



Response Report for Review and Comment – September 2011

Venous Thromboembolism Prophylaxis Guideline

Member Groups Requesting Changes:

Fairview Health Services
Marshfield Clinic
Mayo Clinic

Member Groups that Reviewed the Guideline, No Changes Requested:

CentraCare

Member Groups that Responded but the Guideline Does Not Pertain to Practice:

None

Sponsoring Health Plans Requesting Changes:

None

Sponsoring Health Plans that Reviewed the Guideline, No Changes Requested:

HealthPartners Health Plan

GENERAL COMMENTS:

- 1) Used as a resource by having it as a link in our EHR. (Fairview Health Services)

Thank you for sharing this information.

- 2) Currently there is not a section that addresses DVT prophylaxis in trauma pts who are at high risk of this complication. Please consider adding the information below.

ICSI Guideline: Patients with Acute Traumatic Injuries#

	Dalteparin *	Enoxaparin *	Fondaparinux +	Unfractionated Heparin	Warfarin	Aspirin	Duration
All Admitted Trauma patients with exception of those with minor injuries with no limitation of activity or those with known Injury severity Score of < 9.	5,000 units subQ every 24 hours beginning 12-24 hours after injury + mechanical prophylaxis (see table section #6, “Special situations – Neuraxial Blockade in Patients Receiving Antithrombotics”)	30 mg subQ every 12 hr beginning 12 -24 hr after injury + mechanical prophylaxis (see table section #6, “Special situations – Neuraxial Blockade in Patients Receiving Antithrombotics”)	2.5 mg subQ every 24 hours beginning 12 – 24 hrs after injury + mechanical prophylaxis	Not recommended	INR 2.5 (2-3) during the rehabilitation phase once risk of major bleeding is low	Not recommended	Until discharge from the hospital. If hospital stay, extends beyond two weeks, then consider Warfarin if ongoing risk factors persist.

* follow the existing ICSI guidelines for those patients with neuraxial anesthesia.

+ Limited data on its use in trauma patients to justify its routine use when Dalteparin or Enoxaparin are available.

Excluding patients with burn injury; subspecialty surgical input to assess the need and the safety of prophylaxis should be made for patients with intracranial and spinal column injury with or without spinal cord injury; the decision to start thromboprophylaxis should be assessed on a case- by case basis.

Until prospectively validated risk assessment tools are available for the trauma patients, we recommend following the evidence-based guideline as outlined in the Table and cited below. We reviewed the existing literature to include: 1) The Eastern Association for the Surgery of Trauma (EAST) - Practice Management Guidelines For The Management of

Venous Thromboembolism (VTE) in Trauma Patients and 2) American College of Chest Physicians Evidence-Based Clinical Practice Guidelines (8th Edition) (1-2).

Guideline: Risk factors for deep vein thrombosis (DVT) / pulmonary embolism (PE) after injury:

Level I recommendation – Patients with spinal cord injuries or spinal fractures are at high risk for venous thromboembolism following trauma.

Level II recommendation –

1. Older age is an increased risk factor for VTE but it is not clear at which age the risk increases.
2. Blood transfusions and increasing injury severity score (ISS) appear to be associated with a greater risk of VTE in single institution studies. However, on meta-analysis, these factors did not prove to be of major significance.
3. Traditional risk factors such as long bone fractures, pelvic fractures, or head injuries constitute an increased risk for VTE in single institution studies but, on meta-analysis, these did not prove to be of major significance.

In summary, the existing evidence supports the presence of two risk factors of post-traumatic VTE: spinal fracture and spinal cord injury. Older age is an additional risk factor but it is not clear at which age the risk increases. There is conflicting literature with other frequently reported risk factors such as long bone fractures, pelvic fractures, or head injuries. There is a need for additional research in this area.

Guidelines in the use of low-dose heparin (LDH) and mechanical prophylaxis for prevention of DVT/PE:

1. Unfractionated LDH has not been shown to be effective in preventing VTE in trauma patients (3-4). Med line review from 1966 to the present reveals several hundred articles relating to the use of LDH in medical and general surgical patients.

Level I recommendation – There are insufficient data to support a standard recommendation on this topic.

Level II recommendation –

There is little evidence to support the benefit of LDH as a sole agent for prophylaxis in the trauma patient at high risk for venous thromboembolism (VTE).

2. The use of mechanical prophylaxis such as the calf sequential compression devices (SCD) in the prevention of DVT/PE.

Level I and II – There are insufficient data to support a standard recommendation on this topic.

Level III recommendation - In the subset of spine injury/head injury patients, SCD have benefit in isolated studies. For patients in whom the lower extremities are inaccessible to place SCD at the calf level, foot

pumps may act as an effective alternative to lower the rate of DVT formation.

In essence, more studies need to be done specifically related to the use of SCDs in trauma patients at risk for VTE

Guidelines in the use of low-molecular weight heparin (LMWH) in the prevention of DVT/PE:

The use of LMWH has gained popularity for reducing the risk of VTE over the last 20 years. In multiply injured trauma patients, LMWH has a better efficacy than unfractionated low dose heparin (LDH) and similar bleeding risks when used for VTE prophylaxis (3-5). The use of LMWH is predicated by the absence of other major injuries that put them at high risk for bleeding.

Level I recommendation – There are insufficient data to support a standard recommendation on this topic.

Level II recommendations – LMWH should be used for VTE prophylaxis in trauma patients with the following injury patterns: pelvic fracture requiring operative fixation or prolonged bed rest, complex lower extremity fractures requiring operative fixation, and spinal cord injury with complete or incomplete motor paralysis.

Level III recommendation– Trauma patients with an injury severity score (ISS) > 9 who can receive anticoagulants should receive LMWH as a primary mode of VTE prophylaxis. The use of LMWH or oral anticoagulants for several weeks post injury should be considered in patients who remain at high risk for VTE (i.e. elderly pelvic fracture patients, spinal cord injury patients, patients with expected prolonged bed rest > 5 days) and patients who require prolonged hospitalization or rehabilitation.

In summary, all major trauma patients should receive routine thromboprophylaxis as soon as possible. The preferred form of thromboprophylaxis is LMWH starting as soon as it is considered safe. The thromboprophylaxis should be continued until hospital discharge. For trauma patients with ongoing risk factors such as immobility, continuation of thromboprophylaxis or oral anticoagulation is recommended.

References:

1. Rogers FB, Cipolle MD, Velmahos G, et al. Practice management guidelines for the management of venous thromboembolism in trauma patients: the EAST practice management guidelines workshop. J Trauma 2002; 53(1):142-164.

2. Geerts WH, Bergqvist D, Pineo GF, et al. Prevention of venous thromboembolism: American College of Chest Physicians evidence-based clinical practice guidelines (8th Edition). Chest 2008; 133(6):381S – 453S.
3. Geerts WH, Jay RM, Code KI, et al. A comparison of low-dose heparin with low-molecular weight heparin as prophylaxis against venous thromboembolism after major trauma. N Engl J Med 1996; 335:701-707.
4. Knudson MM, Morabito D, Paiement GD, et al. Use of low molecular weight heparin in preventing thromboembolism in trauma patients. J Trauma 1996; 41:446 – 59.
5. Cothren CC, Smith WR, Moore EE, et al. Utility of once-daily dose of low-molecular-weight heparin to prevent venous thromboembolism in multisystem trauma patients. World J Surg 2007; 31:98-104. (Mayo Clinic)

Thank you for the work you've done. VTE prophylaxis guidelines for trauma patients are out of scope for the ICSI guidelines. The heterogeneity of the patients with splenic/hepatic injuries, head trauma, spine trauma/spinal cord injuries, and isolated or multiple orthopaedic injuries precludes standardized treatment of trauma patients. The work group feels the American College of Surgeons trauma committee would have the expertise to establish guidelines for trauma patients.

MEDICAL CONTENT:

- 3) Annotation Main Table Section 5 Special Situations-Dose Adjustment of Antithrombotics: Data on the use of LMWH in severe renal insufficiency is limited. Most of the available data for thromboprophylaxis in patients with renal insufficiency is short-term and is in a small number of patients. Manufacturer renal dosing recommendations for enoxaparin are based on pharmacokinetic/ pharmacodynamic data. Consider adding a statement about use of heparin in patient populations where LMWH are less reliable (e.g., severe renal insufficiency). Can this area be expanded with annotations for better clarity regarding this patient population? References: Annals of Pharmacotherapy 2009; 43:1064-83. (Marshfield Clinic)

Thank you for your comments. We have expanded the special situation section to include dosing information about renal insufficiency and dialysis and have added the above reference to the annotations.

- 4) Annotation Main Table, Section 6 & Annotation 6; Special Situations-Neuraxial Blockade in Patients Receiving Antithrombotics: In the table on page 1 section 6, it states that for prophylactic once daily dosing needle placement should be at least 12 hours after the last dose, and for prophylactic twice-daily dosing needle placement is not recommended. This is not consistent with annotation 6 which specifies patients on preoperative thromboprophylaxis should have needle placement at least 12 hours after the last dose of LMWH.

The ASRA guidelines states 10-12 hours for thromboprophylaxis dosing and does not specify once or twice daily dosing.

Please clarify the neuraxial blockade recommendations in patients receiving thromboprophylaxis once or twice daily dosing. References: ASRA guidelines. (Marshfield Clinic)

Thank you for your comment. The work group revised Section 6 Special Situations - Neuraxial Blockade. Information has been added to the annotation, and recommendations have been clarified for patients receiving once or twice daily dosing of thromboprophylaxis.

- 5) Annotation Main Table, Section 8 TURP: The bleeding risk in TURP is considered to be high, and heparin is not recommended. Can there be clarification added so providers are aware of this? The incidence of DVT post TURP is only about 0.4%. It is the consensus of Marshfield Clinic urologists that the bleeding risk is always too high therefore, heparin is not given. According to the American Urological Association (AUA) guidelines, for the vast majority of TURP's early ambulation is recommended for DVT prophylaxis. For patients at increased risk of DVT, undergoing TURP, the use of graded compression stockings, intermittent pneumatic compression stockings, postoperative LDUH or LMWH may be indicated. The tables do not clearly indicate special considerations in the current guideline and there are no annotations to aide in the decision-making. Consider adding TURP to the first row of the main table, section 8 and add annotations which would identify certain populations. References: American Urological Association. (2006). Best Practice Statement for the Prevention of Deep Vein Thrombosis in Patients Under going Urological Surgery, pg 9-10. (Marshfield Clinic)

Thank you for your suggestions. We have added the wording "Consider bleeding risk" to table 8 and have added TURP to special situations in table 3 – High risk of bleeding. The reference above has been added to the annotations.

- 6) Annotation Main Table, Section 8 Laproscopic procedure: The guideline states that any laparoscopic procedure with additional risk factors should have pharmacologic agents. The AUA states, "In view of the lack of large RCTs addressing this issue, as well as the concerns for increased retroperitoneal bleeding at the time of urologic laparoscopic procedures, the AUA recommends the use of intermittent pneumatic compression (IPC) devices at the time of laparoscopy - pharmacologic agents are only needed in high risk groups. Table 8 does not separate the various procedures and potential concerns to be taken into consideration such as retroperitoneal bleeding. Can an annotation be added for patients undergoing laparoscopic procedures and the risks of retroperitoneal bleeding? Can the table be more specific with the types of procedures? References: American Urological Association. (2006). Best Practice Statement for the Prevention of Deep Vein Thrombosis in Patients Under going Urological Surgery, pg. 12-13. (Marshfield Clinic)

Thank you for your comments. As described in the previous response #5, urologic lap procedures have been added to special situations. Each type of laparoscopic procedure and patient should be evaluated separately and unfortunately all cannot be included in a table format. As mentioned in response #5, the reference has been added to the annotations.

- 7) Annotation 10-13 Orthopedic Surgery; pg 17; second to last paragraph: Consider changing chemoprophylactic agents to thromboprophylactics. References: NA (Marshfield Clinic)

Thank you, but the term “chemoprophylactic” was purposely used, as it was taken from the AAOS recommendations verbatim. The work group does not use “thromboprophylactics” because the term encompasses mechanical as well as pharmaceutical methods.

AIMS AND MEASURES:

No changes

SUPPORT FOR IMPLEMENTATION:

- 8) While we are not sure exactly what this would entail, we suggest adding information on how EHR’s can be useful as significant Clinical Decision Support (CDS) tools for patient assessment, implementation of VTE prophylaxis, monitoring effectiveness, and prevention of harm related to anticoagulation. Provide some specific CDS suggestions to embed into EHR. (Fairview Health Services)

Thank you for the valid suggestion. Unfortunately this is out of our scope at the current time.

- 9) Please see references for articles related to VTE prophylaxis in bariatric surgery:

Magee, C.J. et al (2010). Extended thromboprophylaxis reduces incidence of postoperative venous Thromboembolism in laparoscopic bariatric surgery. *Surgery for Obesity and Related Diseases* (6), 322-325, doi: 10.1016/j.soard.2010.02.046

Agarwal, R. et al (2010) Venous Thromboembolism prophylaxis for patients undergoing bariatric surgery: a systematic review. *Surgery for Obesity and Related Diseases* (6), 213-220, doi:10.1016/j.soard.2009.11.018

Hamad G. and Bergqvist, D. (2007). Venous Thromboembolism in bariatric surgery patients: an update of risk and prevention. *Surgery for Obesity and Related Diseases* (3), 97-102, doi: 10.1016/j.soard.2006.10.002

Abstracts: American Society for Bariatric Surgery. (2006) (2) 286-309. Abstract # 59. (Marshfield Clinic)

Thank you for the references. While the work group reviewed the literature, it did not incorporate any changes at this time. We invite any specific clinical recommendations or questions you may have at a future revision of the guideline.