Venous Thromboembolism Screening in the Trauma Population—A Randomized Vanguard Trial
VTE is a major problem after trauma

- In patients who survive >72 hours after traumatic insult, VTE is a main cause of death
- Reported incidence in trauma patients:
  - DVT 11.8%-65%
  - PE 1.5%-2.3%
- IMC rate
  - DVT 3%
  - PE 0.6%
Why is VTE an issue in trauma patients?
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- Traumatic injury causes direct or indirect endothelial injury, activates tissue factor, platelet aggregation, propagating the coagulation cascade, e.g. **TRAUMA**
- Trauma patients are often immobile and need surgical procedures, e.g. **STASIS**
- Acute phase reactants from trauma itself and from postoperative state, e.g. **HYPERCOAGULABILITY**
Background

- Venous Thromboembolism (VTE) is responsible for a $69 billion economic impact annually in the US.
- VTE is a major cause of late morbidity and mortality in trauma patients.
- At the time of VTE diagnosis, most patients are already receiving standard chemoprophylaxis.
- VTE will never be a “never” event in trauma, no matter what CMS would like to tell us—it is on the HAC score checklist.
Background

*Therapy* guidelines just published in 2016
Most Recent *Prevention* Guidelines are from 2012
8.4.1. For major trauma patients, we suggest use of LDUH (Grade 2C), LMWH (Grade 2C), or mechanical prophylaxis, preferably with IPC (Grade 2C), over no prophylaxis.

8.4.2. For major trauma patients at high risk for VTE (including those with acute spinal cord injury, traumatic brain injury, and spinal surgery for trauma), we suggest adding mechanical prophylaxis to pharmacologic prophylaxis (Grade 2C) when not contraindicated by lower-extremity injury.

8.4.3. For major trauma patients in whom LMWH and LDUH are contraindicated, we suggest mechanical prophylaxis, preferably with IPC, over no prophylaxis (Grade 2C) when not contraindicated by lower-extremity injury. We suggest adding pharmacologic prophylaxis with either LMWH or LDUH when the risk of bleeding diminishes or the contraindication to heparin resolves (Grade 2C).

8.4.4. For major trauma patients, we suggest that an IVC filter should not be used for primary VTE prevention (Grade 2C).

8.4.5. For major trauma patients, we suggest that periodic surveillance with VCU should not be performed (Grade 2C).
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VTE surveillance in trauma patients

• Quality of evidence to support this recommendation is poor
  • Mostly retrospective
  • Often conflicting
Investigators are interested in this topic, but no one has successfully executed a good quality study!
Based on this grade 2C (mostly retrospective) evidence, most trauma centers in the United States choose not to perform surveillance on trauma patients.

Intermountain Medical Center has traditionally performed Duplex Ultrasound surveillance on high risk trauma patients.

Consequently, our VTE rate (mostly asymptomatic DVT) is higher than has been deemed “acceptable”
There are currently ZERO prospective, randomized studies that specifically examine VTE surveillance in the trauma patient.
Why is this important?

• Asymptomatic lower extremity DVT diagnosis is not really the point—preventing fatal PE is.
• Hospitals under pressure to decrease DVT rate
• If we stop looking, our rate will decrease...
• Is this the best patient care?
HYPOTHESIS:

High risk trauma patients who undergo scheduled ultrasound surveillance for lower extremity DVT will have a lower rate of:

• Symptomatic DVT
• DVT propagation
• Symptomatic or fatal PE
Specific Aims:

1. Determine the rate of VTE (DVT and PE) in high-risk trauma patients who have surveillance for lower extremity DVT versus those who do not have surveillance.

2. Determine the rate of DVT propagation to the popliteal vein or higher by 14 days after discharge in high-risk trauma patients found to have isolated distal DVT.
Outcome Measures:
1. Asymptomatic lower extremity DVT identified during hospitalization (in surveillance group)
2. Symptomatic DVT identified during hospitalization and at 90 days post discharge
3. Symptomatic DVT propagation from calf to proximal veins at 14 days post-discharge
4. Symptomatic/fatal PE identified during hospitalization and at 90 days post-discharge
5. Major bleeding episodes
6. Composite outcome of proximal DVT plus major bleeding episodes
7. All cause mortality at 90 days post-discharge
Study Design:
1. Prospective, randomized trial—surveillance at days 1, 3, 7, weekly vs. no surveillance
2. Exception from informed consent approved by IRB
3. All high risk trauma patients enrolled
Inclusion Criteria:

1. Inpatient on IMC trauma surgery service, admitted within 24 hours of injury
2. Age ≥ 18
3. Meets definition of high-risk for VTE
Exclusion Criteria:
1. Age <18
2. Pregnancy
3. Prisoners
4. Life expectancy <30 days
5. Known hypercoagulable state, including Factor V Leiden, Protein C and S deficiencies, dysfibrinogenemia, active cancer, antiphospholipid antibody syndrome
Data Analysis:

- Used historic baseline of composite outcome of major bleeding plus proximal DVT on trauma service to conduct power analysis.
Current Status:

• Enrolling patients
• Estimate 12-16 months to complete enrollment
• Relatively low ISS and homogeneous population of IMC trauma service will be a limitation
Future Plans

• Results of this vanguard trial will pave the way for a larger, likely multi-institutional trial
• Will answer an important question that will impact trauma patients everywhere—far beyond just Intermountain