Optional Inferior Vena Cava Filters in the Trauma Patient

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ABSTRACT

Trauma patients are at exceedingly high risk of development of venous thromboembolism (VTE) including deep venous thrombosis and pulmonary embolism (PE). The epidemiology of VTE in trauma patients is reviewed. PE is thought to be the third major cause of death after trauma in those patients who survive longer than 24 hours after onset of injury. In fact, patients recovering from trauma have the highest rate of VTE among all subgroups of hospitalized patients. Various prophylactic and surveillance methods have been evaluated and found helpful in certain situations, but VTE complications can occur despite such measures. Therapeutic and prophylactic uses of inferior vena cava (IVC) filters in trauma patients are reviewed. Prophylactic IVC filter use is revealed to be a controversial subject with valid arguments on both sides of the issue. With the lack of prospective randomized trials of IVC filter use in trauma, it is impossible to make evidence-based recommendations. Unfortunately, two sets of guidelines are available for insertion of filters in trauma patients, with conflicting recommendations. The introduction of retrievable IVC filters seems to offer a unique solution for VTE protection in the trauma patient population, which often consists of younger members of our population. Lastly, current generations of FDA-approved retrieval filters are discussed.

KEYWORDS: Venous thromboembolism, inferior vena cava filter, trauma

Objective: Upon completion of this article, the reader should be able to summarize the epidemiology of pulmonary emboli in trauma patients, the use of inferior vena cava filters in both the therapeutic and prophylactic uses, and, finally, identify the unique subset of filters that are retrievable in the setting of trauma patients.

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EPIDEMIOLOGY OF VENOUS THROMBOEMBOLIC DISEASE IN TRAUMATIZED PATIENTS

Several factors have been reported to increase the risk of venous thromboembolism (VTE) after trauma. This is

an expected result as traumatic injury and care of traumatized patients affects Virchow's triad: (1) stasis or reduction of blood flow; (2) injury to the intimal lining predisposing to thrombosis; (3) a state of hypercoagulability.

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The earliest report of VTE in the trauma setting comes from autopsy series. In 1935, McCartney documented a fatal pulmonary embolism (PE) rate of 3.8% (61 patients) in examination of 1604 trauma autopsies.² In 1961, Sevitt and Gallagher found a 65% incidence of deep venous thrombosis (DVT) and a 20.3% incidence of PE in a series of trauma and burn patients.³ These same authors were the first to report on prophylactic use of anticoagulation for high-risk patients.⁴ Two additional studies of fatal traumatic injuries identified evidence for PE or cause of death from PE in ~15% of cases.^{5,6}

More recent studies have documented the high incidence of VTE in trauma patients even despite prophylactic measures usually effective in medical or surgical patients. In 1990, Shackford¹ noted a 7% incidence of VTE in 177 trauma patients despite prophylaxis with subcutaneous heparin or venous compression devices. Attempts to categorize trauma patients at particularly high risk for VTE identified these high risk conditions: fractures of the spine, pelvis, or lower extremity; age greater than 45 years; bed rest longer than 3 days; and previous venous repair.⁷ These investigators concluded that VTE is the third most common cause of in-hospital deaths in trauma patients. To date, the most comprehensive study of VTE and trauma was published by Geerts et al in 1994.⁸ Trauma patients were prospectively studied with lower-extremity venography performed between 7 and 21 days after injury. None of the patients received any type of prophylaxis. They documented that DVT occurred in 201 (58%) of the 349 trauma patients studied, with 63 patients (18%) having proximal DVT (popliteal vein and higher). Only 3 of the 201 patients with DVT (1.5%) had clinical signs suggestive of thrombosis before the diagnosis was made with venography. Seven of the patients had documented PE (2%), and in three of these patients, the PE was fatal. None of the three patient with fatal PE had clinical features suggesting VTE before their sudden deaths on days 15, 16, and 18 after injury. Two of the fatal PEs occurred in patients with spinal cord injury. DVT was found in 65 (50%) or 129 patients with major injuries involving the face, chest, or abdomen; in 41 (62%) of 66 patients with spinal cord injury; and in 126 (69%) of the 182 patients with lower-extremity orthopedic injuries. DVT was detected in 61 of 100 patients with pelvic fractures, in 59 (80%) of 74 patients with femoral fractures, and in 66 (77%) of 86 patients with tibial fractures. A multivariate analysis identified five independent risk factors for DVT: older age [odds ratio (OR)=1.05 per year of age; 95% confidence interval (CI)=1.03 to 1.06]; blood transfusion (OR=1.74, 95% CI=1.03 to 2.93); surgery (OR=2.30, 95% CI=1.08 to 4.89); fracture of femur or tibia (OR=4.82; 95% CI=2.79 to 8.33); and spinal cord injury (OR=8.59, 95% CI=2.92 to 25.28).

Interestingly, in the multivariate analysis, the injury severity score was not associated as a risk factor for DVT, suggesting that the specific pattern of injury plays a larger role in genesis of thrombosis than does the overall severity of trauma.⁸ Reduced mobility and a longer hospital stay were both associated with increased risk of thrombosis.

THE ROLES OF CONVENTIONAL VTE SURVEILLANCE AND PROPHYLAXIS IN TRAUMA PATIENTS

As reported by Geerts et al, fatal PE in patients with trauma may occur without warning, in the absence of clinical evidence of DVT and despite noninvasive venous screening.⁸ In trauma patients, the poor reliability of clinical signs to suggest VTE is explained by the pain and swelling associated with particular injuries of the pelvis or lower extremities. In most trauma patients, the occurrence of DVT is clinically silent, and hypoxia from PE may be mimicked by a multitude of others causes in trauma patients. In medical patients, elevations in D-dimer have been associated with development of VTE. D-dimers are breakdown products of fibrin and are thus elevated in patients with VTE. Unfortunately, D-dimers are also elevated within 48 hours of traumatic injury, making these values useless for diagnosis of DVT with trauma. Because of the clinically silent nature of DVT in trauma, some investigators have advocated using color Doppler ultrasound imaging to diagnose DVT so that treatment of VTE can occur before PE occurs.⁹ Surveillance ultrasound is expensive and has known limitations within the trauma population because of the restrictions of scanning traumatized lower extremities because of splints, dressings, fixation, or casts.^{10,11} In symptomatic nontraumatic patients, ultrasound has excellent sensitivity (91%) and specificity (98%) when compared with venography. Studies have demonstrated that ultrasound is less accurate in diagnosing DVT in asymptomatic patients. Likewise, ultrasound in traumatized patients is expected to offer lower accuracy in diagnosis of DVT than symptomatic nontraumatized patients. Moreover, several PEs have occurred in the absence of documented DVT, suggesting the ultrasound may miss significant DVTs such as occur in the pelvis.

Prophylaxis for DVTs has traditionally come to mean one of four entities including arteriovenous foot pumps, sequential compression device (SCD), low-dose heparin (LDH), and low-molecular-weight heparin (LMWH).¹²⁻¹⁴

Although the exact mechanism of mechanical prophylaxis for DVT is not known, it is thought to occur from two the fold properties of (1) a mechanical increase of blood flow and (2) release of endothelial factors such as nitrous oxide and stimulation of the fibrinolytic pathways in the venous system. Studies

have demonstrated, however, that the fibrinolytic properties begin to decay within minutes of the discontinuation of SCDs, suggesting that the SCDs must be worn continuously for clinical benefit of prophylaxis.¹⁵ The same author also found that there was a decrease in fibrinolytic activity in sites remote from the SCD, challenging the ability of the SCDs that are worn on the arms to prevent lower-extremity DVTs. The clinical efficacy of mechanical compression devices is not well established due to numerous reasons including inconsistencies in duration/method of placement, lack of well-established mechanism, and difficulties in use in multi-injury traumas such as lower-extremity injury precluding placement. Despite these findings, SCDs continue to be used in many institutions for DVT/PE prophylaxis. SCDs may have a specific benefit in a patient with an isolated head trauma whose injury may preclude use of pharmacological DVT prophylaxis, with the caveat that SCDs may increase intracranial pressures.¹⁴

Isolated clinical trials have demonstrated that LDH and SCDs are superior to no prophylaxis in high-risk trauma patients,¹² but several other studies including randomized controlled trials and meta-analysis have failed to confirm this benefit.¹³ The comprehensive meta-analysis performed by Velmahos et al concluded that there was no difference in PE or DVT rates between no prophylaxis and LDH/SCD groups (used separately).¹³ The only appreciable difference found by the meta-analysis was a lower incidence of DVTs in the LMWH when compared with LDH.¹³ Class I data are now present for use of LMWH in trauma patients, but the increased bleeding risks create a difficult decision for clinicians in the trauma setting. As recommended by the Eastern Association of Trauma (EAST) management guidelines, LMWH is suggested for use in all high-risk trauma patients except with head injury.¹⁴

INFERIOR VENA CAVA FILTERS AND TRAUMA

Inferior vena cava (IVC) filters have been used with variable frequency in trauma patients as a method to reduce the incidence of PE. Obviously, this method of therapy offers no prophylaxis or treatment for DVT. Although there is no current prospective data, the use of IVC filters appears to reduce the rate of PE in patients unable to be anticoagulated for various reasons. Indications for IVC filters, as listed in Table 1, are divided into absolute and relative indications.^{16,17} The placement of IVC filters in trauma patients without evidence of VTE is considered prophylactic and remains controversial.

In the trauma literature, much attention has been directed toward the use of prophylactic IVC filters (PVCFs; Tables 2–3).¹⁸ Many different articles in the past 20 years have attempted to clarify the indications and efficacy of PVCFs, but class I data (prospective,

Table 1 Accepted Absolute and Relative Indications for IVC Filters^{16,17,70}

1. Patients with acute deep venous thrombosis of the IVC, iliac, or femoral popliteal veins and who had one or more of the following conditions:
 - a. Contraindication to anticoagulation
 - b. Complication of anticoagulation
 - c. Failure of anticoagulation
 - i. Recurrent PE despite adequate therapy
 - ii. Inability to achieve adequate anticoagulation
 2. Massive pulmonary embolism with residual deep venous thrombus in a patient at risk for further PE
 3. Free-floating iliofemoral or IVC thrombus
 4. Severe cardiopulmonary disease and deep venous thrombosis (e.g., cor pulmonale with pulmonary hypertension)
 5. Poor compliance with anticoagulant medications
- Subsequently several other indications have become common, and those include patients with:
- a. Severe trauma without documented pulmonary embolism or deep venous thrombosis
 - b. Closed head injury
 - c. Spinal cord injury
 - d. Multiple long-bone or pelvic fractures
 - e. High-risk patients (e.g., immobilized, intensive care patients, prophylactic preoperative placement in patients with multiple risk factors for venous thromboembolism)

IVC, inferior vena cava; PE, pulmonary embolism.

randomized controlled trials) are lacking for general high-risk trauma patients.^{19–49} A study supporting the use of IVC filters was reported in 1973 by Fullen et al, who performed a prospective randomized trial in hip fracture patients showing a statistically significant reduction in PE rates with filter insertion.¹⁹ Besides this study, five other studies have demonstrated reduced PE rates after permanent IVC filter insertion in high-risk trauma patients typically when compared with historical

Table 2 Eastern Association for the Surgery of Trauma (EAST) Guidelines for Prophylactic IVC Filter Insertion in Multiple-Traumatized Patients¹⁴

Prophylactic IVC filter insertion should be considered in very high-risk trauma patients:

1. Who cannot receive anticoagulation because of increased bleeding risk
- and
2. Who have an injury pattern rendering them immobilized for a prolonged period of time, including the following:
 - a. Severe closed head injury (GCS < 8)
 - b. Incomplete spinal cord injury with paraplegia or quadriplegia
 - c. Complex pelvic fractures with associated long bone fractures
 - d. Multiple long bone fractures

IVC, inferior vena cava; PE, pulmonary embolism; GCS, Glasgow Coma Score.

controls.^{27,28,30,32,33} The study by Khansarinia et al in 1995 demonstrated a reduction in PE-related mortality with prophylactic filter insertion as well, although overall mortality was not affected.²⁷ The vast majority of the studies are clinical studies without a comparison arm so that firm conclusions about the protective effect of IVC filters cannot be demonstrated. Several studies report no benefit from protection against PE compared with the usual prophylactic measures,^{38,44,48} and others document complications associated with filters.^{38,39,44} The studies with complications indicate frequent occurrences of DVT and, less often, IVC occlusions. Although it is possible that the preexisting conditions in trauma patients may predispose them to DVT, it is hypothesized that in certain cases the filter may be adding to this risk. The high incidence of DVT and recurrent DVT in trauma patients places those patients at risk for development of chronic venous stasis.

Additional information about the performance of IVC filters came to light in 1998 with the publication of a study by Decousus et al (PREPIC group).⁵⁰ This prospective study randomized 400 patients with proximal DVT, with or without PE, either to receive or not receive a filter in addition to standard anticoagulation for at least 3 months. This study demonstrated a statistically significant reduction in PE rates at 12 days with filters, but during a 2-year follow-up there was a 20.8% incidence of recurrent DVT rate in patients with filters versus 11.6% rate in patients without filters. Many of the patients with IVC filters had thrombus within the cava and filter. Although the study used filters in ways not commonly used in trauma patients, it suggests that the risk-benefit ratio of filters becomes less favorable as filters remain in situ for longer periods of time. The authors have reported their 8-year follow-up data.⁵¹ They showed a statistically significant decrease in PE rates in patients with filters (6.2%) compared with patients without filters (15.1%, $P = 0.008$). The rate of recurrent DVT was higher in patients with filters (35.7%) versus those without filters (27.5%, $P = 0.04$). The study showed no change in mortality between the two groups (~50%); and no difference in postthrombotic venous stasis (~70%) between the two groups. This has heralded the push for filters that can be removed when no longer needed. Several reports have included either retrievable or temporary filters,^{38,41-49} and essentially all are case series with most reporting favorable results, but at least two had cautionary conclusions.^{44,48} The negative studies have not shown reduced PE rates with more liberal use of retrievable filters. Several unique complications are added with the secondary procedure needed to remove the filter. Lastly, most studies report that the majority of retrievable filters are left in place as permanent filters, obviating the benefits of removal.

At least two meta-analyses of IVC filters for trauma have been done. Velmahos et al completed the

first study, which was reported in 2000.⁵² He noted that all the filter trials were not randomized trials but rather uncontrolled studies with observational designs, including varying assessment of outcomes and different degrees of follow-up, which limited direct comparisons. Velmahos et al divided the patients into PVCF patients, contemporaneously managed trauma patients without filters, and historical trauma patient controls. Of the 321 patients managed with prophylactic filters, there were two nonfatal PEs (0.2%). Among the 1083 contemporaneously patients managed without filters, there were seven patients with PEs (1.5%) and one fatal PE (0.1%). Among historical controls, the rates of PE and fatal PE were 5.8% and 3.3%, respectively. Velmahos et al concluded that the reported incidence of PE in patients who undergo PVCF placement is lower than the incidence of PE among patients without PVCF. The observational design of these studies did not allow firm conclusions to be drawn about the use of PVCFs. Definitive answers can only be given by future research focused on well-designed prospective randomized trials. The second analysis by Girard et al in 2003 offers similar findings.⁵³ The authors' literature search included articles from 1988 to 2002. Many methodological shortcomings were identified, and in the absence of prospective randomized controlled clinical trials, they authors stated that it is difficult to draw conclusions about the efficacy of PVCFs in trauma patients. Girard et al documented a 0.6% incidence of PE in 1112 patients who had PVCF inserted, with two of the PEs being fatal. The studies with historical controls typically showed higher PE rates than in patients with prophylactic filters. The most common adverse outcome after PVCF insertion was DVT, which occurred in 9.3% of patients. Other complications included insertion site thrombosis (2.0%), IVC occlusion/thrombus (2.0%), complication during insertion (1.4%), and filter migration (0.4%). None of the meta-analyses included studies involving retrievable filters.

At least three studies have included useful information about the costs associated with PVCF insertion and prophylaxis for VTE in trauma patients. The first study by Nunn et al in 1997 (Table 3) documented reduced charges of \$69,800 over a 4-month period by using bedside placement of filters with percutaneous ultrasound as compared with insertion within radiology.³¹ The study by Brasel et al, also in 1997, found that a cost-effectiveness analysis concluded that the cost per PE prevented using serial ultrasound is US\$46,300 compared with US\$93,700 when using PVCFs.⁵⁴ In the last study by Spain et al, it was estimated that the annual cost of PVCF insertions would exceed \$900,000 if only 1% of the trauma population was treated with filters.⁵⁵

Guidelines regarding the use of IVC filters in trauma patients have been suggested by the EAST and

Table 3 Trials of IVC Filters for Trauma¹⁸

First Author and Year	No. of Patients	Study Type	Filter Used	PE with Filter/ PE with control ^{1*}	Follow-up (mo)	Complications (%)	Comments
Fullen 1973¹⁹	100	PRCT	SSGF	1/41 and 1/59 (S)	NR	NA	Patients with hip fracture only
Thomas 1988 ²⁰	22	CS	SSGF	0/NA	NR	36	Evaluated extended indications for filters
Rohrer 1989 ²¹	66	CS	SSGF	3 (1 fatal)/NA	NR	4.5 IVC occlusion rate	Patients with acetabular fractures
Webb 1992 ²²	24	CS	SSGF	0/24 and 2 (1 fatal)/27	NR	17 (all with lower-extremity edema)	Patients with spinal cord injury
Wilson 1994 ²³	15	CS	TGF	0/15 and 7/111	6-24	0	Trauma patients
Rosenthal 1994 ²⁴	129	CS with HC	SSGF	0/29 and 15 (3 fatal)/161	Avg 32.8 (4-58)	0	Trauma patients
Winchell 1994 ²⁵	29	CS with HC	NA	0 and 13/9721	NR	NA	Trauma patients
Leach 1994 ²⁶	200	CS with HC	TGF	0 fatal/200 and 4 (4 fatal)/10,948	NR	1.5 (one migration to PA; two did not open properly)	Trauma patients
Zofaghar 1995	45	CS	VT	9/NA	NR	0	Trauma patients
Khansarinia 1995²⁷	108	CS with HC	SSGF	0/108 and 13 (9 fatal)/216 (S, P<0.009)	NR	10.85 (1 episode of filter misplacement migrated to RV required thoracotomy)	Trauma patients; mortality rate 16% and 22% (P=0.28, NS)
Rogers 1995²⁸	63	CS with HC	TGF	1/63 and 25/2525 (S, P<0.0007)	NR	30% developed DVT after filters; 30-d patency of 100%, 1-y patency of 96.1%	Trauma patients
Patton 1996 ²⁹	110	CS	TGF	0/NA	Avg 18 (4-42)	7 (3 insertion site thromboses, one migration in patient with megacava to hepatic vein, 3 erroneous insertions into renal, iliac, and lumbar veins; high incidence of chronic venous stasis)	Trauma patients
Rodriguez 1996³⁰	40	CS with HC	TGF	1/40 and 14/80 (S, P=0.02)	NR	10 vena cava thrombus, one extending above filter with pulmonary embolus; 1-y caval patency rate of 95%	Trauma patients
Nunn 1997 ³¹	55	CS	TGF	PE-related and overall mortality lower in filter group but not significantly 0/NA	NR	10.9 (could not insert filter because could not see right renal vein (5) or megacava (1)); 8.2 (1 each filter tilt, access thrombosis, minor migration, IVC occlusion)	Trauma patients with filters inserted at bedside with portable abdominal US; US insertion saved \$69,800 in 1 y vs. insertion in radiology
Gosin 1997³²	99	CS with HC	TGF	1.6/4.8 (S, P=0.045)	NR	0	Trauma patients
Headrick 1997³³	228	CS with HC	NA	0/29 and 6/234	NR	17	Trauma patients: patients were identified by serial US to diagnose LEDVT and then insert filters; the combination of US and filters reduced the PE rate compared with historical controls (P<0.05)
Rogers 1997 ³⁴	35	CS with HC	TGF (32), BN (3)	1/35 and 11/1150	NR	7.4 (1 tachyarrhythmia, 2 insertion site thromboses, a patient with thrombus above filter on US required second filter)	Orthopedic trauma patients; IVC patency of 93.6% at 1 and 2 y
Rogers 1998 ³⁵	132	CS	TGF (93), SSGF (21) VT (10), BN (8)	3 (1 fatal)/NA	Avg 559 d (9-1946)	12 DVTs with 3% insertion related and 9% in course of hospitalization	All 3 PE cases had filter tilt or strut malposition; 3-y IVC patency rate of 97%
Langen 1999 ³⁶	187	CS	TGF, SSGF	1/NA	Avg 19.4 (7-60)	12.8 incidence of DVT after filter insertion	Trauma patients
Hughes 1999 ³⁷	2	CS	Temp filter	0/NA	NR	0; devices had dwell times of 5 and 6 d	Used to protect infusion catheter in trauma patients

Table 3 (Continued)

First Author and Year	No. of Patients	Study Type	Filter Used	PE with Filter/ PE with control*	Follow-up (mo)	Complications (%)	Comments
McMurtry 1999³⁸	248	CS	TGF or SSGF (14), VT (80), SN (11), BN (4), ? (11)	PE rate 0.3% during low use of proph filters vs. 0.48% with high use of proph filters; fatal PE filters vs. 0.07% high use of proph filters	NR	8.4 (6 patients with DVT, 4 patients with PE, 3 patients with IVC thrombosis, 2 patients with misplaced filters, 2 patients with venous insufficiency)	Trauma patients
Wojcik 2000³⁹	191	CS	TGF (72), BN (28), SN (5)	0/NA	Avg 28.9	10.4 with leg swelling; 1 vena cava occlusion and 1 <1-cm migration; 44% of patients with filters developed DVT after filters	Trauma patients identified with DVT with filter insertion plus proph filters
Sekharan 2000 ⁴⁰	108	CS	TGF, SSGF	0/NA	Avg 67.7	8 (mostly DVTs but 1 case of migration to RV on insertion-required thoracotomy)	Trauma patients
Rosenthal 2004 ⁴¹	94	CS	Opt	NA	NR	5.3 (2 groin hematomas; 3 misplaced filters in iliac veins, which were retrieved and reinserted); 1 symptomatic (SOB) PE after filter removal	Trauma patients using IVUS to insert the filters; 3 filters with significant thrombus at retrieval attempt
Morris 2004 ⁴²	55	CS	GT, Trap, SSGF, VT, SN	0/NA	NR	0.4; 1 nonfatal PE 1 d after filter removal	Mixed population but 55 patients were trauma patients
Allen 2005 ⁴³	51	CS	GT	0/NA	NR	4 (associated with inability to retrieve filter in 1 of 25 patients attempted); 1 patient developed PE after filter removed	Trauma patients
Antevil 2006⁴⁴	216	CS	R, GT, Opt	0.2% rate of PE in low proph filter group vs. high-use proph group	NR	2.7 (1 PE, 2 filter infections, 1 IVC occlusion, 1 retrieval lodged in jugular vein)	Trauma patients
Meier 2006 ⁴⁵	32	CS	Opt	0/NA	NR	1 (1 patient had a PE 5 d after removal and another had minor inferior filter migration)	Trauma patients
Rosenthal 2006 ⁴⁶	127	CS	GT (49), R (41), Opt (37)	0/NA	NR	6.2 (3 groin hematomas, 3 early filters misplaced in iliac vein successfully replaced, 2 access thromboses)	Trauma patients with IVUS placement; 1 PE occurred after filter removal; 52% of filters successfully removed; 4 filters not removed with trapped clot
Karmy-Jones 2007⁴⁷	446	CS	GT, R, Opt		NR	2.5 [3 cases of migration (R), 2 PEs (GT, R), 6 IVC occlusion (GT 0%, R 1%, Opt 11%)]	Multicenter trauma; only 22% of filters were retrieved; retrieval failures in 15 patients: 10% GT, 14% R, 27% Opt
Cherry 2008⁴⁸	244	Prosp	R (64), G2 (116), GT (1)	PE rate 0.7%/0.4% in 2004 vs. 2006 NS despite increase use of proph filters; 4 overall PEs or 1.6%		0.1% [(2 fractures (R), 2 caudal migrations (G2), 1 filter tilt (G2))]	Trauma patients; of 140 retrieval filters with 18-mo follow-up, only 58.6% were removed
Johnson 2009 ⁴⁹	72 (32% proph and 68% therap)	CS	R (1), Opt (1), GT (70)	0/NA	Avg 28	3% (1 guide wire entrapment and deployed filter in iliac vein both replaced); no access site thrombus and no IVC occlusions but large number anticoagulated	Military trauma; only 18% of retrieval filters were retrieved mostly because of persistent indication and not loss of follow-up

*Number of cases with PE in filter patients/number of PE in patients in the control arm if there was one.

Bold font indicates studies where favorable outcomes were documented by insertion of IVC filters. Bold italic font indicates studies where complications or unfavorable results occurred with IVC filter insertion in trauma patients. PRCT, prospective, randomized controlled trial; CS, clinical series; HC, historical control; IVC, inferior vena cava; Prosp, prospectively collected clinical series; SSGF, stainless steel Greenfield (Boston-Scientific/Meditech, Natick, MA); TGF, titanium Greenfield; BN, bird's nest; VT, Venatech (B. Braun, Bethlehem, PA); Temp, Tempo (B. Braun-Celsa, Chasseneuil, FR); infusion filter; ? , unknown filter used; SN, Simon (Bard Peripheral Vascular, Tempe, AZ); nitinol; R, Recovery (Bard Peripheral Vascular, Tempe, AZ); GT, Gunther Tulip (Cook Inc, Bloomington, IN); Opt, OptEase (Cordis Corp, Miami Lakes, FL); G2, G2 filter (Bard Peripheral Vascular); S, statistically significant; NS, not significant; P, P value for statistic test used; NA, not applicable; NR, not reported; PE, pulmonary embolism; DVT, deep venous thrombosis; proph, prophylactic; therap, therapeutic; IVUS, intravascular ultrasound probes; Avg, average; US, ultrasound; RV, right ventricle; SOB, Shortness of Breath; LEDVT, Lower extremity DVT.

the American College of Chest Physicians (ACCP).⁵⁶ The EAST guidelines suggest that PVCFs should be considered in immobilized patients at high risk of a DVT/PE who cannot be anticoagulated. High-risk patients include those with a severe closed head injury (Glasgow Coma Score < 8), incomplete spinal cord injury with paraplegia or quadriplegia, complex pelvic fractures with associated long-bone fractures, and multiple long-bone fractures (Table 2). In contrast to the EAST guidelines, the ACCP guidelines state: "We and others do not recommend the use of an IVC filter as thromboprophylaxis, even in patients who are at high risk for VTE. IVC filter insertion is indicated for patients with proven proximal DVT, and either an absolute contraindication to full-dose anticoagulation or planned major surgery in the near future. In either case, even with an IVC filter, therapeutic anticoagulation should be commenced as soon as the contraindication resolves." One recent study from a level 1 trauma center looking at both guidelines seemed to favor the ACCP guidelines.⁵⁷ The authors concluded that the data do not support placing a filter for patients who do not have VTE and can be anticoagulated, but unfortunately the lack of a control group does not answer the question about prophylactic use of IVC filters. The UCSD Medical Center trauma group has actively participated in research related to IVC filters and trauma^{7,25} and has followed the 2002 EAST guidelines.¹⁴

INSERTION TECHNIQUE

Traditional insertion of IVC filters is performed in an angiographic suite or operating room with C-arm access. Often, a right femoral vein access site is chosen, followed by a cavagram with or without selection of the renal veins bilaterally, and finally insertion of the filter. Alternative approaches can include the left groin or right internal jugular vein access sites if there is a contraindication such as a thrombus or traumatic injury present in the right lower-extremity venous system. Generally, the venous punctures are performed with ultrasound guidance and with single-wall needle technique to minimize complications such as groin hematoma or arteriovenous fistula formation.

An alternative approach that has been tried in other centers is bedside insertion using intravascular ultrasound probes (IVUS; Table 3).^{41,46,58-60} This technique has proven safe as it avoids transportation of potentially unstable patients to the angiography suite, but there are some pitfalls to consider. The technique also offers avoidance of iodinated contrast media used in the angiography suites and may also be useful in patients excluded from the interventional radiology suite because of excessive body habitus. There are single- and double-puncture techniques in the groin. The single-puncture technique involves using IVUS to evaluate the vascular

anatomy and then estimating the length of deployment for the IVC filter, although this technique has potential for erroneous deployment of the filter. The double-puncture technique uses two femoral vein punctures separated by several centimeters, which allow access by IVUS and the IVC sheath together. This technique allows for real-time visualization of the vasculature and filter deployment. Although theoretically safe, because to the high cost of IVUS probes, there is no cost benefit to these alternate bedside insertion techniques. Potential pitfalls of this technique include erroneous filter placement, a long learning curve, problems with operator errors with using the IVUS, inability to perform problem solving in complex or complicated cases, and, lastly, potential for loss of sterility at the bedside.

A final method that has been described in the literature is insertion at bedside using transabdominal ultrasound imaging. However, because of reported failure rates up to 15%, this technique is less appealing.^{31,61,62} The cost-effectiveness with this approach already mentioned could easily be negated when taking into account a 10 to 15% rate of failed filter deployments. The malpositioned filter would then have to be retrieved and possibly replaced in the traditional method. As with IVUS, it avoids contrast media and transport to the angiography suite, and it may be useful in patients who cannot be treated in an angiography suite because of obesity.

In both ultrasound and venographic techniques, it is important to note that the transverse width of the IVC should be measured as filters currently on the market are generally indicated only for IVC sizes up to 28 or 30 mm. If the IVC is greater than 30 mm, it is considered a megacava, a condition that can occur in up to 2.5% of the population. Placement of any of the retrievable filters in a megacava may be associated with migration or embolization of the filter. Only the permanent bird's nest filter can be placed in the larger IVC, up to 40 mm. Alternatively, a retrievable filter may be placed in bilateral common iliac veins in the case of a megacava.⁶³

RETRIEVAL ALGORITHM

Retrievable filters were first approved for use in the United States by the FDA in 2003. Although retrievable filters have opened the door to reducing or eliminating many of the possible long-term complications commonly associated with IVC filters, many limitations and unknowns still exist in their optimal use. The Society of Interventional Radiology (SIR) conducted a multidisciplinary panel to discuss retrievable filters.⁶⁴ This panel recognized that no unique indications exist for retrievable as opposed to permanent IVC filters. Discontinuation of filtration is an individualized decision and should only occur when the risk of clinically significant PE is

Figure 1 Algorithm for removal of retrievable inferior vena cava filters.⁶⁴ DVT, deep venous thrombosis; VTE, venous thromboembolism.

reduced to an acceptable level and is estimated to be less than the risk of leaving the filter in situ. Lastly, the quality of the literature on retrievable filters is not sufficient to support evidence-based recommendations at this time. The retrieval algorithm adapted from the SIR guideline is illustrated in Fig. 1.

For retrievable filters to be effective, three conditions must be met. First, and perhaps the most important, the patient must be available for retrieval of

the filter. Second, the filter must be ready for retrieval (Fig. 1). Third, the filter must be retrievable without technical limitations such as filter tilt, intimal overgrowth, or residual thrombus in the filter. If there is no thrombus in the filter, removal is then attempted. If there is thrombus in the filter, this usually signifies that the filter has functioned properly in trapping potential pulmonary emboli. If the patient is already anticoagulated for VTE, the volume of clot is judged by the

operator to be small (typically <25% of estimated filter cone depth), and the risk of filter removal is acceptable, the filter may be removed. If the thrombus is large, a decision to abort removal should be considered with addition or continuation of anticoagulation. Restudy of the filter after a certain time period may reveal that the filter can be safely removed at that time. The safety of retrieval of filters on patients with full anticoagulation (international normalized ratio 2 to 3.4) has been studied by Schmelzer et al,⁶⁵ who safely removed 113 such filters without any bleeding complications. The filters retrieved included Recovery (Bard Peripheral Vascular, Tempe, AZ), G2 (Bard Peripheral Vascular), Gunther Tulip (GT; Cook Inc., Bloomington, IN), and OptEase (Cordis Corp., Miami Lakes, FL; femoral removal). The patients were treated with a 10-minute compression after the filter sheath removal (10 to 11 French) and 2-hour recovery period.

Unfortunately, reports have indicated that poor follow-up has been a dominant factor limiting the retrieval of filters in trauma patients. Some have also reported that despite good follow-up, retrieval rates are not as high as expected (Table 3).⁴⁶⁻⁴⁹ Too many filters are left in place for long periods of time, reducing their retrieval success rate; but the reported optimal window for retrieval has been recently challenged and may be longer than previously suggested.⁶⁶ This study included four trauma centers with 25,658 admissions. They documented 146 patients (0.6%) with PEs. They documented PE rates of 54, 29, 5.5, 5.5, and 5.5% at <7 days,

7 to 14 days, 15 to 21 days, 22 to 28 day, and >28 days, respectively. The mortality of trauma patients identified as having postinjury PEs was 17.8% ($n=26$). Fatal PEs occurred as late as 21 and 43 days after injury. Table 3 indicates several instances where PEs have been documented after filter retrieval. There is no evidence base for optimum filter retrieval times at this point. As retrievable filters have evolved, the recommended time for their removal has extended, and current-generation IVC filters may not indicate a time limit beyond which retrieval may not be attempted. Innovative interventional techniques have evolved to facilitate filter retrieval in difficult situations.⁶⁷⁻⁶⁹

IVC FILTERS

IVC filters have been evolving over the past 30 years.^{70,71} Presently there are seven FDA-approved retrievable filters in the United States: the GT, Celect (Cook Inc.), G2, G2X (Bard Peripheral Vascular), OptEase, ALN (Implants Chirurgicaux, Chisonaccia, France), and Option (Angiotech Pharmaceuticals, Vancouver, BC, Canada) filters (Fig. 2).

GT and Celect Filters

The GT filter is made of conichrome: a blend of cobalt, nickel, chromium, and other metals. The GT was launched in 1992 in Europe for permanent implantation, and was approved by the FDA in 2000 as a permanent

Figure 2 FDA-approved retrievable filters.

filter. Cone shaped with an apical hook, it consists of four primary struts with 1-mm caudal hooks for IVC fixation. There are four secondary struts interposed between the main struts to increase clot trapping. When deployed, the filter base opens to a diameter of 30 mm, with a height of 45 mm. The GT is recommended for IVC diameters up to 30 mm. Jugular or femoral deployment is possible with an 8.5-French delivery sheath, and retrieval is from the jugular approach using an 11-French system. The GT was approved by the FDA for retrieval in the United States in 2003, and initial instructions for use indicated removal within 12 days. Presently, the retrieval time is not indicated, and several studies demonstrate highly successful retrievals of this filter beyond a year. The Celect filter is fabricated from similar material as the GT and has four anchoring struts and eight secondary struts to improve centering and clot entrapment. Similar to the GT, it can be placed from a femoral (8.5-French) or jugular (7.0-French) route, and it is retrieved by the jugular route using an 11-French sheath. The Celect filter appears to be more likely to be successfully retrieved after a long dwell time than with the GT.

Recovery, G2, and G2X Filters

The Recovery, G2, and G2X filters have all been designed to be removable. The Recovery filter was the first FDA-approved retrievable filter in the United States, but it is no longer available as instances of strut fracture and cephalad migration occurred. It has been replaced by a reengineered filter marketed as the G2 filter. It is indicated for an IVC that is less than 28 mm in diameter. Fabricated from nitinol, it has six radially oriented arms and legs and is 40 mm high. The six legs have elastically deformable hooks, allowing fixation and removal. The shorter, more cephalad-positioned arms help center the device. Deployment is from a femoral or jugular approach using a 10-French delivery sheath. The retrieval system for the G2 uses a special cone set, which is introduced via the jugular route with a 12-French sheath. The 20-mm cone has nine steel struts within a urethane membrane with a base diameter of 15 mm when opened. The G2X filter is a G2 filter modified with an apical hook enabling snare retrieval.

OptEase Filter

The OptEase filter is FDA approved for retrieval as well. It was first filter approved by the FDA for permanent implantation in 2002, as a modified version of the permanent Trapease filter (Cordis Corp.). It was approved for use as either a retrievable or permanent filter in 2004. The OptEase filter is constructed of nitinol in a conical shape with a double basket and is inserted with a

6-French sheath allowing femoral, jugular, and even brachial venous insertions. It has six unidirectional hooks oriented superiorly on the cephalad portion of the filter, allowing retrieval from the femoral approach via a 10-French system. There is a hook on the caudal end of the filter that allows a snare to grasp the filter during retrieval, which is recommended as early as 12 days. Several studies show it is possible to remove the OptEase filter longer than this interval of up to 69 days.⁷² The relatively long side-rail contact with the cava wall encourages intimal overgrowth limiting the retrieval times of this filter in comparison to the other devices. The same side-rail feature allows excellent centering of the filter.

ALN Filter

The ALN filter was launched in 1999 and received FDA approval in 2008. The ALN filter is designed with six short legs to ensure IVC wall fixation and three longer, centering legs to avoid filter tilt. The filter is manufactured from stainless steel and can be inserted from a jugular, brachial, or femoral approach using a 7-French system. There is also a cephalad hook to enable jugular retrieval using a 9-French retrieval system.

Option Filter

The most recent addition to the list of retrievable filters available is the Option filter. It was granted FDA approval on June 8, 2009, for both permanent and retrievable indication. The filter is made of nitinol with a cephalad hook similar to other filters on the market for retrieval. The clinical trial that facilitated FDA approval was presented at the 34th Annual Scientific Meeting of the Society of Interventional Radiology in March of 2009. The single-arm, multicenter clinical trial, which enrolled 100 patients and aimed for clinical success (defined as placement with technical success without subsequent PE, significant filter migration or embolization, symptomatic thrombosis, or other complications requiring filter removal or intervention) was achieved in 88% of subjects. Retrieval success was achieved in 92% (36/39) of cases when retrieval was attempted, with a mean implantation time in those cases of 67 days.

IVC FILTER COMPLICATIONS

IVC filters have had reported complications including caval thrombosis, filter migration, filter perforation, increased DVT rates, as well as insertion site complications such as access site thrombosis, groin hematomas, and arteriovenous fistulas (Table 3).^{70,71} Fortunately, the most common complications are minor in nature, but in rare instances, serious and even life-threatening complications may occur. The issues of IVC thrombosis and

suggested increase in recurrences of DVT reported by Decousus et al are serious and may lead to chronic venous stasis.^{50,51} These implications, plus the relatively early occurrences of PE after traumatic injury referred to earlier, suggest that retrievable filters offer the best risk-benefit ratio for traumatized patients with regards to VTE protection with IVC filters.

CONCLUSION

The use of IVC filters has progressively increased over the past 20 years, and indications for insertion that were once absolute have evolved to include a range of prophylactic indications. Although there are many studies that indicate good outcomes including low complication rates, longer length safe removal, and lower PE rates, there are other studies that show conflicting results. No large, multicenter prospective studies exist to provide definitive evidence-based data. The EAST guidelines suggest when prophylactic filters should be placed. Although the need for a large multicenter trial cannot be ignored, some comfort can be taken in the safety of the IVC filters currently in use and in development, as well as new findings that demonstrate a much longer optimal window for removal. This alleviates many of the fears of permanent placement of these filters in younger patients, such as the trauma population. In addition, limitations that have historically hindered removal of these filters, including poor rates of follow-up by the patients, can and should be addressed by the interventional radiology services involved. Solutions can include simple follow-up appointments made at the time of insertion and thorough education regarding the filter and its removal. Insertion and retrieval algorithms as decided upon by each institution can be a tool that facilitates the decision-making process, creating less variability in the use of PVCFs.

With increasing amounts of data regarding the various filters, the safety profiles of the currently available filters are becoming more lucid. Cooperation between the interventional radiology services and trauma surgery services would be beneficial in planning and enacting larger trials that could provide the much needed evidence-based data.

Although this article cannot serve as a replacement for the prospective trials, it does take into account several of the most widely cited literature across different specialties to evaluate the use of PVCFs. The need for prospective trials is not trivialized by these conclusions, but rather the additional available information regarding these filters can help sculpt good prospective trials to answer the remaining questions.

The trials need to be matched in patient age, population (separating trauma and other), hardware, technique, and control groups. The control group arm becomes the most problematic for the studies because

without prophylaxis, the morbidity and mortality can be so consequential. One possible solution that may limit the study but would provide a path to safely having control groups would be close ultrasound follow-up of all groups with obvious treatment of the patients found to have DVTs. Other suggestions that would be more difficult to deploy include using venograms to follow all patients, theoretically using the gold standard in diagnosis to avoid PEs all together within the study.

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