INFERIOR VENA CAVA FILTER USE IN PATIENTS AT HIGH RISK FOR PULMONARY EMBOLISM

SUMMARY

Pulmonary embolism (PE) remains a significant cause of morbidity and mortality in the critically ill surgical or trauma patient. PE may occur even in the presence of appropriate deep venous thrombosis (DVT) prophylaxis. Patients at high risk for PE may benefit from placement of a inferior vena cava (IVC) filter if they cannot be anticoagulated. While these devices have been shown to be effective in the prevention of PE, they are associated with an increased risk of deep venous thrombosis and have not been proven to reduce mortality.

RECOMMENDATIONS

- **Level 1**
  - **Routine prophylactic IVC filter insertion should not be performed.**
  - **Routine IVC filter placement is not indicated in patients with DVT who can be anticoagulated.**
- **Level 2**
  - **IVC filter insertion is indicated in patients with proximal DVT who cannot be anticoagulated. Such patients should be anticoagulated when their bleeding risk resolves.**
  - **Temporary IVC filters may considered when the risk of PE or contraindications to anticoagulation is anticipated to be less than two (2) weeks and the risk of PE is high.**
  - **IVC filters may be safely placed at the patient's bedside under either fluoroscopic or ultrasound guidance.**
- **Level 3**
  - **None**

INTRODUCTION

Deep venous thrombosis (DVT) and pulmonary embolism (PE) remain common, challenging, and often-devastating complications in the surgical or trauma patient. The average incidence of DVT in the general trauma population is 42% (range 18-90%) and the reported incidence of PE in patients with spinal cord injury (SCI) is 10% (range 4%-22%). Up to 4% of injury-related deaths in the U.S. are caused by PE-related “sudden death”, frequently in patients that would otherwise have recovered from their injuries. A patient’s risk increases within the first several hours after injury with DVT and/or PE frequently being noted within the first 72 hours. Reports exist of PE in the first 24-48 hours post-injury.

PE following development of DVT is one of the most preventable causes of death in hospitalized patients. DVT prophylaxis using either unfractionated / fractionated heparin or intermittent pneumatic compression devices represents the first-line of therapy, but is neither 100% protective against DVT formation nor subsequent PE. This is especially true in the critically ill, high-risk patient who may have barriers or

EVIDENCE DEFINITIONS

- **Class I:** Prospective randomized controlled trial.
- **Class II:** Prospective clinical study or retrospective analysis of reliable data. Includes observational, cohort, prevalence, or case control studies.
- **Class III:** Retrospective study. Includes database or registry reviews, large series of case reports, expert opinion.
- **Technology assessment:** A technology study which does not lend itself to classification in the above-mentioned format. Devices are evaluated in terms of their accuracy, reliability, therapeutic potential, or cost effectiveness.

LEVEL OF RECOMMENDATION DEFINITIONS

- **Level 1:** Convincingly justifiable based on available scientific information alone. Usually based on Class I data or strong Class II evidence if randomized testing is inappropriate. Conversely, low quality or contradictory Class I data may be insufficient to support a Level I recommendation.
- **Level 2:** Reasonably justifiable based on available scientific evidence and strongly supported by expert opinion. Usually supported by Class II data or a preponderance of Class III evidence.
- **Level 3:** Supported by available data, but scientific evidence is lacking. Generally supported by Class III data. Useful for educational purposes and in guiding future clinical research.

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contraindications to the use of such methods of prophylaxis such as complex wounds, CNS (brain and spinal cord) or ocular injuries, external fixators, or traction devices.

IVC filters have been proven to decrease the risk of PE in various patient populations including the critically ill and traumatically injured. Reported complication rates range from 0-35% with patency rates in excess of 90%. Concerns include the safety and long-term effects of these devices, especially in younger patients, for whom the risk of thromboembolism may be time-limited. The recent availability of removable devices may solve some of these problems, offering protection against PE during the early, highest-risk period, while avoiding the potential long-term complications of a permanent filter. To-date, however, few studies have shown that these filters are truly "temporary" with many such devices being left in place permanently.

The Eastern Association for the Surgery of Trauma (EAST) has published extensive evidence-based medicine guidelines on the management of DVT in the trauma patient (1). These guidelines, which have not been updated since 2001, recommend IVC filter placement in patients with the following findings:

- Recurrent PE despite full anticoagulation (Level I)
- Proximal DVT and contraindications to full anticoagulation (Level I)
- Proximal DVT and major bleeding while on full anticoagulation (Level I)
- Progression of iliofemoral clot despite anticoagulation (rare) (Level I)
- Large free-floating thrombus in the iliac vein or IVC (Level II)
- Following massive PE in which recurrent emboli may prove fatal (Level II)
- During/after surgical embolectomy (Level II)
- "Prophylactic" vena caval filter insertion in very high risk trauma patients who: (Level III)
    1. Cannot receive anticoagulation because of increased bleeding risk, and
    2. Have one or more of the following injury patterns:
        - Severe closed head injury (GCS < 8)
        - Incomplete spinal cord injury with para or quadriplegia
        - Complex pelvic fractures with associated long-bone fractures
        - Multiple long-bone fractures

The American College of Chest Physicians Evidence-Based Clinical Practice Guidelines (8th Edition) recommends the following regarding IVC filter placement:

- For patients with DVT, we recommend against the routine use of a vena cava filter in addition to anticoagulants (Grade 1A)
- For patients with acute proximal DVT, if anticoagulant therapy is not possible because of the risk of bleeding, we recommend placement of an inferior vena cava (IVC) filter (Grade 1C)
- For patients with acute DVT who have an IVC filter inserted as an alternative to anticoagulation, we recommend that they should subsequently receive a conventional course of anticoagulant therapy if their risk of bleeding resolves (Grade 1C).

LITERATURE REVIEW

Indications for IVC Filter Insertion

Author	Year	Evidence	Findings
Leach (3)	1985	Class II	Review of 201 trauma patients. Negligible morbidity and no mortality. No pulmonary emboli seen.
Rogers (4)	1993	Class III	Retrospective review of 2525 high-risk trauma patients. Four high-risk groups that account for 92% of PE were identified. 1. Patients > 55 years of age with isolated long bone fractures 2. Patients with severe head injury and coma 3. Patients with multiple long bone fractures and pelvic fracture 4. Patients with spinal cord injury and paraplegia or quadriplegia Overall incidence of PE was 1%.

Winchell (5)	1994	Class III	Retrospective review of 9721 trauma patients. 0.37% sustained a clinical or autopsy documented PE. Only 22% had a known DVT. 80% of patients with PE were receiving some form of prophylaxis (including 22% who were receiving both pneumatic compression stockings AND subcutaneous heparin). High-risk patient categories included 1. Head and spinal cord injury 2. Head and long bone fracture 3. Severe pelvis and long bone fracture 4. Multiple long bone fractures
Rosenthal (6)	1994	Class III	Retrospective case-control study of 151 trauma patients evaluating an aggressive approach to IVC filter placement in high-risk patients. From 1984-1988, 19 of 94 patients (20%) developed DVT despite prophylaxis (mechanical/ subcutaneous heparin). 8 patients developed PE (2 fatal). 15% of patients sustained PE without DVT (3 fatal). No patient sustained PE after filter placement. 23% of patients with ISS>16 developed PE. From 1988-1992, 29 of 67 patients with ISS>16 had filters placed. 13% of all patients developed DVT. Only 1% of patients with ISS>16 developed PE with the more aggressive approach.
Wilson (7)	1994	Class III	Retrospective evaluation of PE in 2525 trauma patients. 6% of patients with traumatic spinal cord injury (SCI) developed PE. Following a more aggressive utilization of IVC filters, no PE has been noted in 15 patients with SCI over a 6-24 month follow-up period.
Khansarinia (8)	1995	Class II	Prospective case-control evaluation of prophylactic IVC filters in 224 patients. 0% incidence of PE in 108 patients with prophylactic IVC filter vs. 6% in 216 historically matched control patients (4% fatal) ($p<0.009$).
Rodriguez (9)	1996	Class III	Prospective case (40 patients) vs. injury-matched historical control (80 patients) study. PE decreased from 14% to 1% ($p=0.02$) with prophylactic IVC filter placement. 44% of PE's occurred in the first week.
Gosin (10)	1997	Class III	Prospective case (250 patients) vs. historical control (249 patients) study. Prophylactic IVC filter placement in high-risk trauma patients decreased the PE rate from 4.8% to 1.6% ($p=0.045$). No clinically evident complications of IVC filter placement were noted.
Rogers (11)	1997	Class II-III	Retrospective review of high-risk orthopedic trauma patients. High-risk injury patterns for PE included: 1) Lower extremity fractures (0.62%) 2) Pelvic fractures (1.3%) 3) Pelvic and LE fractures (2.5%) 4) Non-orthopedic trauma patients (0.15%) IVC filters were placed in 35 of 940 patients who met 2 or more of the following criteria: 1) Age > 55 years 2) ISS > 16 3) Complex pelvic fractures 4) Long bone and pelvic fractures 5) Lower extremity or pelvic fracture requiring prolonged bedrest Incidence of PE decreased from historical rate of 1% to 0.2% in study population ($p<0.04$).
Rogers (12)	1998	Class II	Prospective evaluation of IVC filter placement in 792 trauma patients with 35 at high-risk and a contraindication to

			anticoagulation. No high-risk patient developed PE with a filter in place. 0.25% incidence of PE in trauma patients not deemed to be at high-risk.

Bedside Insertion, Ultrasound Guidance and Temporary Filters

Author	Year	Evidence	Findings
Nunn (13)	1997	Class II	55 patients undergoing bedside IVC filter placement under ultrasound guidance. 89% had successful placement. Failures were mostly due to inability to visualize the right renal vein due to bowel gas. No procedure related mortality and no PE. Four complications (8.2%) included 1 tilted filter, 1 DVT at the needle puncture site, 1 IVC occlusion, and 1 minor filter migration. Estimated annual cost savings were significant ($69,800-$118,300). Various other reports confirm the safety, feasibility, and cost effectiveness of this approach (13-16).
Linsenmaier (14)	1998	Class II	Prospective evaluation of 50 temporary IVC filter (Gunther, Gunther Tulip, Antheor) placements. 100% placement success. All temporary filters were removed in 1-12 days (mean 7.3 days). On removal, 18% showed thrombi in the filter. No patients developed a PE with a filter in place. 2 filters migrated and 1 patient developed an IVC thrombosis. 2 filters required femoral venotomy for removal.
Offner (15)	2003	Class II	Prospective evaluation of 44 temporary IVC filter (Gunther Tulip) placements. 84% were in severely injured patients. Filters were in place an average of 14 $\pm$ 1 days (range 3-30 days). Three filters could not be retrieved, 2 because of significant clots below the filter and 1 because of abnormal angulation. No complications associated with insertion or retrieval.

Timing of Prophylaxis

Author	Year	Evidence	Findings
Owings (16)	1997	Class III	Retrospective review of 63 trauma patients with PE. 25% of PE's occurred within the first 4 days of injury. 4 patients had their PE (1 fatal) the day following injury.
Carlin (17)	2002	Class III	Retrospective review of 22 trauma patients who developed PE prior to IVC filter placement. On average, PE was diagnosed 4 $\pm$ 2 days from admission and 36% occurred in the first 72 hours.

Follow up & Complications

Author	Year	Evidence	Findings
Greenfield (18)	1995	Class III	20-year follow-up of long-term safety and efficacy of IVC filter placement. Data were available for 54% of placements. Mean follow-up was 56.5 months. 93% had a patent insertion site vein. 5% had significant tilting or migration. 2% had a fractured filter strut. No clinical sequelae were noted for tilt, migration or limb fracture. Caval patency was 96%.
Rogers (11)	1998	Class III	Retrospective review of prophylactic IVC filter placement in 132 trauma patients. 3% demonstrated insertion-related thrombosis and 2.3% PE. 36% had follow-up ultrasound examinations. Mean follow-up time 599 days (range 9-1946 days). One asymptomatic IVC thrombosis was detected. 5.5% demonstrated strut malpositioning with a higher incidence of PE in these patients (6.3% vs. 0%; p=0.05).
Langan (19)	1999	Class III	Retrospective review of 160 trauma patients with prophylactic IVC filters. 47% survey response rate and return for examination, duplex ultrasound, and fluoroscopy. Mean follow up was 19.4

			months (range 3 to 57 months). The IVC was visualized in 93% and patency was 100% in these patients. Fluoroscopy failed to show any evidence of filter migration. One known clinical PE in 187 patients (0.5%) in whom a filter was inserted.
Sekharan (20)	2000	Class III	Retrospective review of 90 multi-system trauma patients receiving prophylactic IVC filters. 37% returned for evaluation. Mean follow-up was 68 months. 6% demonstrated DVT, 18% lower extremity edema, 0% PE, 0% migration / limb fracture. No IVC thrombosis.
Greenfield (21)	2000	Class III	Retrospective review of IVC filters in 385 trauma patients (249 prophylactic). Long-term outcome was available in 79%. Mean follow up 2.4 years. 2% had insertion site thrombosis and 15.6% DVT. Migration and tilt were rare and clinically and statistically insignificant. IVC patency was 96.5%. 3 PE's (1.5%).
Wojcik (22)	2000	Class III	Retrospective review of 178 trauma patients. 59% returned for follow-up. Mean follow-up 28.9 months. No clinically symptomatic pulmonary emboli. One IVC filter migration (0.95%). One IVC occlusion (0.95%). In the prophylactic group (n=64), 28 (44%) developed a DVT. 11 patients (10.4%) had LE swelling.
Duperier (23)	2003	Class III	Retrospective review of 133 trauma patients receiving IVC filters. 77% had post-insertion duplex studies. 26% had de novo thrombi. No arteriovenous fistulae were noted. No patients developed clinical evidence of IVC occlusion. One patient had a fatal PE.
Prepic Study Group (24)	2005	Class I	Four hundred patients randomized to permanent IVC filter placement vs. no filter in addition to standard anticoagulation were reassessed 8 years post-study. Symptomatic PE occurred in 6.2% of the filter group and 15.1% in the no-filter group (p=0.008). DVT occurred in 35.7% of the filter group and 27.5% of the no-filter group (p=0.042). Post-thrombotic syndrome occurred equally between the groups. There was no difference in long-term mortality. The authors concluded that while IVC filters reduce the risk of PE, they increase the risk of DVT and do not alter mortality. The prophylactic insertion of such filters in the general population with DVT cannot be recommended.
Singh (25)	2008	Class III	Retrospective review of 558 patients receiving an IVC filter. 362 filters met currently accepted indications while 196 filters did not (i.e., did not have a contraindication to or had not failed anticoagulation). The within-guidelines group had a 1.4% post-filter PE incidence, a 13.6% IVC thrombosis rate, and 9.4% with DVT. The out of guidelines group had a 0.5% post-filter PE incidence, a 1% IVC thrombosis rate, and 3.6% with DVT. No patient without DVT at IVC filter insertion subsequently developed a PE. The authors concluded that IVC filter placement cannot be supported in patients without DVT who can be anticoagulated.

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