careful consideration of secondary risk factors and severity
  - Individually seldom sufficient to justify use of chemical prophylaxis
- Clinicians should consider a multimodal approach
### ACFAS Risk Factors For Venous Thromboembolism

<table>
<thead>
<tr>
<th>Patient Specific</th>
<th>Treatment Specific</th>
<th>Surgery/Injury Specific</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Personal history of VTED</td>
<td>Immobilization &gt; 4wks</td>
<td></td>
</tr>
<tr>
<td>Hypercoagulability</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Active/recent (&lt;6 mo) cancer</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Secondary</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Advanced age (&gt; 60)</td>
<td>Non-weightbearing</td>
<td>Achilles tendon rupture‡</td>
</tr>
<tr>
<td>Obesity (BMI &gt; 30)</td>
<td>Hospitalization</td>
<td>Ankle fracture‡</td>
</tr>
<tr>
<td>Family history of VTED</td>
<td>Bed rest</td>
<td>Total ankle replacement</td>
</tr>
<tr>
<td>OCP or HRT use†</td>
<td></td>
<td>Hindfoot arthrodesis</td>
</tr>
<tr>
<td>Varicose veins</td>
<td></td>
<td>General anesthesia</td>
</tr>
<tr>
<td>Diabetes mellitus or &gt; 1 comorbidity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Severe foot/ankle injury</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

† Consider also if patient is a current smoker, as this may further VTED risk.
‡ Includes operative and nonoperative management.

• Achilles ruptures

  – 6 studies with an incidence of DVT 0.43 to 34%

  – Makhdom, et.al., JFAS, 2013

    • Incidence of symptomatic DVT was 23.4% in patients undergoing surgery
Options for chemical prophylaxis

- Low molecular weight heparin
- Warfarin
- New oral agents – Factor X inhibitors
  - Thrombin inhibitor
Low molecular weight heparin

- Lovenox (enoxaparin)
- Arixtra (fondaparinux)
- Fragmin (dalteparin)

- Subcutaneous injection
- No lab monitoring
- Now generic
- Risk of thrombocytopenia
New oral anticoagulants (NOAC)

- Factor Xa inhibitors
  - Xarelto
  - Eliquis
- Direct thrombin inhibitor
  - Pradaxa
Downsides to NOAC

- Cost
  - Discount coupons

- No active reversal agents for Xarelto, Eliquis
  - Adexanet alfa completed phase III clinical trials
  - Praxbind now approved for reversal of Pradaxa
Considerations with NOAC

- No aspirin, NSAIDs, Plavix
- GI bleeding more common with Xarelto and Pradaxa (Eliquis favored)
Potential drug interactions

- Verapamil, amiodarone
- Sporono, Ketoconazole, Diflucan
- Norvir, Kaletra, Crixivan
- Dilantin, Phenobarbital, Carbamazepine
- Rifampin
- St. John’s Wort
Why not warfarin?

- Inexpensive
- Increased bleeding potential compared to NOAC
- Need for monitoring
- More potential drug interactions
- Affected by diet
• Bleeding complications
  - Confounding factors in assessment of risk
    - Initiation of therapy
    - Dosage
    - Definitions
  Testroote – 8% minor events
  Lower than other studies
Primary complication of prophylaxis

- Bleeding complications
- Major
  - Death
  - Bleeding into a critical organ
  - Bleed associated with 2g/dl drop in Hgb or transfusion of 2 units
  - Bleed requiring reoperation
Assessing bleeding complications in studies

- Dose of medication
- Timing of dose
- Medication related?
- Nature of the surgery
- Xarelto
  - 10 to 40 mg
- Preop vs. postop
- Bleeding evident before or after dosing
• Major orthopedic surgery
  – LMWH (Lovenox)
  – 10 – 14 days vs. 35 days
  – ↓ risk of DVT, no ↑ risk of major bleeding

• LMWH vs. warfarin
  – Substantial increased risk of major bleeding with warfarin over extended intervals
Aspirin?
Compression pumps
Exercises

Confers no protection
“Limited data suggest that concurrent use of anticoagulation with IPCD may lower the risk of VTE compared to anticoagulation alone...”

Pavon, et.al., 2015
VA Evidence-based Synthesis Program Reports
• Weightbearing significantly reduces risk
• Calf muscle pump

• Hickey, et.al., 2014  Foot Ankle Inter
  – Active dorsiflexion/plantarflexion of toes, ankle
  – Maximum velocity at popliteal vein 75% of normal
• Risk assessment of patients over age 18 with casts
• Discussion of risks
• Xarelto 10 mg QD
• Knee/toe exercises if feasible
• Problems
  – Increased swelling
  – Two patients with increased menstrual bleeding, one with nose bleed
• Literature to support either approach to prophylaxis
• European approach – more aggressive
• Newest terminology – “risk assessment”
  “risk stratification”

• Ask the question!
57 year old female

- Fracture 5^{th} metatarsal 1 day prior
- No significant PMH
- No medications
- Normal BMI

- Family history!
Prophylaxis does not eliminate risk of VTE

The benefits are relative and not absolute

Testroote – 6 RCT

Incidence of symptomatic DVT reduced from 2.5% to 0.3%
• VTE appears to develop later as opposed to sooner below the knee
  – More common presentation is after 30 days
  – Exception may be found in achilles ruptures
• Overall risk of DVT is low in most patients
• Risk assessment is recommended by all organizations
• Threshold for risk varies depending on the assessment tool
• Have the discussion with your patients
Go to
forum.podiatricsuccess.com
to continue the discussion and
ask questions