


The Risk and Prevention of Venous Thromboembolism (VTE) in Patients With Foot and Ankle Pathology

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The slide features a dark teal background with a red vertical bar on the right and a light blue circle. It includes an anatomical diagram of a leg with a red clot in a vein, a photograph of a surgical leg, a photograph of a patient's abdomen, and images of medical products including Brack and Xarelto.

Disclosure

- ▶ I am a designer for a VTE Prevention device – Patent pending

Goals

- ▶ 1. Define the problem of VTE
- ▶ 2. Determine if VTE is a problem in foot/ankle surgery
- ▶ 3. Determine what prophylactic treatment if any is indicated based on guidelines
- ▶ 4. Discuss various prophylactic measures

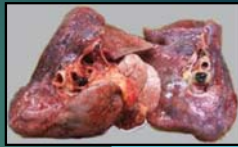
Why Is VTE a Problem?

- ▶ **Deep Venous Thrombosis (DVT):**
 - ▶ Post phlebitic syndrome (Chronic swelling and leg pain after a DVT)
- ▶ **Pulmonary Embolism (PE):**
 - ▶ Can lead to chronic pulmonary compromise
- ▶ **Adds tremendous cost, inconvenience, and risk of long term anticoagulation (usually 6 months)**



Fatal PE – The Real Issue

- ▶ Is this a real problem after foot and ankle injury or surgery?
 - ▶ Probably not
- ▶ **But it does occur !!!**
 - ▶ Is devastating to all parties involved



- ▶ Hamilton, et. Al., FAS 2011 June
 - ▶ 33,500 elective foot and ankle surgeries per year in UK
 - ▶ Incidence of DVT (0.6%), PE (0.1%), and fatal PE (0.02%)
 - ▶ Would have to treat 10,000 patients to prevent 1 fatal PE

Not only Is it Devastating, It can Lead To a Law Suit

DVT Disease Injury Lawsuits Linked To Side Effects ...
[www.gourlayyer.com / Topics / Diseases](#) ▶
 Deep Vein Thrombosis (DVT) | [Lawsuits, Lawyers](#) | Disease: Injury, Infection |
 Side ... Deep vein thrombosis (DVT) can lead to a very serious and life threatening ...

Pulmonary Embolism and Medical Malpractice Lawsuit Help ...
[www.ericweinberg.com/pulmonary-embolism/](#) ▶
 The Law Firm of Eric H. Weinberg is currently assisting individuals who have ...
 Medical Malpractice - Deep Vein Thrombosis and Pulmonary Embolism. Medical ...

DVT Study May Clot 'Economy Class' Lawsuits - Injured
[blogs.findlaw.com / ... /dvt-study-may-clot-economy-class-lawsuits.html](#) ▶
 Feb 8, 2012 - The study and the lawsuits involve deep vein thrombosis, or DVT --
 when a blood clot forms in a vein, usually in the legs, and causes painful ...

Xarelto Lawsuit Information - Accidents and Injuries - FindLaw
[injury.findlaw.com / ... / Accidents and Injuries / Product Liability](#) ▶
 A look at the problems associated with Xarelto and the lawsuit that have been filed ...
 a risk of developing blood clots in the legs, known as deep vein thrombosis.



There are Forces "Promoting" Anticoagulation




So What Do The Experts Say

CDC Home
CDC Centers for Disease Control and Prevention
 CDC 24/7: Saving Lives. Protecting People.™

Box 2.06. Venous thromboembolism (VTE) risk factors


General risk factors for VTE include the following:

- Older age (increasing risk after age 40)
- Obesity (BMI > 30 kg/m²)
- Estrogen use (hormonal contraceptives or hormone replacement therapy)
- Pregnancy and the postpartum period
- Thrombophilia (such as factor V Leiden mutation or antiphospholipid syndrome) or a family history of VTE
- Previous VTE
- Active cancer
- Serious medical illness (such as congestive heart failure or inflammatory bowel disease)
- Recent surgery, hospitalization, or trauma
- Limited mobility
- Central venous catheterization



How The SCIP Initiative Has Influenced the Issue

- ▶ Hospitals use scoring systems for VTE
- ▶ Many of my patients have multiple risk factors
- ▶ Thus, anticoagulation becomes "mandatory" even if the literature does not support it (Score ≥ 4)



Venous Thromboembolism Risk Factor Assessment

Patient's Name: _____ Age: _____ Sex: _____ Hgt: _____ Hgt: _____

Choose All That Apply

Each Risk Factor Represents 1 Point	Each Risk Factor Represents 2 Points
<input type="checkbox"/> Age ≥ 65 years <input type="checkbox"/> Male or female gender <input type="checkbox"/> History of prior major surgery <input type="checkbox"/> Hospital stay <input type="checkbox"/> History of immobilization (bed rest) <input type="checkbox"/> Recent surgery <input type="checkbox"/> Recent VTE <input type="checkbox"/> History of thrombophilia (such as factor V Leiden mutation or antiphospholipid syndrome) or a family history of VTE <input type="checkbox"/> Active cancer <input type="checkbox"/> Serious medical illness (such as congestive heart failure or inflammatory bowel disease) <input type="checkbox"/> Recent surgery, hospitalization, or trauma <input type="checkbox"/> Limited mobility <input type="checkbox"/> Central venous catheterization	<input type="checkbox"/> Age ≥ 75 years <input type="checkbox"/> History of prior major surgery <input type="checkbox"/> Hospital stay <input type="checkbox"/> History of immobilization (bed rest) <input type="checkbox"/> Recent surgery <input type="checkbox"/> Recent VTE <input type="checkbox"/> History of thrombophilia (such as factor V Leiden mutation or antiphospholipid syndrome) or a family history of VTE <input type="checkbox"/> Active cancer <input type="checkbox"/> Serious medical illness (such as congestive heart failure or inflammatory bowel disease) <input type="checkbox"/> Recent surgery, hospitalization, or trauma <input type="checkbox"/> Limited mobility <input type="checkbox"/> Central venous catheterization

Total Risk Factor Score:

*Standard only use from the surgery category

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With That Said:

- ▶ If you do nothing, VTE may occur
- ▶ **Anticoagulation has risks -**
 - ▶ Bleed at the operative site
 - ▶ Lovenox - Overall - 3 - 7% of patients, major bleeding 0.7 - 1.4 %
 - ▶ Arixtra, Xarelto - Any bleeding 10%, major - 0.1 to 1%,
 - ▶ Can lead to an increased risk of infection
 - ▶ Bleed at a remote site
 - ▶ Heparin Induced Thrombocytopenia (Lovenox, etc.)
 - ▶ Affect renal and hepatic function

What Do Surgeons Do Currently ???

How Do Surgeons Address VTE Prophylaxis - Surveys

- | | |
|---|---|
| <ul style="list-style-type: none"> ▶ Gadgil A, Thomas RH. FAJ. 2007 ▶ American and British foot and ankle surgeons ▶ 19% - routine use of thromboprophylaxis <ul style="list-style-type: none"> ▶ postoperative patient, immobilized and nonweightbearing. | <ul style="list-style-type: none"> ▶ Shah K¹, et. Al. Foot Ankle Spec. 2015 ▶ Active AOFAS members ▶ Ankle fusion - Scenarios : ▶ No risk factors - 57% "No prophylaxis" ▶ Patient with history of PE - 97.5% prophylaxis ▶ Patient on BCP - 61.3% of respondents - some type of thromboprophylaxis. ▶ aspirin, 49% and low-molecular-weight heparin, 47% |
|---|---|

Methods of Anticoagulation Currently Available

- ▶ Early Ambulation
- ▶ Sequential Compression Devices
- ▶ Aspirin alone
- ▶ Aspirin and SCD's
- ▶ Aggressive anticoagulation (LMWH's, Arixtra, Xarelto, Coumadin, etc.)
- ▶ Multimodal

Can The Literature Guide Us ???

In Favor of Aggressive Prophylaxis

Foot Ankle Surg, 2011 Dec; 17(4):263-9. doi: 10.1016/j.fas.2010.12.002. Epub 2011 Jan 20

The incidence of venous thromboembolism in patients undergoing surgery for acute Achilles tendon ruptures.

Saravala NP, Farnas PN

- 88 pts.
- DVT – 5, PE nonfatal – 1
- They recommend routine prophylaxis

Argument Against "Aggressive Drugs" – Studies Showing Very Low Risk of VTE

- ▶ Achilles' – Perc Vs. Open, FAJ 2015
 - ▶ Hsu AR, et. Al.
 - ▶ 270 cases - No DVTs
- National Trauma Data Bank 2007 - 2009
 - Foot and Ankle trauma
 - DVT and PE - 0.28% and 0.21%
- SooHoo NF, et. Al., FAS, 2011
 - 57,183 Ankle fractures
 - Readmission rate DVT - 0.05%.
 - PE - 0.34%.
- Pelet S, et. Al. JBJS Am., 2012
 - Ankle Fractures (surgery) - 1540 pts
 - 2.66% - DVT, 0.32% - nonfatal PE
- Horne PH, et. Al., FAJ, 2015
 - Total Ankle Replacement
 - DVT clinically detected - 0.45%
 - 1- nonfatal pulmonary embolism
- Jameson SS, et. Al., JBJS Br., 2011
 - Ankle fracture, first MT osteotomy, hindfoot fusions, ankle replacement
 - DVT, PE, fatal PE all very rare
- Patil S, et. Al., JBJS BR., 2007
 - 100 ankle fractures (cast) - No thromboprophylaxis
 - 5 - DVT, all asymptomatic, No PE
- ▶ Mizel MS, et. Al., CORR 1998, March
 - ▶ DVT - 6/2733 (0.22%)
 - ▶ Nonfatal pulmonary emboli 4/2733 (0.15%)

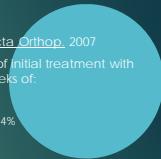
The Big But !!!!

- Increased Risk:
 - Over 50,
 - More comorbidities,
 - Nonweight bearing, Immobilization
 - The more risk factors the greater the risk



Let's Say You Want To Lower the Risk: Aggressive Anticoagulation Vs. Placebo

- ▶ Goel DP, et. Al., JBJS Br., 2009
- ▶ Fractures Below the Knee
- ▶ Placebo (111)
 - ▶ DVT - 11 (8.7%)
- ▶ LMWH (127) - 14 days
 - ▶ DVT - 14 (12.6%)
- ▶ No difference
- ▶ Ankle Fractures
- ▶ Lapidus LJ, et. Al., Acta Orthop., 2007
- ▶ All patients - 1 week of initial treatment with Dalteparin then 5 weeks of.
- ▶ Dalteparin (n = 136)
 - ▶ DVT - 21%, Proximal 4%
- ▶ Placebo (n = 136)
 - ▶ DVT - 28%, Proximal 3%
- ▶ No Difference




Anticoagulation has real risks

- ▶ Sachs RA., et. Al. J Arthroplasty. 2003
- ▶ 785 patients - no prophylaxis
 - ▶ Total complications - 2.2%
 - ▶ Death rate from thromboembolic disease - 0.0%
 - ▶ Total death rate - 0.2%
- ▶ 957 patients - 6 weeks of low-dose warfarin
 - ▶ Total complications - 4.7%
 - ▶ Death rate from thromboembolic disease of 0.0%
 - ▶ Total death rate of 0.1%
 - ▶ 1 death - massive gastrointestinal bleeding
 - ▶ Twice the infection rate


So Now We Know That We Do Not Need Aggressive Drugs Do We Need Anything ?

What Are The "Other Less Aggressive But Effective" Methods



Mobilizing Alone Is Not Enough

- ▶ Craik JD. et. Al., FAI 2015
- ▶ Normal venous blood flow only with full weight bearing in below-knee casts or walking boots
- ▶ Most patients are at limited weight bearing




Aspirin – Similar Prophylaxis in (Low Risk Patients) and Lower Risk of Bleeding

<p>Brown GA. J Arthroplasty. 2009</p> <ul style="list-style-type: none"> ▶ Pooled analysis of 14 randomized controlled trials ▶ VTE rates not significantly different vs. vitamin K antagonists, (LMWH), and pentasaccharides. ▶ Lower bleeding risk 	<p>Dresscher FS. et. Al. J Hosp Med. 2014</p> <ul style="list-style-type: none"> ▶ Randomized trials comparing aspirin to anticoagulants (Hip fx, TJA) ▶ 1408 pts <ul style="list-style-type: none"> ▶ DVT did not differ statistically for arthroplasty ▶ The risk of bleeding was lower with aspirin 	<p>Jameson SS, et. Al. JBJS Br. 2012 TKA</p> <ul style="list-style-type: none"> ▶ Aspirin - 36,159 vs. LMWH - 120,639 ▶ No statistically significant differences
<p>Gesell MW. et. Al. J Arthroplasty. 2013</p> <ul style="list-style-type: none"> ▶ 2017 pts TKA, multimodal thromboprophylaxis. ▶ Aspirin Vs. Coumadin ▶ No difference except higher rate of wound related complications with coumadin 	<p>Anderson DR. et. Al. Ann Intern Med. 2013</p> <ul style="list-style-type: none"> ▶ Aspirin noninferior to Deltaparin – extended proph THA 	<p>Bozic KJ. et. Al. J Arthroplasty. 2010</p> <p>93,840 pts. TKA</p> <ul style="list-style-type: none"> ▶ (55%) - warfarin, (40%) – injectables, (5%) - aspirin <p>Aspirin –</p> <ul style="list-style-type: none"> ▶ lower or similar odds for thromboembolism ▶ No differences in risk of bleeding, infection, or mortality after adjustment.

Sequential Compression Devices are a Viable Alternative

- ▶ Gelfer Y, et. Al. J Arthroplasty. 2006
- ▶ 121 pts. THA or TKA
 - ▶ Miniature, mobile, battery-operated SCD plus low-dose aspirin Vs. Lovenox
 - ▶ **Lower rate of all DVT's**



Aggressive Anticoagulants are NO BETTER than SCD's

No Benefit

- ▶ [Khatod M, et. Al., J Arthroplasty, 2012](#)
 - ▶ 30,000 total knee arthroplasty
- ▶ [Poullisides LA, et. Al., JBJS Br, 2012](#)
 - ▶ 70 studies (99,441 patients; 373 deaths), metaanalysis
- ▶ [Jiang Y, et. Al., Chin Med J 2014](#)
 - ▶ TKA, aspirin plus SCD Vs. LMWH
- ▶ [Colwell CW Jr., Surg Technol Int., 2014](#)
 - ▶ THA and TKA
 - ▶ Mobile SCD with or without aspirin Vs. warfarin, enoxaparin, rivaroxaban, and dabigatran
 - ▶ Non-inferior, Lower Cost

No Benefit and Higher Risk

- ▶ [Sharrock NE, et. Al., CORR 2008](#)
 - ▶ Twenty studies 1998 to 2007 THR and TKR
 - ▶ **Aggressive drugs - higher all-cause mortality rate**
- ▶ [Colwell CW Jr, et. Al., JBJS Am, 2010](#)
 - ▶ Total Hip
 - ▶ **Higher risk of bleeding with LMWH**
- ▶ [Colwell CW Jr, et. Al., JBJS Am](#)
 - ▶ 414 THA, 10 days of prophylaxis
 - ▶ **More Bleeding with Lovenox**

ACFAS clinical consensus statement (foot and ankle surgery and injuries requiring immobilization.)

- ▶ [Fleischer AE, et. Al., JFAS 2015](#)
- ▶ Routine chemical prophylaxis - not warranted
- ▶ Patients should be stratified and have a prevention plan tailored to their individual risk level
- ▶ Multimodal
 - ▶ Address modifiable risk factors
 - ▶ Mechanical prophylaxis
 - ▶ Early mobilization
 - ▶ Careful use of chemical prophylaxis
- ▶ Come up with the plan in an informed consent model

What I do:

- ▶ Written education about VTE
- ▶ Sign a form stating that they have received this information and have had there questions answered
- ▶ Informed decision making process
- ▶ Individualized Treatment
 - ▶ All pts are instructed to walk and move joints immediately
 - ▶ Low Risk patients - Frequent use of Portable SCD's and Aspirin (not for forefoot)
 - ▶ High risk patients - (multiple risk factors) aggressive pharmacologic prophylaxis

In Summary:

- ▶ No Risk assessment models specifically for foot and ankle
- ▶ The literature does not support using Aggressive pharmacologic anticoagulation **(Exception in patients with Multiple Risk Factors)**
- ▶ However, If your patient develops a DVT or a PE or dies from a PE, and you did not anticoagulate them then what?
 - ▶ They must deal with the sequelae
 - ▶ You may be dealing with a law suit
- ▶ Options to prevent VTE that are proven and pose low risk at lower cost (Majority of patients)
 - ▶ Aspirin
 - ▶ SCD's

Thank You

- ▶ [J Orthop Sports Phys Ther. 2014 Sep;44\(9\):690-701. C1-7. doi: 10.2519/jospt.2014.5294. Epub 2014 Aug 6.](#)
- ▶ [Early ankle movement versus immobilization in the postoperative management of ankle fracture in adults: a systematic review meta-analysis.](#)
- ▶ Keene DJ1, Williamson E, Bruce J, Willett K, Lamb SF.
- ▶ Data base analysis
- ▶ The odds of venous thromboembolism were significantly lower with early ankle movement compared to immobilization (Peto odds ratio = 0.12; 95% confidence interval: 0.02, 0.71; P = .02; I(2) = 0%). Deep surgical site infection (Peto odds ratio = 7.08; 95% confidence interval: 1.39, 35.99; P = .02; I(2) = 0%), superficial surgical site infection, fixation failure, and reoperation to remove metalwork were more common after early ankle movement compared to immobilization.



- ▶ 2.
- ▶ [J Arthroplasty. 2015 Dec;30\(12\):2299-303. doi: 10.1016/j.arth.2015.06.045. Epub 2015 Jul 2.](#)
- ▶ [Thromboembolism Prophylaxis in Hip Arthroplasty: Routine and High Risk Patients.](#)
- ▶ [Naim D¹, Nuntley RM¹, Johnson SB¹, Keeney JA¹, Cichocky JP¹, Ranavick R¹.](#)
- ▶ [Author information](#)
- ▶ ¹Department of Orthopaedic Surgery, Washington University School of Medicine/Barnes-Jewish Hospital, St. Louis, Missouri.
- ▶ **Abstract**
- ▶ The study's purpose was to present the use of a risk stratification protocol in which "routine" risk patients receive a mobile compression device with aspirin and "high" risk patients receive warfarin for thromboprophylaxis after hip arthroplasty. 1859 hip arthroplasty patients were prospectively enrolled (1402 routine risk - 75.4%, 457 high risk - 24.6%). The cumulative rate of venous thromboembolism events was 0.5% in the routine versus 0.5% in the high-risk cohort within 6 weeks postoperatively (P=1.00). Patients in the routine risk cohort had a lower rate of major bleeding (0.5% versus 2.0%, P=0.006) and wound complications (0.2% versus 1.2%, P=0.01). Use of our risk stratification protocol allowed the avoidance of more aggressive anticoagulation in 75% of patients while achieving a low overall incidence of symptomatic VTE.
