

JOINT TRAUMA SYSTEM CLINICAL PRACTICE GUIDELINE (JTS CPG)



The Prevention of Deep Venous Thrombosis – Inferior Vena Cava Filter (CPG ID: 36)

To establish guidance for 1) anti-thrombotic therapy for the prevention of deep venous thrombosis (DVT) and pulmonary embolism (PE) and 2) the management of inferior vena cava filters (IVCs) placed in the combat theater for the purpose of either primary or secondary prophylaxis of pulmonary embolism.

Contributors

CDR Daniel Grabo, MC, USN
LTC Jason Seery, MC, USA
LCDR Matthew Bradley, MC, USN
MAJ Scott Zakaluzny, MC, USAF

CDR Michel Kearns, MC, USN
CDR Nathaniel Fernandez, MC, USN
CDR Matthew Tadlock, MC, USN

First Publication Date: 01 Jul 2006

Publication Date: 02 Aug 2016

Supersedes CPG dated 24 Apr 2012

Opinions, interpretations, conclusions, and recommendations are those of the authors and are not necessarily endorsed by the Services or DoD.

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BACKGROUND

Trauma patients are known to be at high risk for Venous Thromboembolism (VTE) including Deep Venous Thrombosis (DVT) and Pulmonary Embolism (PE). Major trauma patients can have up to 58% incidence of DVT.¹ Sevitt and Gallagher reported an even higher incidence (65%) in injured and burned patients and reported a 16.5% incidence of PE found at autopsy in this cohort of patients.^{2,3}

In addition to the hypercoagulable state induced by severe injury in trauma, combat casualties have additional risk factors for DVT, including:^{1,4-8}

- Early transfusion of blood products (≤24 hours);
- Transfusion of old blood (≥28 days);
- Multiple and/or above the knee amputations

The use of Fresh Frozen Plasma (FFP) outside of large volume blood product transfusion (less than 4 U PRBC's) incurs an increased risk of VTE.⁹ Early prophylaxis in this patient population is recommended provided hemostasis has been achieved.

The nature of the current combat theater has provided our deployed medical team's ample opportunity to care for children injured as non-combatants. The incidence of DVT after trauma is much lower (6.2%) than that of adults in the civilian literature.¹⁰ The presence of multiple risk factors including immobility and central venous line, however, were associated with the development of DVT in pediatric trauma patients.

There is an increasing recognition of DVT in individuals who complete an extended period of travel on an airplane. One study noted a 10% prevalence of asymptomatic DVT in individuals undergoing flights of 8 hours or more.¹¹ Combat casualties are at high risk for VTE during recovery and evacuation, which can be associated with long flights and immobility, thus it is important to start VTE prophylaxis as soon as clinically possible.¹²

Landstuhl Regional Medical Center is uniquely positioned to receive patients who have undergone extensive periods of travel prior to admission.

Different medical societies and working groups have published varying recommendations for DVT prophylaxis.^{13,14} The clinical guidance recommended here represent the guidelines with either a higher level of scientific evidence supporting the recommendation, or the more conservative recommendation. It is recommended to begin DVT prophylaxis therapy as soon as coagulopathy is corrected in patients not otherwise at increased risk of bleeding.

RECOMMENDATIONS FOR DVT PROPHYLAXIS

Unless contraindicated by lower extremity injury, all trauma patients should receive:

1. Sequential Compression Device (SCD) therapy as primary DVT prophylaxis in addition to;
2. Low dose Unfractionated Heparin (UFH)¹³⁻¹⁵ or;
3. Low Molecular Weight Heparin (LMWH), Enoxaparin 30mg subcutaneous (SC) twice daily.¹⁶
4. Alternatively, low doses LMWH such as Dalteparin 5000 U SC or Enoxaparin 40mg SC can be given daily and in one study has a lower incidence of DVT when compared to 30mg BID dosing in post-operative patients.^{14,17,18}

5. Unfractionated Heparin (5000 U) administered subcutaneously three times daily has been demonstrated to be as effective as or at least non-inferior to Enoxaparin in the prevention of DVT in trauma patients.^{19,20}

Consideration should be given to the use of LMWH in patients with impaired renal function (CrCL=30ml/min or less), as there is a concern for LMWH accumulation and increased risk of bleeding.

1. Despite this concern, no clear evidence exists for dose modification or contraindication to the use of LMWH for DVT prophylaxis in renal impaired patients.²¹
2. Godat et al. reported, however, that trauma patients who are considered to be at the highest risk to develop VTE (especially spinal cord injury with/without pelvic fracture) are at the greatest risk during the first three months after injury and that this risk decreases at six months post injury.²³

The role of **duplex ultrasound** in the diagnosis of DVT should be reserved for the symptomatic patient. Serial screening duplex ultrasound for the diagnosis of DVT is not recommended.¹⁴

CHEMICAL DVT PROPHYLAXIS

Provided coagulopathy and ongoing bleeding is corrected, chemical DVT prophylaxis (<48 hours post injury) has been shown to be safe after blunt solid organ injuries.^{24,25}

Chemical DVT prophylaxis (<48-72 hours) following traumatic brain injury with intracranial hemorrhage does not increase the progression of intracranial bleed.^{26,27} Prior to starting chemical DVT prophylaxis, you should:

1. Consult a Neurosurgeon;
2. Obtain a stable CT scan of the head at 24 hours post injury.

Prophylaxis should be withheld in the setting of progression of intracranial hemorrhage or presence of an intracranial monitor.

Modification of enoxaparin dosing to 40mg daily in the combat casualty requiring an epidural pain catheter does not increase the incidence of venous thromboembolism.²⁸

Inferior Vena Cava Filter (IVCF) placement in the combat theater may be used for:

1. Primary Prophylaxis (no evidence of VTE disease at the time of placement).
2. Secondary Prophylaxis (documented DVT) of PE in the polytrauma patient.

Patients felt to be at particularly **high risk for VTE development** and who have a clinical contraindication to prophylactic anticoagulation are the most likely to have an IVCF placed.

Most series examining the use of **IVCF placement for primary prophylaxis of PE** in the trauma patient support a low rate of subsequent PE (1.6%), although the studies are of variable design and a strong consensus supporting this clinical practice cannot be made based upon available data.²⁹

There is no evidence that **prophylactic use of IVCF** is associated with a decreased PE rate or fatal PE rate. It should be noted that when IVCF are placed they are done so to prevent FATAL Pulmonary Emboli as DVT and PE still can occur.³⁰⁻³⁴

IVCF has no benefit in the prevention of DVTs and may be associated with the development of IVC and Deep Venous Thrombosis.^{14,35}

RETRIEVABLE INFERIOR VENA CAVA FILTERS (RIVCF)

The vast majority of IVCF devices placed in the combat theater are Retrievable Inferior Vena Cava Filters (RIVCF).

RIVCF are preferred to avoid some of the long-term complications of filter placement. Additionally, many patients only need this form of VTE prophylaxis for a defined period of time early after injury.

Despite successful removal of IVCF beyond 180 days and high success and low complication rate for attempted **IVCF removal**, rates of eventual removal of RIVCFs in multiple studies of trauma patients in the United States have been as low as 14% to 22%.^{36,37,38,39,40}

Combat injured patients from Operation Iraqi Freedom (OIF) and Operation Enduring Freedom (OEF) who had RIVCFs placed have an overall retrieval rate of 18%.⁴¹

It should be noted however; that the majority of patients was lost to follow up or did not have filters removed due to ongoing indications for use (82%). Therefore, the overall retrieval technical success rate may be much higher. Most series support removal of the most commonly used RIVCFs as early as they are no longer necessary and no later than approximately three months.⁴² While it is possible to remove any of these later than this time period, the technical success declines significantly as potential complications associated with removal increase. Clear electronic documentation and a dedicated tracking system at the final CONUS MTF must be in place to improve retrieval rates and minimize loss to follow up.⁴³

EDUCATION AND TREATMENT

Refer to Appendix A for specific guidance on different subsets of patients after various surgical procedures.

Refer to Appendix B for additional recommendations regarding IVC filters.

PERFORMANCE IMPROVEMENT (PI) MONITORING

INTENT (EXPECTED OUTCOMES)

- When Lovenox or Unfractionated Heparin is ordered, there is documentation in the record that the medication was administered to the patient in the correct dose.
- When an IVCF is inserted in a patient, there is documentation in the medical record and TMDS as to whether the IVCF is retrievable or not, manufacturer, brand, MRI compatibility, serial number, lot number and exact location.

PERFORMANCE/ADHERENCE MEASURES

- All patients for whom Lovenox or Unfractionated Heparin was ordered received the medication in the correct dose as documented in the patient's medical record.
- In every patient in whom an IVCF was inserted, the medical record and TMDS contained documentation as to whether it was retrievable or not, manufacturer, brand, MRI compatibility, serial number, lot number and exact location of placement.

DATA SOURCE

- Patient Record
- Department of Defense Trauma Registry (DoDTR)

SYSTEM REPORTING & FREQUENCY

The above constitutes the minimum criteria for PI monitoring of this CPG. System reporting will be performed annually; additional PI monitoring and system reporting may be performed as needed.

The system review and data analysis will be performed by the Joint Trauma System (JTS) Director and the Joint Trauma System (JTS) Performance Improvement Branch.

RESPONSIBILITIES

It is the trauma team leader's responsibility to ensure familiarity, appropriate compliance and PI monitoring at the local level with this CPG.

All Health Care Providers will:

- Become familiar with the guidelines for the prevention of DVT (see Appendix A).
- Appropriately manage patients who may be at risk of developing DVT.
- Provide feedback on these guidelines and suggestions for changes to the CPG to the JTS Director.

The senior surgeon and/or Intensivist at each Role III facility will:

- Review all thromboembolic events in the Level III facility to assess ways to reduce the risk to the patient.
- Coordinate with the JTS Performance Improvement Division Chief on the appropriateness of the guidelines being used and provide input for updates on an as needed basis.

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APPENDIX A: PREVENTION OF VENOUS THROMBOEMBOLISM GUIDELINES

| RISK GROUP | PROPHYLACTIC MEASURES |
|--|---|
| TRAUMA PATIENTS | |
| <ul style="list-style-type: none"> ▪ Emergency trauma surgical procedures in patients with prohibitive risk of bleeding, or ongoing coagulopathy ▪ Emergency trauma surgical procedures in all patients, except patient with prohibitive risk of bleeding (once coagulopathy not present) ▪ Isolated major orthopedic surgery of extremities, spine, and pelvis | <ul style="list-style-type: none"> ▪ SCD (sequential compression device) until able to be anticoagulated (ideally start Lovenox within 12 hours of cessation of coagulopathy); see IVC filter and Duplex screening sections below. ▪ SCD (unless contraindicated by injury) + Lovenox 30 mg SC BID or 40mg SC QD; alternatively Heparin 5000 U SC q 8 hours ▪ SCD (unless contraindicated by injury) + Lovenox 30 mg SC BID |
| IVC FILTER PLACEMENT | |
| <p>Patients with:</p> <ol style="list-style-type: none"> 1. Recurrent PE despite full anticoagulation 2. Proximal DVT and contraindications for full anticoagulation 3. Proximal DVT and major bleeding while on full anticoagulation 4. Progression of iliofemoral clot despite anticoagulation <p>Patients with established DVT or PE and:</p> <ol style="list-style-type: none"> 5. Large free-floating thrombus in the iliac vein or IVC 6. Following massive PE in which recurrent emboli may prove fatal 7. During/after surgical embolectomy <p>Very High Risk Patients: those who cannot receive anticoagulation because of increased bleeding risk and :</p> <ol style="list-style-type: none"> 8. Severe closed head injury (GCS<8) 9. Incomplete spinal cord injury with paraplegia or quadriplegia 10. Complex pelvic fractures with associated long-bone fractures 11. Multiple long-bone fractures | <ul style="list-style-type: none"> ▪ Placement of retrievable IVC filter (RIVCF) ▪ Document if the IVCF is retrievable or not, manufacturer, brand, MRI compatibility, serial number, lot number and exact location in record and TMDS; PE may still occur despite IVC filter ▪ “Extended” indications for placement of IVC filter for patients with established DVT or PE ▪ Consideration of placement of prophylactic placement of IVC filter. |
| ROLE OF DUPLEX SCREENING | |
| <ul style="list-style-type: none"> ▪ Asymptomatic patients ▪ Symptomatic patients | <ul style="list-style-type: none"> ▪ Serial duplex ultrasound imaging of high-risk patients is not recommended. ▪ Duplex ultrasound may be used without confirmatory venography. |
| GENERAL, VASCULAR, UROLOGIC SURGERY | |
| LOW RISK: | |
| <p>Minor procedure in patients < 40 years, no risk factors</p> | <p>Early mobilization</p> |
| MODERATE RISK: | |
| <ul style="list-style-type: none"> ▪ Minor procedure with additional risk factors for thrombosis; ▪ Non major surgery in patients 40-60 years, with no additional risk factors; ▪ Major surgery in patients < 40 years with no additional risk factors) | <ul style="list-style-type: none"> ▪ SCD + Unfractionated Heparin 5000 units SCq 8 hours or Lovenox 40 mg SC QD ▪ Chemical DVT prophylaxis is withheld in patients with high risk of bleeding. |

| RISK GROUP | PROPHYLACTIC MEASURES |
|---|---|
| HIGH RISK: | |
| <ul style="list-style-type: none"> ▪ Non major surgery in patients > 60 years or have additional risk factors; ▪ Major surgery in patients > 40 years or have additional risk factors | <ul style="list-style-type: none"> ▪ SCD + Unfractionated Heparin 5000 units SC q 8 hours or Lovenox 40 mg SC QD ▪ Chemical DVT prophylaxis is withheld in patients with high risk of bleeding. |
| NEUROSURGERY | |
| <ul style="list-style-type: none"> ▪ Intracranial neurosurgical procedures ▪ High Risk neurosurgery patients | <ul style="list-style-type: none"> ▪ SCD ▪ SCD ▪ Chemical DVT prophylaxis following stable CT scan in consultation with neurosurgeon |

APPENDIX B: IVCF RECOMMENDATIONS

1. All IVCFs placed in the combat theater should be retrievable.
2. Documentation detailing the IVCF brand, model, MRI compatibility, and exact location of placement should be documented in ALTA T or TC2.
3. All RIVCFs placed in the combat theater should be removed as soon as contraindications to chemical prophylaxis of VTE disease no longer exist or there is no longer a need for VTE prophylaxis. Exceptions include those that were placed for secondary prophylaxis in a patient who demonstrated new VTE disease while on therapeutic anticoagulation or in patients who are still deemed to be high risk.
4. All RIVCFs should be removed within three months unless a long term indication for their continued use is present.
5. The decision to remove an RIVCF placed in the combat theater (versus leaving it in place permanently) should be made at the first CONUS Level V MTF the patient transitions through while returning from deployment. When possible, the removal should take place at this same facility prior to transition to the next level of care. This approach decreases the chance that a decision will be deferred until removal becomes technically prohibitive.
6. **The presence of a RIVCF in a patient receiving care at the Level IV MTF should be made known to the receiving Level V MTF. Typically, retrieval of the RIVCF will be accomplished at the Level V MTF.**
7. Any patient with a known DVT and without a current contraindication to therapeutic anticoagulation who has an IVCF in place should receive full dose anticoagulation. This is preferably accomplished with Coumadin to target an INR of 2.0-3.0. If further surgical procedures are planned, consideration may also be given to the use of low molecular weight heparin dosed at 1 mg/kg bid or an unfractionated heparin drip until such time as the use of Coumadin is felt to be appropriate.
8. The presence of an IVCF, brand, model, MRI compatibility, whether or not it is retrievable, its exact location and the date of insertion should be clearly annotated in TMDS and again in AHLTA when the patient has returned to the United States.
9. Efforts should be made in the future to standardize the type of RIVCF used at all combat theater locations.

APPENDIX C: ADDITIONAL INFORMATION REGARDING OFF-LABEL USES IN CPGS

PURPOSE

The purpose of this Appendix is to ensure an understanding of DoD policy and practice regarding inclusion in CPGs of “off-label” uses of U.S. Food and Drug Administration (FDA)–approved products. This applies to off-label uses with patients who are armed forces members.

BACKGROUND

Unapproved (i.e. “off-label”) uses of FDA-approved products are extremely common in American medicine and are usually not subject to any special regulations. However, under Federal law, in some circumstances, unapproved uses of approved drugs are subject to FDA regulations governing “investigational new drugs.” These circumstances include such uses as part of clinical trials, and in the military context, command required, unapproved uses. Some command requested unapproved uses may also be subject to special regulations.

ADDITIONAL INFORMATION REGARDING OFF-LABEL USES IN CPGS

The inclusion in CPGs of off-label uses is not a clinical trial, nor is it a command request or requirement. Further, it does not imply that the Military Health System requires that use by DoD health care practitioners or considers it to be the “standard of care.” Rather, the inclusion in CPGs of off-label uses is to inform the clinical judgment of the responsible health care practitioner by providing information regarding potential risks and benefits of treatment alternatives. The decision is for the clinical judgment of the responsible health care practitioner within the practitioner-patient relationship.

ADDITIONAL PROCEDURES

Balanced Discussion

Consistent with this purpose, CPG discussions of off-label uses specifically state that they are uses not approved by the FDA. Further, such discussions are balanced in the presentation of appropriate clinical study data, including any such data that suggest caution in the use of the product and specifically including any FDA-issued warnings.

Quality Assurance Monitoring

With respect to such off-label uses, DoD procedure is to maintain a regular system of quality assurance monitoring of outcomes and known potential adverse events. For this reason, the importance of accurate clinical records is underscored.

Information to Patients

Good clinical practice includes the provision of appropriate information to patients. Each CPG discussing an unusual off-label use will address the issue of information to patients. When practicable, consideration will be given to including in an appendix an appropriate information sheet for distribution to patients, whether before or after use of the product. Information to patients should address in plain language: a) that the use is not approved by the FDA; b) the reasons why a DoD health care practitioner would decide to use the product for this purpose; and c) the potential risks associated with such use.