Vena Cava Filters: Current Concepts and Controversies for the Surgeon

History and Development of Modern Vena Cava Filters

The development of modern endovenous vena caval filter interruption to mitigate the mortality and morbidity from deep venous thrombosis (DVT) and its associated pulmonary embolism (pulmonary embolus [PE]) is a journey that parallels the evolution of vascular and endovenous surgery, supported by historic developments in radiology and pharmacology. In 1856, Rudolf Ludwig Karl Virchow (1821-1902) proposed the most common mechanisms of pulmonary thromboembolism: endothelium damage, hypercoagulability, and venous stasis.1-3 Furthermore, Virchow coined the term “embolism.” He noted that blood clots in the pulmonary artery (PA) originated first from venous thrombi: specifically in the lower extremity deep veins. Virchow wrote, “The detachment of larger or smaller fragments from the end of the softening thrombus which are carried along by the current of blood and driven into remote vessels. This gives rise to the very frequent process on which I have bestowed the name of Embolia.”1,2 Decades after his death, an eponym with a triad of etiologies would be ascribed to his name, Virchow’s triad.2,4 The recognition of the pathophysiology of PE resulted in the inception of methods to interrupt a lower extremity borne thrombus’ sojourn in the heart and/or lungs where it can inflict fatal consequences.

Lower Extremity Venous Interruption

Scottish surgeon John Hunter (1728-1793) originally introduced the concept of femoral ligation in 1784 for thrombophlebitis.5 After the introduction of general anesthesia techniques, an Italian surgeon Enrico Bottini (1837-1903), who supported Joseph Lister’s (1827-1912) antisepsis work, speculated in 1893 that femoral vein ligation or inferior vena cava (IVC) ligation could be used to treat PE.6 However, it was not until the 1930s that the performance of bilateral common femoral vein and
superficial femoral vein ligation to prevent PE was popularized by John Homans (1877-1954) and others.\textsuperscript{7} Unfortunately, a high incidence of lower limb edema and high operative mortality rate of approximately 15\% resulted with these techniques.

**Open Thoracic Pulmonary Artery Embolectomy**

Although German surgeon Friedrich Trendelenburg (1844-1924) unsuccessfully attempted a transthoracic PA embolectomy in 1908 to treat PE, it would be his student Martin Kirschner (1879-1942) who would perform the first successful open PA embolectomy in 1924.\textsuperscript{8,9} Introductions of heparin and warfarin in 1935 and 1948, respectively, became adjuncts to these procedures with minimal improvement in outcomes.\textsuperscript{10} Next, John Gibbons’ (1903-1973) introduction of the cardiopulmonary bypass pump oxygenator in 1953 allowed Edward Sharp to perform a pump oxygenator assisted PA embolectomy in 1962 to treat massive PE.\textsuperscript{11} Other surgical greats, such as Denton Cooley (1920 to present), would follow Sharp’s example and refine the technique of PA embolectomy assisted by cardiopulmonary bypass in response to massive PE.\textsuperscript{12} Still, the emphasis of this extreme treatment would have few survivors and merely act as a heroic salvage method.\textsuperscript{11,12}

**Open Inferior Vena Cava Interruption**

Eventually, a Hunterian type of IVC ligation was adopted for thrombi at or above the level of the inguinal crease and was advocated by Ochsner and others.\textsuperscript{13-15} IVC ligation remained a standard practice until the mid-1960s because of the presumed prevention of DVT embolization to the heart. As the body of data accumulated, the morbidity and mortality associated with IVC ligation were undeniable.\textsuperscript{14-16} Mortality rates after IVC ligation reached approximately 19\%.\textsuperscript{14-16} Unfortunately, lower extremity edema, venous stasis, and even exacerbation of cardiac failure resulted from the complete ligation of the IVC.\textsuperscript{14-18} Decrement in cardiac output due to reduction in venous return occurred after vena cava ligation.\textsuperscript{18} Other complications from complete IVC ligation included: failure to provide complete protection from recurrent PE due to new thrombus development above the level of suture ligation; embolism that bypasses the IVC entirely via the engorgement of the ovarian veins or ascending lumbar veins; phlegmasia cerulean dolens; dermatofibrosclerosis; venous claudication; varicosity; and others.\textsuperscript{14-18} In short, IVC ligation failed to protect the heart and lungs from recurrent emboli and resulted in significant morbidity and mortality. Consequently, it was abandoned.
Partial Open Inferior Vena Cava Interruption and Plication

In an effort to reduce the impact of cardiac compromise and lower extremity venous stasis from total IVC ligation, the concept of open surgical “partial” IVC suture plication or caval clip (eg, Miles Clip) application was attempted. Other caval clip procedures included the Moretz and Adams-DeWeese clips. Because of partial clip application or suture plication, IVC occlusion decreased by almost two thirds with resultant concomitant reduction in lower extremity edema; however, operative mortality and recurrent PE persisted. These partial open operative techniques were proposed between 1957 and 1967. Again, the partial IVC plication or caval clip application techniques were considered reactive treatments for PE. Prophylactic or reversible procedures were not yet part of the surgical vernacular.

Endovascular Cohn Inferior Vena Cava Filter

The limited success of open IVC partial plication and caval clip as well as the progress on the vascular access front in 1957 with the introduction of needle and wire vascular access by Swedish inventor Sven Ivar Seldinger (1921-1998) led to the inception of endovenous partial IVC interruption with an intraluminal filter. Pediatric surgeon Bertram Cohn (1926-2002) developed the first patented conical-shaped endovascular deployed IVC filter in 1964. He tested the IVC filter implantation in numerous dogs. Five of the 12 dogs maintained a patent IVC at 8 months. Although 3 dogs developed recanalization, 4 dogs had total IVC occlusion.

Mobin-Uddin Umbrella Inferior Vena Cava Filter

Dr Kazi Mobin-Uddin introduced a silastic-covered umbrella-type filter with the intent to trap thromboemboli in the IVC en route to the lungs in 1967. Disadvantages with this proposed “partial” occlusion endovenous approach often resulted in complete IVC thrombosis (85% incidence) due to a design issue that resulted in accumulated thromboemboli. In addition, the initial 23-mm-diameter filters migrated; therefore, Mobin-Uddin increased the filter diameter to 28 mm. Other complications associated with the Mobin-Uddin umbrella filter included wound hematoma, sepsis, recurrent pulmonary embolism (up to 12%), filter migration, acute and delayed IVC thrombosis (up to 66%), limb edema (2.5%-37%), venous insufficiency, retroperitoneal hemorrhage (0.5%-2%), and perforation of the IVC and adjacent structures.
Lazar Greenfield, a surgeon at an Oklahoma City Veterans Affairs Hospital, crystallized the problem of the evolving endovenous approach to PE: prevent massive PE due to DVT in a trauma patient who cannot tolerate therapeutic anticoagulation. After the death of a 23-year-old motorcycle accident patient with a PE from lower extremity fractures who underwent sternotomy, cardiopulmonary bypass, and PA thrombectomy, Greenfield recounted, “I thought it was a triumph because we got all the clots out.” On the contrary, the lungs were too severely damaged by the procedure, and the “patient bled to death.” Greenfield sought “a better way.”

Greenfield took the deadly dichotomy to Garman Kimmell who operated a company, Kimray, which manufactured valves and other machinery for oil and gas wells and pipes. Upon hearing about pulmonary embolism, Kimmell told Greenfield, “That sounds a lot like the problem we have in the oil field with sludge.” In oil pipelines, sludge and debris are trapped by a cone-shaped device that allowed oil to flow at the pipe’s periphery and concentrated sludge in the center. By contrast, a flat screen filter completely clogged the pipelines in which they were placed.

Kimmell and Greenfield applied the conical oil filter concept to the IVC filter concept and the first stainless steel IVC filter was tested in 1972. Greenfield added hooks to secure it in place and incorporated corrugations into the filter struts to prevent emboli from passing. The design showed promising results in animals and later in humans: recurrent PE (3%) and high caval patency (96%). Greenfield’s first major paper on the Kimray-Greenfield filter appeared in the journal Surgery in 1973. Over the years, the Greenfield filter would undergo continual upgrades; nonmagnetic titanium alloy was implemented in 1989 and subsequently smaller and improved sheath designs (24-14 Fr became available).

Modern and Currently Available Filters

With the increasing appreciation of the incidence and importance of venous thromboembolism (VTE) and the reported success and efficacy of the Greenfield filters, several products have been subsequently developed and released. These have incorporated a variety of newer materials, filter design changes, and improvements in the delivery systems. In addition to stainless steel and titanium, other filter materials now available include
nitinol, phynox, and conichrome. The filters and delivery systems have been modified to allow placement via smaller introducers, ranging from 7 to 14 Fr in diameter. This now allows placement via the traditional femoral vein route, or alternative sites such as the internal jugular or even brachial veins.

Arguably the most important recent advancement in vena cava filter (VCF) design has been the introduction of removable or temporary filters. The terminology of these filters has become somewhat confusing, but has been defined in 2006 by guidelines from the Society of Interventional Radiology. “Optional” filters are devices that may remain permanently or can be removed. The 2 subcategories of optional filters are “convertible” and “retrievable.” Convertible filters are permanent filters that can be structurally altered at some point after placement via a catheter-based procedure to no longer function as a filter for thrombus. However, all or some of the device remains within the vena cava. Retrievable filters are permanent filters that can be entirely removed at some point after placement via a percutaneous approach. Although retrievable devices have been attempted and used since 1967, only recently have they become approved and widely available. In 2003 and 2004 the US Food and Drug Administration (FDA) approved additional instructions for the percutaneous removal of several of the currently available permanent filters. There is now a variety of permanent and retrievable VCFs that are FDA approved for use in the USA (Table 1). An additional category of devices are the truly “temporary” filters, which must be removed shortly after placement and cannot be left in situ as a permanent filter. These devices are not currently FDA approved or available in the USA.

### Table 1. Currently available FDA-approved vena cava filters

<table>
<thead>
<tr>
<th>Permanent</th>
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<tr>
<td>Stainless steel Greenfield filter</td>
<td>(Boston Scientific/Meditech, Boston, MA)</td>
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<tr>
<td>Titanium Greenfield filter</td>
<td>(Boston Scientific/Meditech)</td>
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<tr>
<td>Bird’s nest</td>
<td>(Cook, Bloomington, IN)</td>
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<tr>
<td>Simon nitinol</td>
<td>(Bard, Covington, GA)</td>
</tr>
<tr>
<td>Vena Tech LGM and LP Filters</td>
<td>(B. Braun, Boulogne, France)</td>
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<tr>
<td>TrapEase</td>
<td>(Cordis, Europa NV, L.J. Roden, the Netherlands)</td>
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<tr>
<td>Bard nonrecovery</td>
<td>(Bard Peripheral Vascular, Tempe, AZ)</td>
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<td>Retrievable</td>
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<td>Gunther tulip</td>
<td>(Cook)</td>
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<td>Recovery</td>
<td>(Bard Peripheral Vascular)</td>
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<tr>
<td>G2 recovery</td>
<td>(Bard Peripheral Vascular)</td>
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<tr>
<td>OptEase</td>
<td>(Cordis Endovascular, Miami Lakes, FL)</td>
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Venous Thromboembolic Disease in the Surgical Patient

VTE is a term used to describe thromboses that may occur in any vein as well as the embolus that results when 1 of these thrombi break off and migrate to other areas in the systemic venous network, most notably the pulmonary circulation. When the veins involved are superficial, the resultant superficial phlebitis may be painful but is of minor consequence. When the affected veins are from the deep system, the phenomenon is termed DVT, which has more serious implications than its superficial counterpart. Because the lower extremities are the usual areas affected with thrombosis, the term DVT is often used in reference to lower extremity thromboses alone. However, it is important to recognize and consider all DVTs, including those of the upper extremities and those of the trunk as well as those of the lower extremities.

VTE is of particular significance and concern to the surgeon or surgical intensivist. Multiple factors place the surgical patient at high risk for the formation of DVT, with subsequent risk for PE or other complications. Some of the highest risk patient populations identified are trauma patients, cancer patients, the morbidly obese, and the critically ill. These patients often require major surgical intervention and are primarily managed by surgeons, who must be familiar and up to date on how to prevent, identify, and treat VTE. The universal general risk factors that these patients share include hypercoagulability, intimal injury, or stasis, all of which predispose to venous thrombosis or may cause preexisting thromboses to propagate. Because of their injuries or need for surgical interventions, they are often difficult to adequately prophylax or treat with anticoagulant medications.

An additional concern that is only recently becoming fully appreciated is the prolonged period of risk for DVT and PE that exists in the surgical patient. It has long been recognized that surgery is 1 of the most common inciting events for VTE, and protocols have been developed to ensure appropriate perioperative prophylaxis. These typically include universal application of mechanical compression devices intraoperatively and postoperatively for patients undergoing major surgery, and emphasis on early ambulation. In addition, chemical prophylaxis is usually administered postoperatively, and immediately before surgery in select patients. However, these measures are typically only continued for the duration of inpatient hospitalization and are not continued past discharge. New evidence is now accumulating that the risk for VTE persists for a significant period, and that our current methods of prophylaxis may need
to be extended beyond the inpatient stay. A recently published analysis of data from the Million Women Study found a 70-fold increased risk of VTE after an inpatient surgical procedure among this cohort of middle-aged women.39 This risk peaked at 4 weeks after operation, but remained significantly elevated for up to 12 weeks postoperatively (Fig 1). Similarly, the ENOXACAN II trial examined VTE among patients undergoing oncologic surgery and found a 14% incidence of VTE at 3 months after operation.40 This was reduced to 5.5% (60% risk reduction) among patients randomized to receive 3 weeks of postoperative chemical prophylaxis versus the standard 1 week regimen.

Pathogenesis of Deep Venous Thrombosis

Virchow’s triad of hypercoagulation, endothelial damage, and hemothasis has long been recognized as the etiologic factors for VTE. When 1 or all 3 of these factors are present, the result is the same, which is initiation of the coagulation cascade and clot formation. Multiple other contributing factors may be present in the surgical patient that can accelerate or multiply this process. These include the presence of procoagulant factors (cancer), major extremity or pelvic fractures (trauma), increased intraabdominal pressure and venous stasis (morbid obesity), and the presence of indwelling venous catheters (critically ill or injured).

Clot Formation. When the integrity of the endothelial lining of the blood vessels is disrupted, the first blood element on the scene is the platelet. The platelet is exposed to the collagen of the vessel wall, which
causes the usually smooth-surfaced platelet to become irregular and "sticky." The platelet adheres to the area of the injury and becomes activated. The activated platelet secretes several factors including von Willebrand factor, which recruits more platelets to the area of injury and stimulates them to adhere. Other factors released by the platelets initiate the coagulation cascade.

Coagulation occurs via 2 main pathways, the intrinsic and extrinsic pathway. The intrinsic pathway is primarily involved in situations where disruption of vessel integrity exposes blood vessel collagen to circulating blood. The extrinsic pathway is seen more often in conditions such as sepsis, infection, and trauma, where tissue factor and factor VII initiate coagulation without exposed collagen. Regardless of which pathway initiates coagulation, the final common event is the conversion of prothrombin to thrombin, which catalyzes the conversion of soluble fibrinogen to insoluble fibrin filaments. These filaments form a net that traps more blood cells and causes a clot to form, grow, and mature.

Like many other physiologic responses in the body, clotting has its own negative feedback controls. Almost as soon as clot formation begins, processes begin that turn off (or downregulate) clotting and dissolve the already formed clots. Under the direction of plasmin, the formed fibrin network is broken down into fibrin split products. The critically important elements of clotting and clot dissolution are proper regulation and correct timing. These 2 systems are often grouped together as the coagulofibrinolytic system, which is especially important for critically ill patients because its homeostasis may be disturbed by the systemic inflammatory response syndrome, multiple organ dysfunction syndrome, surgery, and trauma.41 The recent Protein-C Worldwide Evaluation in Severe Sepsis (PROWESS) study demonstrates that treatment with activated protein C reduces thrombosis, which may confer a survival advantage.42

**Hypercoagulation States.** The body forms a clot in response to an injury that causes loss of blood from the vascular system and is able to dissolve that clot when it has served its purpose. It should not form unnecessary clots such as those that result in DVT and should be able to dissolve unwanted clots when they do occur. It is usually overactivity of the procoagulant system or underactivity of the anticlotting or thrombolytic systems that result in a hypercoagulable state, also termed thrombophilia.

Examples of overactivity of procoagulants would be the presence of Factor V Leiden, or high levels of homocysteine, factors VIII, IX, XI, thrombin activatable fibrinolysis inhibitor, and fibrinogen.43 There are certain acquired conditions such as pregnancy, malignancy, trauma,
surgery, and ingestion of oral contraceptives that also result in overactivity of the coagulation cascade. Of note, many of these conditions are found in the surgical or critically ill patient. Examples of underactivity of the anticlotting system are deficiencies of protein C, protein S, plasminogen, Factor XII, or heparin cofactor II.44

**Endothelial Damage.** Endothelial damage is a key element of Virchow’s triad, yet is difficult to separate out as an independent risk factor in patients following surgery or trauma who may have other predisposing factors, such as immobility, that lead to clot formation. It is clear, however, from the discussion below of indwelling catheters that intimal damage done by penetration of the vein wall or its continuous irritation with an indwelling foreign body predisposes to clot formation. Of all the major operations performed, the ones that involve the major blood vessels of the pelvis and lower extremities, such as hip arthroplasty, cystectomy, major vascular procedures, and total knee arthroplasty, carry the highest risk of VTE that develops in this area.45,46 This suggests that injury to these vessels is an independent risk factor. Intravenous drug abuse, which is not associated with the major morbidity of surgery or trauma, has also been shown to be associated with DVT, indicating that intimal damage alone can lead to clot formation.47 The natural response of the endothelium to injury is to initiate clot formation to achieve hemostasis, through activation of clotting cascades and attraction of platelets to the site of injury. When this process occurs in the presence of the other cofactors listed above, at either the local or the systemic level, then pathologic clot formation such as DVT results.

**Venous Stasis.** Venous stasis is probably the most important VTE risk factor for patients who are critically ill or recovering from trauma or surgery. Because these patients are often bedridden, sedated, or paralyzed, they have sluggish blood flow and poor venous return. Blood flow may also be compromised by hypotension, low cardiac output, increased intraabdominal pressure, vasodilatation, and elevated intravenous pressure (eg, right heart failure),48,49 all of which are seen in the intensive care unit (ICU). Of note, any condition that contributes to patient immobility, such as ventilation, complex drains, paralytic drugs, sedatives, indwelling catheters, or traction, has been associated with a greater risk for VTE. An additional contributor to stasis and VTE may be the surgeons themselves. Many patients may be inappropriately placed at bed rest due to their primary pathology or injuries. An example of this is the traditional management of major solid organ injuries managed nonoperatively. This would often include a prolonged period of bed rest, which was thought to decrease the chance of recurrent bleeding. These protocols have no
proven benefit and serve only to increase the risk for DVT formation and subsequent PE. There has also been a widespread practice of placing patients with a newly diagnosed DVT at bed rest due to fear of dislodging the clot and causing embolization. There have now been several recent studies demonstrating that bed rest does not decrease the incidence of PE following DVT, and this practice likely only further increases the risk of further clot formation and other sequelae of immobility.

The diagnosis of VTE is difficult to make in surgical patients because their comorbidity or injury often leads to edema, respiratory compromise, decreased sensorium, pain, decreased perfusion, and other signs that are important clinical indicators of DVT or the resultant emboli. Examination or imaging of the extremities may also be limited due to bulky dressings, splints, casts, or external fixation devices. Estimates of VTE in trauma and ICU patients range from 5% to 35%, but these estimates may be low for the reasons pointed out above. It is clear however that one or more elements of Virchow’s triad are present in most surgical and critically ill patients, making diagnosis, prevention, and treatment of this disorder a top priority.

**Location of DVT Formation**

*Lower Extremity and Pelvic Veins*

The lower extremity has 2 systems of venous drainage, the deep and superficial systems. The superficial veins communicate with the deep system via venous perforators and directly at the saphenofemoral junction. Thrombosis of the deep veins of the lower extremity can propagate into the iliac system and further into the IVC. DVTs of the lower extremity can be classified by the location in the lower extremity with proximal (thigh) veins being considered more clinically important than distal (calf) veins in terms of potential for subsequent PE. Despite the increased prevalence and recognition of the incidence of alternative sites of DVT formation, the lower extremities continue to remain the most common location of DVT formation and source of PE.

An underrecognized and underappreciated location of DVT is in the pelvic venous system. Clot formation in the pelvic veins may be caused by local injury to the pelvic veins or conditions that increase local venous stasis. This includes pelvic fractures or penetrating pelvic vascular injuries, pregnancy, increased abdominal pressure, laparoscopic surgery, and pelvic surgery. The variable symptoms (if any) produced by these clots and their inaccessible location makes diagnosis of pelvic DVT particularly difficult. In addition to carrying the standard risk of PE or
systemic embolization, these also have the potential to bypass an appropriately placed VCF via collaterals through the lumbar or renal venous system.

**Inferior Vena Cava**

Thrombosis may occur anywhere in the IVC, such as with Behçet’s disease; however most IVC clotting occurs near the hepatic veins because of Budd-Chiari syndrome (BCS) or adjacent to the renal veins because of nephrotic syndrome (NS).

**Budd–Chiari Syndrome.** Although BCS may be loosely defined as any process that causes obstruction of hepatic blood outflow, it is more typically reserved for thrombosis of the hepatic veins and adjacent IVC. Although there are many inciting events that may lead to veno-occlusive disease of the hepatic veins, myeloproliferative disorders, malignancies, infections, oral contraceptives, and other hypercoagulable states are most often involved. Although mechanical obstruction may play a role in some of these conditions, hypercoagulability is the primary etiologic factor that leads to BCS.

**Nephrotic Syndrome.** NS is characterized by proteinuria greater than 3.5 g/m²/d. Hypoalbuminemia, edema, hyperlipidemia, and lipiduria may also be seen but are variable in expression. There is a high incidence of renal vein thrombosis with NS for reasons that are not clear. Patients with NS are hypercoagulable and have an increased incidence of generalized arterial and venous thromboemboli; however, the incidence of clotting is highest in the renal veins. This may be due to the decreased perfusion of the kidneys seen in NS and resultant low flow and hemoconcentration in the post glomerular circulation.

**Upper Extremity and Central Veins**

A DVT of the upper extremity or central veins may be due to an indwelling foreign body, such as an intravenous catheter, or may be spontaneous, in which case it is referred to as the Paget-Schroetter syndrome. Of these 2 entities, the former is of greater significance for surgical and ICU patients insofar as they often have catheters placed in their central veins for intravenous resuscitation, administration of medications, parenteral nutrition, hemodynamic monitoring, cardiac pacing, or hemodialysis. The 2 veins most commonly involved are the axillary and subclavian; therefore, the term axillosubclavian vein thrombosis is generic for this condition. The incidence of upper extremity venous thrombosis has been reported to occur in 0.06% of unselected hospitalized patients. This incidence is higher in selected populations such as those with...
malignancy or indwelling intravenous catheters. Similar to DVT in the lower extremities, emboli that break off the upper extremity thrombi may travel through a right-to-left shunt in the heart to embolize to the brain. When emboli originate from the vessel wall, they are termed mural thrombi. When emboli originate from an indwelling catheter, they are termed sleeve emboli. Sleeve emboli have a significantly greater risk of embolizing to the pulmonary or systemic circulation than mural thrombi. It is critical for the surgeon to realize that upper extremity vein thrombosis and embolization are a real risk, and that a standard filter placed in the IVC will offer no protection. The placement of filters in the superior vena cava (SVC) has been well described, but there is significantly less experience with this indication and technique.

**Catheter-Induced Subclavian Vein Thrombosis**

Because of its relative ease of performance, central access is usually obtained via percutaneous puncture of veins in the antecubital fossa, subclavian region, or base of the neck. This leads to direct damage to and the presence of a foreign body adjacent to the intima of the brachial, axillary, subclavian, or superior caval veins. When thromboses result, the consequences range from minor swelling of an extremity to life-threatening SVC syndrome.

The incidence of axillosubclavian vein thrombosis is highest in patients with indwelling intravenous catheters. The incidence in this subset of patients is related to the material used for the catheter as well as the position of the catheter. Polyethylene and polyvinyl chloride (PVC) catheters are more prone to PE than polyurethane or siliconized catheters, whereas the heparin-bonded catheters seem to be better than those without heparin bonding. Catheters placed so the tips are in the SVC or the right atrium have a lower incidence of thrombi than those placed in the innominate or subclavian veins.

**Superior Vena Cava Thrombosis**

SVC thrombosis and the resultant SVC syndrome may be caused by thrombi originating within the SVC or may be initiated by external compression of the SVC. It can be a complication of thoracic or mediastinal malignancies, but there are other benign causes of this syndrome as well. Malignancy remains the most common cause of SVC syndrome, and the malignant conditions most often associated with SVC syndrome are bronchogenic carcinoma and lymphoma. More recently the increased use of intravenous catheters has made intrinsic
causes of thrombi more common so that a careful diagnostic evaluation
must be done before definitive treatment can be initiated.

Although catheter-related thrombosis represents a relatively small
percentage of patients who develop SVC syndrome, it is more likely to be
seen in the ICU patients who have multiple indwelling catheters or lines
for pacemakers and cardiac defibrillators. Although the phenomenon of
catheter-related thrombus was described in the section on upper extremity
DVT, SVC thrombosis is more serious than upper extremity thrombosis
because of the hemodynamic consequences of an obstructed SVC. It is
important to accurately diagnose and treat catheter-related SVC syndrome
because it usually develops acutely and with life-threatening sequelae.
When SVC syndrome develops slowly, such as with many malignant or
infection conditions, collateral circulation, especially through the azygous
system, may develop to return blood to the right atrium. When the clot
forms acutely around indwelling catheters, collaterals do not have time to
develop and the hemodynamic consequences the obstruction are more
severe.

Diagnosis of Deep Venous Thrombosis

Physical Examination. Classic findings of lower extremity DVT
include the following: pain, swelling, and variable discoloration of the
involved extremity. In the ICU setting, symptoms may be difficult to elicit
from a sedated, paralyzed, or intubated patient. Therefore, a high index of
suspicion must be maintained and physical examination revealing unilat-
eral swelling, a palpable cord, or superficial venous dilation must be
followed by further testing. Diagnosis in trauma patients may be
particularly difficult in the setting of altered pain and sensation of the
extremities due to fractures, as well as limited ability to perform clinical
examination due to bulky casts or dressings. Clinical suspicion and
grouping patients into low, moderate, and high likelihood has been shown
to increase diagnostic accuracy.

Like the more typical lower extremity DVT, the clinical signs and
symptoms of upper extremity vein thrombus are pain and swelling.
However, occasionally thrombi, even when they totally occlude the vein,
may be asymptomatic. This is more likely to occur in a critically ill
patient who has multiple comorbidities and may not recognize that an arm
is swollen or painful. In these patients signs such as asymmetrical arm
edema or distended upper arm and chest wall veins may be seen. Less
commonly, venous thrombus of the upper extremity may manifest as
pulmonary emboli, which occurs in 20% of catheter-related thrombi.
**Ultrasound/Duplex.** Doppler ultrasound examination of the lower extremity is useful in that it is noninvasive and can be performed at the bedside, eliminating the need to transport critically ill patients. Venous interrogation is most accurate when compression ultrasonography (US) is used. The vein is identified and followed along its course until the thrombus is identified. The chronicity of the thrombus can be inferred from its appearance on US since older clots have a more echodense appearance. Finally, the vein is compressed and duplex scanning is used to determine if there is an appropriate flow response. The obvious limitation of compression US is in imaging veins that cannot be compressed such as those above the inguinal ligament. Serial studies should be performed if the initial study is negative because 2% of patients with an initially negative study will have a positive study when studied 7 days later. A carefully performed ultrasound examination has been found in 1 series to have a 100% sensitivity and 99% specificity. A complete and adequate duplex examination may not be possible in many surgical or trauma patients due to altered anatomy, bulky dressings or casts, the presence of external fixation devices, or factors limiting the acoustic window such as morbid obesity, edema, or subcutaneous emphysema.

**Impedence Plethysmography.** Impedance plethysmography is another noninvasive test that is useful to define venous obstruction. A pneumatic cuff is placed around a patient’s thigh and 2 electrodes are placed on the calf. The cuff is inflated and then rapidly deflated while the resistance between the electrodes is measured. The outflow fraction, which is related to the degree of obstruction, may be calculated. The sensitivity and specificity of this technique are 91% and 96%, respectively, in some series; however, there are limitations to this study in the ICU setting. It has been demonstrated that there are significant variabilities of measurements, even in the same patient. In addition, patients must be correctly positioned and immobile for 2 minutes, which may not be possible in an ICU patient. Finally, as the experience with and success of ultrasound increases and the use of plethysmography decreases, there are fewer people familiar with performing this technique.

**Venography.** Contrast venography is still the “gold standard” for the diagnosis of DVT. Adequate imaging requires visualization of the deep venous structures from the calf veins to the IVC. The most reliable finding indicating a DVT is an intraluminal filling defect seen on 2 or more views of the same area. In 1 study, only 1.3% of patients developed a DVT following an initially negative venogram over a 6-month follow-up period. However, due to the invasive nature of the study and the need...
to transport ICU patients to an interventional suite, venography is not the first choice of studies for critically ill patients. If the ultrasound is read as inconclusive (such as the suspicious for but not diagnostic of iliac or pelvic vein thrombosis) or is unavailable, then contrast venography can be used. It is also not recommended for patients with renal insufficiency unless other studies are inconclusive and the risk of empiric anticoagulation is great.

The gold standard for diagnosing upper extremity thrombi, as for lower extremity thrombi, is venography. Although a properly performed venogram has close to 100% sensitivity and 100% specificity, it is performed only infrequently because the safer and less expensive noninvasive techniques are usually sufficient. Venography is an invasive procedure that carries risks such as renal toxicity and allergic reactions. It may also be difficult to access small veins in the hand or distal extremity to inject contrast material. Digital subtraction venography allows studies to be performed with less contrast material and is associated with fewer side effects than plain venography. The upper extremity is particularly suited to this modality because of the inaccessibility of the axillary, subclavian, and innominate veins to physical examination and other noninvasive tests.

Prophylaxis and Treatment of Venous Thromboembolism in the Surgical Patient

Pneumatic Compression Devices. Intermittent pneumatic leg compression has both local and systemic effects. Locally it acts by simulating the calf muscle pump and, thereby, preventing venous stasis. Systemically it acts by inhibiting plasminogen activator inhibitor-1 and increasing the body’s fibrinolytic activity. Therefore, compression devices placed on an arm may be expected to have some value in preventing clot formation in the lower extremities. Although there is little risk in using pneumatic leg compression devices, they should be used with caution in patients with severe peripheral occlusive vascular disease. In addition, some clinicians believe they should not be started on patients who have been at bed rest for longer than 72 hours due to the possibility of dislodging a previously formed clot. The literature has clearly demonstrated benefits of intermittent pneumatic leg compression in moderate risk patients undergoing general surgical, cardiac, and neurosurgical procedures. Compression should be initiated preoperatively and be used throughout the postoperative period until the patient is ambulatory.

Early Mobilization. Of the triad of risk factors Virchow identified as causative for VTE, the 1 that is most easily addressed is venous stasis. It
is also the risk factor that is most often seen in critically ill, traumatized, anesthetized, or postoperative patients. Although elastic compression and pneumatic compression devices restore some of the lost blood flow, mobilization and, specifically, ambulation provide complete restoration of flow and the greatest protection against VTE. Although there are numerous studies demonstrating the protective effects of prophylactic anticoagulation and mechanical compression, there is very little documentation of the benefits of early ambulation. This effect of ambulation must be inferred from studies that show that lack of ambulation in patients with no other comorbid conditions, such as those who have prolonged periods of sitting, traveling, or lying in a bed, results in stasis and VTE. This information is the basis for many surgical protocols that call for early ambulation. Despite many protocols calling for early operative intervention and early restoration of ambulation in bedridden patients, there has been no convincing evidence that this approach decreases VTE. The recent interest in minimally invasive surgical procedures is partially inspired by the benefits of reduced postoperative morbidity, leading to early ambulation.

**Heparin Compounds.** A full discussion of the use of heparin compounds for the prophylaxis and treatment of VTE is beyond the scope of this article. Multiple prospective randomized trials and meta-analyses have established the efficacy of both unfractionated heparin (UFH) and the newer low molecular weight heparin compounds (low molecular weight heparins [LMWH]) at preventing DVT and PE in surgical patients. However, there is also a large body of data on the limited efficacy of these compounds to prevent VTE in several very high risk surgical populations, such as the ICU population or severely injured trauma patients. This has been the primary factor driving the increasing use of VCFs for primary VTE prophylaxis in these high risk populations. At increased doses, both UFH and now LMWH remain the primary initial therapeutic modality for the patient with established VTE. However, concerns about bleeding, efficacy, or complications are typical factors that may lead to a decision to discontinue or forego anticoagulation in the surgical patient in favor of VCF placement.

UFH is an indirect thrombin inhibitor and combines with antithrombin (AT) to accelerate the inactivation of thrombin and factor Xa. This inactivation involves the formation of a ternary complex in which heparin binds to AT and to thrombin. This requires an adequate saccharide length, which is common in the unfractionated molecule but less common in LMWHs, which have less AT activity. Complications of UFH include bleeding, heparin-induced thrombocytopenia (HIT), and, with chronic
Bleeding can occur without a supratherapeutic partial thromboplastin time (PTT), especially in patients who have undergone surgery or trauma. If a patient is bleeding while receiving UFH, protamine sulfate can reverse the anticoagulant effects with 1 mg protamine sulfate for every 100 U of heparin administered. The usual prophylactic regimen for UFH is 5000 U administered subcutaneously either twice or 3 times daily. Therapeutic dosing requires intravenous dosing and continuous infusion based on the patient’s weight, and adjusted to obtain a PTT of at least 2 times normal.

Other forms of heparin in use are the LMWH. These smaller molecules are made by treating UFH with a variety of depolymeration reactions. The ones that are approved for use by the FDA include enoxaparin, daltiparin, and tinzaparin. They are all factor Xa inhibitors like UFH but inhibit thrombin to a lesser extent and, as a result, do not prolong the PTT. LMWHs are given subcutaneously and their anti-Xa activities correlate well with body weight, allowing a fixed dosing regimen to be used. Laboratory monitoring is not necessary unless the patient is pregnant or has renal insufficiency and LMWHs do not cause as much immune thrombocytopenia as the unfractionated molecule. Prophylactic dosing typically involves a fixed, non-weight-based dose administered once or twice daily. Normal dosing for full anticoagulation is 1 mg/kg twice per day or 1.5 mg/kg once a day. Complications and concerns with LMWH include bleeding, hematoma at the administration site, HIT, decreased clearance in renal failure, and the difficulty of full reversal of the anticoagulation effect.

Nonheparin Compounds. Nonheparin agents may be used for anticoagulation and are particularly helpful when HIT develops. Two large classifications of agents are the heparinoids and the direct thrombin inhibitors. Danaproid is a low molecular weight heparinoid, which is a more selective factor Xa inhibitor than the LMWHs. Its activity can be measured by an anti-Xa assay. Because of concerns with its expense and nonreversibility, however, this agent may soon be removed from the market. Currently, the most useful alternatives to heparin in the face of HIT are the direct thrombin inhibitors. This classification of agents includes hirudin, an anticoagulant extracted from the saliva of the medicinal leech; lepirudin, a recombinant form of hirudin; argatroban; and bivalirudin. Unlike the other anticoagulants, these drugs are difficult to monitor with laboratory tests. Similar to the heparinoids, there are no reversal agents for thrombin inhibitors. A newer and promising agent that is now available in the USA is fondaparinux sodium. This agent selectively binds to AT III to potentiate inhibition of Factor Xa and has
no known antiplatelet effects. It is administered subcutaneously with 100% absolute bioavailability. Like LMWH, it is cleared renally so it must be adjusted or not used in renal failure patients. It has demonstrated equivalent efficacy to LMWH as a prophylactic agent in major surgery and trauma patients and appears to be a viable alternative anticoagulant for patients who develop HIT.

**Vena Cava Filtration Devices.** As previously discussed, manipulation of the vena cava to prevent pulmonary and systemic embolization of peripheral vein thromboses has long been used with varying levels of success and associated complications. The current indications and guidelines for VCF all revolve around the concept of inadequacy of the above listed measures for adequately providing prophylaxis or treatment for VTE. This is particularly true for the higher risk populations, most whom are of direct interest to the surgeon or traumatologist. Although research into new filter materials and techniques are important for improving the safety and outcomes with these devices, the greatest impact on both VTE and on the use of VCFs will likely come from better understanding VTE and improving our ability to prevent and treat this disease. The remainder of this monograph focuses on the current status and literature regarding the modern applications of both permanent and retrievable VCFs.

**Anatomical Considerations for Filter Placement**

Most venous thrombosis and VTE originate in the deep veins of the extremities. This was traditionally thought to be a problem in the lower extremities, but several recent series have documented a not-insignificant incidence of upper extremity clot formation, particularly in hospitalized patients. This is likely due to the presence of traditional prothrombotic factors in conjunction with the increased use of upper peripheral and central venous catheterization. The lower extremities are more prone to venous stasis, particularly in persons who have chronic or temporary mobility limitations. In addition to gravity, any factor that increases the pressure gradient working against venous return, such as increased intraabdominal pressure, will worsen venous stasis and pooling in the legs. Extremity trauma, another important etiologic factor in venous thrombosis, also tends to affect the lower extremities more than the upper extremities.

It is important to understand the venous anatomy to recognize the difference between the significance of clot formation in the superficial veins versus the deep venous system. The lower extremity has 2 connected venous systems, the superficial and the deep system. The superficial system comprises the lesser and greater saphenous veins and
the deep system comprises paired common femoral veins, superficial femoral veins, profunda femoral veins, popliteal veins, and tibial veins. The superficial veins communicate with the deep system via venous perforators and directly at the saphenofemoral junction. Superficial venous thrombosis (or thrombophlebitis) typically requires only topical treatment and does not carry the significant risk of embolization that is seen with DVT. This distinction is often made difficult by the use of confusing nomenclature and terminology. For example, despite its name, the superficial femoral vein is actually a component of the deep venous system and thrombosis of this vessel carries a risk of life-threatening VTE sequelae. When an extremity venous thrombosis is identified, it is critical to classify accurately the vessel as being in the superficial or deep systems, and the location of the clot as proximal or distal. The clinical significance and risk of thromboembolic complications appears to be significantly lower for DVT of the calf veins compared with popliteal or above knee thrombosis. This has led to controversy regarding the role of diagnosis and treatment of distal DVT, with some recommending against any treatment for distal DVT or even including the distal extremity in routine ultrasound DVT screening examinations. The clinical significance of distal venous thrombosis has important clinical and financial implications, since approximately 50% of all DVTs are identified in the calf. The risk of systemic or pulmonary embolization appears to increase with more proximal clot formation. Thrombosis of the iliac veins does have the greatest risk of massive PE. Anatomically, a DVT occurs most commonly in the left common iliac vein. This is explained by the right common iliac artery compressing the left common iliac vein as it crosses over it. Repetitive pulsations may cause a “web” or “spur” to form and make this vein more prone to thrombosis. This well-described condition has been termed May–Thurner syndrome. The superior and inferior vena caval systems represent the final common pathway for the return of blood from the head, trunk, and extremities to the heart. They also represent the pathway for embolization of peripheral clot to either the pulmonary or the systemic circulation, with the possibility of death or severe morbidity. The IVC arises from the junction of the left and right common iliac veins at the L5 level and is the largest vein in the body. It courses superiorly on the right side of the aorta and receives multiple lumbar branches. At the L1 to L2 level, the right and left renal vein join the IVC and this junction divides the vein into the infrarenal and suprarenal portions. The IVC then courses superiorly as it receives the portal inflow via the hepatic veins and enters the right atrium immediately above the diaphragm. Although VCFs can be placed

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in the SVC in select situations, the IVC is the standard location for filter placement and will be the primary focus of this section.

There are several anatomic anomalies and abnormalities that have been reported with the IVC that can significantly impact the utility and feasibility of VCF placement. Three of these are of particular importance for the successful placement of a VCF and prevention of VTE (Fig 2). These anomalies may occur in 5% to 15% of the population and have prompted the recommendation for either routine preprocedure imaging of the vena cava or a high quality contrast cavagram at the time of filter placement. Hicks and colleagues performed a prospective study in 108 patients referred for VCF placement and found variant anatomic structures in 37% of patients using selective renal venography in addition to cavography. These anatomic variants caused significant alterations in the placement or selection of the VCF in 18% of the population. In another series of 1014 patients, Trigaux and colleagues performed spiral computed tomographic (CT) examination of the vena cava and identified anatomic variants in 114 (10%). This included 3 bilateral or duplicated IVC (0.3%) and 102 (10%) left renal vein variants that could significantly impact the placement of a VCF. These series highlight the need for careful attention to the IVC anatomy and an understanding of the common variants to maximize the chance of successful VCF placement and to minimize complications.

Duplication of the IVC can occur with failure of the embryologic left-sided IVC to regress, resulting in a dual left and right IVC providing venous drainage from the lower extremities and pelvis (left

![FIG 2. Three most common inferior vena cava (IVC) anomalies that can impact the placement of a vena cava filter. Transposition of the IVC (left panel) to the left of the aorta (Ao), duplication of the IVC (center panel) with 2 separate vessels on either side of the aorta below the renal veins, and circumaortic left renal vein (right panel) with accessory left renal vein connecting the IVC to the main left renal vein. (Adapted with permission from Royal and Callen.)]
The left IVC is often significantly smaller than the right and can be mistaken for a large collateral or tributary. This duplicated vein usually arises from the left common iliac vein, courses superiority on the left side of the aorta, and drains into the left renal vein. The importance of this anatomic variant is that the left-sided IVC can provide an unobstructed route for VTE from the lower extremities or pelvis if a VCF is placed only in the right IVC. There are now multiple case reports of successful placement of dual right and left IVC filters in this patient population.123-125

Transposition of the IVC, or “left-sided” IVC, is a less common anomaly that results in the vena cava forming to the left of the aorta (middle panel, Fig 2).117 The vessel typically courses superiority on the left side where it joins the left renal vein. At this point it crosses to the right side either anterior or posterior to the aorta and then continues to ascend in the typical right-sided location in the suprarenal position.126 Placement of a VCF in patients with this anomaly is possible but may require an alteration in the planned access site to the internal jugular or left femoral veins.118

The third and most common anomaly that must be appreciated when considering VCF placement is the circumaortic left renal vein (right panel, Fig 2). This anomaly may be seen in up to 9% of the population126 and was the most frequently identified anomaly impacting filter placement in 1 series.121 This malformation results in a vascular ring around the aorta formed by the main left renal vein and an anomalous accessory left renal vein. There is an average length of vena cava of 4 cm between these 2 left renal vein branches, and a filter placed in the typical position just inferior to the main left renal vein can be bypassed by emboli via the anomalous vascular ring.122 In these cases it is important to identify the abnormality and place the filter either inferior to the anomalous left renal vein or in a suprarenal position.121,126

Other anatomic factors besides developmental anomalies must be considered and identified before or during filter placement. The presence of a significant narrowing of the vena cava or of the access vessel may limit the ability to successfully traverse it with the device. This could be due to an intrinsic stricture or clot, or to extrinsic compression and may require balloon dilation or even stent placement to facilitate successful deployment of the VCF.127 The location of the renal veins must be appreciated and used as landmarks for device placement as described later in the section on filter placement techniques. Finally, the presence of significant iliac or vena cava clot burden or thrombosis should be identified to avoid inadvertent manipulation with dislodgment and embo-
lization. These findings should prompt termination of the procedure or placement via an alternative access point (such as internal jugular vein) that will not traverse the area of concern.

In rare situations there may be an indication for placement of a VCF in the SVC. The SVC is the great vein that drains all structures above the diaphragm except the heart and lungs. It forms from the junction of the right and left brachiocephalic veins at the level of the first costal cartilage and courses inferiorly to enter the right atrium at the level of the third costal cartilage.\textsuperscript{116} There are multiple anomalies that have been reported involving the SVC and thoracic vessels, and these are often associated with complex cardiac or great vessel defects.\textsuperscript{128-131} These anomalies can create confusion and difficulty for procedures such as central venous catheter placement, placement of transvenous pacemaker wires, or placement of an SVC filter.\textsuperscript{129,132-134}

The most common of these anomalies is a persistent left-sided SVC, which represents a failure of degeneration of the left cardinal vein (Fig 3). This has been documented in 0.5\% of the population and 0.47\% of patients undergoing pacemaker or defibrillator placement.\textsuperscript{134} The usual result is a double SVC (persistent left and right), but in 1\% of cases there is a persistent left SVC with an absent right SVC, as demonstrated in Fig 3. In addition to congenital anomalies that may complicate filter placement, acquired pathology of the SVC or subclavian veins may also be encountered. This is particularly true in the population undergoing placement of a VCF, who often are older and have had previous placement of jugular or subclavian venous catheters.\textsuperscript{135-138} In 1 series, more than 80\% of upper limb deep venous thromboses were found to be due to catheter placement or malignancy.\textsuperscript{139} Stenosis or thrombosis of the jugular veins, subclavian vessels, or SVC may be present and may require alteration in the filter choice, access route, or even abandonment of the procedure. As with the placement of an IVC filter, preprocedure imaging and/or a high quality cavogram should be obtained before filter placement.

**Indications and Considerations for Vena Cava Filter Placement**

The indications and patient selection criteria for vena caval filter placement remain the most controversial and widely debated topic surrounding this technology.\textsuperscript{52,140-145} Despite several decades of widespread use of these devices, there remains a glaring paucity of prospective controlled trials regarding the indications, safety, and efficacy of VCFs.
Without solid data to support a strong evidence-based approach to filter use, the decision to place a VCF is often driven more by individual practice patterns and preferences than actual patient disease and clinical factors. This lack of evidence-based data has resulted in the promulgation of a variety of guidelines based on individual interpretation of uncontrolled prospective and retrospective series, literature reviews, consensus panel guidelines, and expert opinion. In addition, the decision regarding filter placement may be further clouded by the increasing number and type of devices available and the various marketing claims and strategies of their manufacturers. The relatively recent development and widespread use of temporary or retrievable VCF has added an additional layer of data and considerations to this already confusing picture, which is discussed in more detail later in this article.
The lack of reliable and high quality data for VCF use is even more evident when compared with the large volume of prospective controlled trials that are available for other aspects of management of the patient with VTE. Girard and colleagues\(^8\) performed a systematic search of the medical literature regarding VCFs and identified 568 pertinent references between 1976 and 2001. Of these, 33% were retrospective series, 32% were case reports, 13% were animal or in vitro studies, 15% were reviews or miscellaneous, and only 7% were prospective series or trials. Only 2.8% were prospective trials with more than 100 patients and there was only 1 (0.02%) prospective randomized trial identified. A similar search of articles related to heparin anticoagulation and VTE yielded 531 articles, with 47% of these being randomized controlled trials. To our knowledge, this pattern has not been significantly altered in the nearly 10 years since the publication of this study.

Current indications for VCF placement can be divided into 2 broad categories based on the clinical situation: (1) therapeutic and (2) prophylactic. Table 2 lists the currently accepted and relative or controversial indications for VCF placement. It is important to classify which of these indications is present when examining the data and rationale for intervention. There will also be a significant alteration of the risk to benefit analysis depending on which of these 2 categories the patient is in, and this should always be factored into the final decision for performing an invasive procedure. Although the therapeutic indication has achieved a higher level of evidentiary support and expert consensus, the most rapidly expanding indication for VCF placement in surgical patients is for prophylaxis.\(^1\) This is the primary area of current debate and controversy in the literature regarding VCF use.

Therapeutic indications include medical or surgical patients with proven venous thromboembolic disease who are now at risk for PE or have had a documented PE. These have become the most widely accepted and used indications for VCF placement in the USA and worldwide. The goal of VCF placement in this cohort is prevention of an initial clot embolization (known as DVT) or additional clot embolizations (known as PE). Patients with a therapeutic indication should be further divided into those who can be safely anticoagulated or those with a contraindication to or failure of anticoagulation. In the first group, it is widely accepted that serious and fatal pulmonary embolism can still occur in patients with a known DVT who are receiving adequate anticoagulation.\(^8\) In these cases the argument for VCF placement is to maximize the VTE therapy and rests on the unproven assumption that there is an additional benefit from adding
the VCF compared with anticoagulation alone. In the second group, there is a more clear indication for VCF placement when the patient cannot be safely anticoagulated or is experiencing recurrent pulmonary emboli despite adequate anticoagulation. In this situation, there is often no reliable alternative and a VCF may represent the only option for prevention of an initial or recurrent pulmonary embolism. Additional information that must be factored into this decision includes the size and location of the DVT, the age and overall prognosis of the patient, the expected duration of prothrombotic sequelae, and the amount of pulmonary reserve or estimated tolerance to future pulmonary events.

<table>
<thead>
<tr>
<th>Accepted indications</th>
<th>Relative and controversial indications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Known VTE with contraindication to anticoagulation</td>
<td>Known VTE without contraindication to anticoagulation</td>
</tr>
<tr>
<td>Known VTE with severe complication of anticoagulation</td>
<td>High risk trauma</td>
</tr>
<tr>
<td>Recurrent PE while on therapeutic anticoagulation</td>
<td>Severe head injury</td>
</tr>
<tr>
<td>Progression of DVT while on therapeutic anticoagulation</td>
<td>Spinal cord injury</td>
</tr>
<tr>
<td>Recent VTE and operative procedure requiring prolonged withholding of anticoagulation</td>
<td>Vertebral fracture pelvic and long bone fractures</td>
</tr>
<tr>
<td></td>
<td>Prolonged immobility complex venous injury</td>
</tr>
<tr>
<td></td>
<td>extremism</td>
</tr>
<tr>
<td></td>
<td>Venous repair contraindication to LMWH</td>
</tr>
<tr>
<td></td>
<td>&gt;72 h</td>
</tr>
<tr>
<td></td>
<td>High risk bariatric surgical patient</td>
</tr>
<tr>
<td></td>
<td>BMI &gt;50 (superobese)</td>
</tr>
<tr>
<td></td>
<td>Elderly venous stasis disease obesity</td>
</tr>
<tr>
<td></td>
<td>Hypoventilation/sleep apnea pulmonary hypertension</td>
</tr>
<tr>
<td></td>
<td>Prior VTE episode</td>
</tr>
<tr>
<td></td>
<td>High risk ICU patient</td>
</tr>
<tr>
<td></td>
<td>Malignancy</td>
</tr>
<tr>
<td></td>
<td>Free-floating iliofemoral thrombus</td>
</tr>
<tr>
<td></td>
<td>Thrombolysis of DVT</td>
</tr>
<tr>
<td></td>
<td>Known VTE with poor cardiopulmonary reserve</td>
</tr>
<tr>
<td></td>
<td>Chronic thromboembolic pulmonary hypertension</td>
</tr>
<tr>
<td></td>
<td>Hypercoagulable state</td>
</tr>
<tr>
<td></td>
<td>High risk with heparin-induced thrombocytopenia</td>
</tr>
<tr>
<td></td>
<td>History of VTE and undergoing major surgery</td>
</tr>
<tr>
<td></td>
<td>Septic thromboembolism</td>
</tr>
</tbody>
</table>

VTE, venous thromboembolism; PE, pulmonary embolus; DVT, deep venous thrombosis; LMWH, low molecular weight heparin; BMI, body mass index.
Prophylactic indications involve VCF placement in patients with no documented DVT or PE, but who are assumed to be at increased risk for the development and resultant morbidity of venous thromboembolic disease. This scenario is almost universally encountered and reported with surgical and trauma patients, and rarely described or analyzed in medical patients. The creation of these indications has revolved around identifying a set of criteria that reliably predict which patients are at “high risk” of developing a DVT and PE despite standard preventive measures. Multiple schemes of risk assessment and patient identification for prophylactic VCF placement have been created and championed, with considerable ongoing debate about their accuracy and reliability. The utility (if any) of VCF placement in this population will thus be highly dependent on the sensitivity and specificity of the criteria used as indications. A major limitation of much of the literature that attempts to identify these risk factors is that there are often incomplete or absent data regarding the independent contribution of each factor or the exact sensitivity and specificity of each risk factor. Thus, although many of these proposed risk factors may be statistically significant, they have little clinical value as decision points for VCF placement. Other factors that must be taken into consideration when developing indications for prophylactic VCF placement are the exact patient population, the presence of any contraindications to standard preventive measures (anticoagulation, compressive devices), the degree and expected duration of disease and immobility, and the ability of the patient to tolerate any adverse pulmonary events (“pulmonary reserve function”).

Despite the lack of rigorously proven safety and efficacy of VCFs in most patient populations, they are being increasingly used in the USA and worldwide for an expanding number of indications. Stein and colleagues performed a review of trends in VCF use over a 21-year period from 1979 to 1999 using a large nationwide database. They found a greater than 20-fold increase in the numbers of filters placed over the period. Of these, 19% were placed for “prophylactic” indications in patients with no documented diagnosis of PE or DVT. Interestingly, there was also a regional difference in the use of VCF, with increased use found in the northeastern states and lower use in western states. There appears to be a similar and continued trend of increased use of VCF over the past decade, particularly with the advent of retrievable filters. Figure 4 demonstrates the rapid increase in the use of VCFs in a single center series of 385 trauma patients from 1990 to 1996. Note that the vast majority of the increase seen in this patient population was due to the placement of VCF for “prophylactic” rather than “therapeutic” indications.
Prospective Randomized Trials

A summary and detailed analysis of prospective randomized data regarding VCFs is made simple by the fact that there is only 1 such trial that has been completed and published. This was a multicenter randomized trial performed by the PREPIC group (Prevention du Risque d’Embolie Pulmonaire Par Interruption Cave Study Group) at 44 centers in France and published in 1998. It included patients with a documented proximal DVT, with or without associated PE. Of note, patients with a contraindication to anticoagulation were excluded from this study, since all patients received therapeutic anticoagulation with or without a VCF. Among the 400 patients entered, 200 were randomized to receive a permanent VCF. Figure 5 shows the principal endpoints at 2-year follow-up. Although there was a statistically significant decrease in early PE (within 12 days) with VCF placement (from 4.8% without VCF to 1.1% with VCF), this table shows that there were no identifiable benefits in PE or mortality reduction demonstrated in the VCF group. In addition, there was almost a 2-fold increase in the development of recurrent DVT in the filter group, most of which occurred at the filter site.

In 2005, the PREPIC group reported the results of 8-year follow-up data in this patient population. The authors were able to obtain outcome data on 396 (99%) of the original 400 patients enrolled in the trial. They demonstrated a statistically significant reduction in significant PE from 15.1% in the no-filter group to 6.2% in the VCF group ($P = 0.008$). Despite this reduction, there was no difference in the incidence of fatal PE or overall survival between the groups. Similar to the original trial, they demonstrated a persistent increased incidence of recurrent DVT in the filter group (37.5%) compared with the no-filter group (27.5%).

FIG 4. Number of prophylactic and therapeutic filters inserted at a single institution from 1990 to 1996. (Adapted with permission from Greenfield et al.)
The conclusion of the authors and the general consensus based on this trial was that the data did not support routine VCF use in this patient population.\textsuperscript{152,153} Although this was an extremely well-done trial that provided important information about VCFs, the data have limited applicability to much of the current debate regarding this technology. This trial examined VCF placed for a therapeutic indication and did not address the issue of prophylactic use. It specifically excluded patients who had a contraindication to anticoagulation, which is 1 of the most frequently cited indications for considering a VCF in the surgical patient population. In addition, this was primarily a medical patient population, with only a small fraction of the study group (8\%) having undergone recent surgery.

\textbf{FIG 5.} Principal end points during the 2-year follow-up period in patients randomized to vena cava filter versus no filter. (Adapted with permission from Decousus et al.\textsuperscript{152})

<table>
<thead>
<tr>
<th>Event and Time of Occurrence</th>
<th>Filter</th>
<th>No Filter</th>
<th>Odds Ratio (95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptomatic pulmonary embolism†</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Enrollment–3 mo</td>
<td>2</td>
<td>6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;3 mo–1 yr</td>
<td>0</td>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;1–2 yr</td>
<td>4</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>All</td>
<td>6 (3.4)</td>
<td>12 (6.3)</td>
<td>0.50 (0.19–1.33)</td>
<td>0.16</td>
</tr>
<tr>
<td>Recurrent deep-vein thrombosis</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Enrollment–3 mo</td>
<td>9</td>
<td>6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;3 mo–1 yr</td>
<td>8</td>
<td>7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;1–2 yr</td>
<td>20</td>
<td>8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>All</td>
<td>37 (20.8)</td>
<td>21 (11.6)</td>
<td>1.87 (1.10–3.20)</td>
<td>0.02</td>
</tr>
<tr>
<td>Major bleeding</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Enrollment–3 mo</td>
<td>11</td>
<td>10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;3 mo–1 yr</td>
<td>5</td>
<td>8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;1–2 yr</td>
<td>1</td>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>All</td>
<td>17 (8.8)</td>
<td>22 (11.8)</td>
<td>0.77 (0.41–1.45)</td>
<td>0.41</td>
</tr>
<tr>
<td>Death</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Enrollment–3 mo</td>
<td>15</td>
<td>10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;3 mo–1 yr</td>
<td>12</td>
<td>12</td>
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<tr>
<td>&gt;1–2 yr</td>
<td>16</td>
<td>18</td>
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<tr>
<td>All</td>
<td>43 (21.6)</td>
<td>40 (20.1)</td>
<td>1.10 (0.72–1.70)</td>
<td>0.65</td>
</tr>
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</table>

*Estimates of incidence were derived from Kaplan–Meier survival analysis. CI denotes confidence interval.
†The category includes certain or highly probable fatal pulmonary embolism.
In addition to the primary findings regarding the effectiveness of VCF placement in this patient population, the PREPIC trial raised several concerns regarding the impact of permanent filter placement. The initial trial and subsequent follow-up report both identified an increase in the incidence of recurrent DVT in the filter group, with an odds ratio of 1.8 and 1.5, respectively.\textsuperscript{152,153} In addition to carrying a risk of life-threatening PE, recurrent venous thrombosis can result in the development of significant postthrombotic sequelae or “syndrome” characterized by swelling, pain, skin changes, ulceration, and even limb loss.\textsuperscript{112,154} This certainly should be factored into any decision or algorithm regarding VCF placement. This also raises the issue of whether anticoagulation should be initiated or continued indefinitely (if possible) based solely on the presence of the VCF, which is discussed later in this article. Finally, an important point to keep in mind is that although placement of a VCF

\begin{table}
\begin{tabular}{|l|l|}
\hline
\textbf{Group} & \textbf{Indication(s)} \\
\hline
ACCP Consensus Conference on antithrombotic and thrombolytic therapy (2008): Prevention of venous thromboembolism\textsuperscript{211} & Prophylaxis of VTE in: Trauma patients Spinal cord injury \\
ACCP Consensus Conference on Antithrombotic and Thrombolytic Therapy (2008): Antithrombotic Therapy for Venous Thromboembolic Disease\textsuperscript{212} & DVT or PE + anticoagulation DVT or PE + contraindication to anticoagulation Chronic thromboembolic pulmonary hypertension undergoing thromboendarterectomy \\
American College of Physicians and American Academy of Family Physicians (2007)\textsuperscript{116} & DVT or PE VTE + contraindication to anticoagulation VTE + anticoagulated PE + anticoagulant failure Free floating thrombus DVT or PE in cancer patients \\
British Committee for Standards in Haematology (2006)\textsuperscript{112} & \\
American College of Chest Physicians, Consensus Committee on Pulmonary Embolism (1998)\textsuperscript{111} & High risk trauma patients: Contraindication to anticoagulation + injury pattern including: Severe head injury Spinal cord injury Pelvic + long bone multiple long bone Trauma patients (excluding burn, pregnant, and low-mechanism elderly) \\
Eastern Association for the Surgery of Trauma, Practice Management Guidelines for the Prevention of VTE in Trauma Patients (2002)\textsuperscript{115} & \\
Southern California Evidence-Based Practice Center Meta-Analysis (2000)\textsuperscript{57,117} & \\
\hline
ACCP, American College of Chest Physicians; DVT, deep venous thrombosis; PE, pulmonary embolism; VTE, venous thromboembolism; VCF, vena cava filter.
\end{tabular}
\end{table}
reduced the incidence of PE, it did not completely prevent either asymptomatic or fatal PE. The 6% incidence of PE in both series highlights the fact that patients may remain at risk for the development of PE even with a permanent VCF and adequate anticoagulation.

**Evidence-Based Consensus Guidelines**

The problems of diagnosis and management of venous thromboembolic disease have been well recognized and characterized by the medical and surgical community. There are several well-written and researched guidelines based on expert opinion and consensus conferences that are available to guide the treating physician and surgeon. Although VCFs are not the primary focus, most of these guidelines do address the issue of indications for placement of a VCF. One immediately obvious feature that

<table>
<thead>
<tr>
<th>Recommendation(s)</th>
<th>Level or Grade</th>
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<tr>
<td>Against VCF</td>
<td>IC</td>
</tr>
<tr>
<td>Against VCF</td>
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</tr>
<tr>
<td>VCF not indicated</td>
<td>IA</td>
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<tr>
<td>VCF indicated</td>
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</tr>
<tr>
<td>VCF before procedure indicated</td>
<td>2C</td>
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<tr>
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<td>N/A</td>
</tr>
<tr>
<td>VCF indicated</td>
<td>III (Grade B)</td>
</tr>
<tr>
<td>VCF not indicated</td>
<td>IB (Grade A)</td>
</tr>
<tr>
<td>Consider VCF only if other options not available</td>
<td>IV (Grade C)</td>
</tr>
<tr>
<td>VCF not indicated unless contraindication to anticoagulation</td>
<td>III (Grade B)</td>
</tr>
<tr>
<td>VCF not indicated unless contraindication to anticoagulation</td>
<td>III (Grade B)</td>
</tr>
<tr>
<td>“Consider” VCF placement</td>
<td>III</td>
</tr>
<tr>
<td>No firm conclusions drawn about VCF</td>
<td>III</td>
</tr>
<tr>
<td>Consider in high risk group (elderly, spine fractures, spinal cord injury)</td>
<td>III</td>
</tr>
</tbody>
</table>
is universally demonstrated in these guidelines is the disparity in the quality of evidence cited supporting standard management of VTE (higher grade) compared with the evidence guiding the decision for VCF placement (lower grade). Most of these guidelines give weak or noncommittal recommendations regarding indications for VCF placement. It should also be noted that very few of these have focused specifically on surgical and trauma patients, who often have specialized risk factors for anticoagulation and disease profiles not seen in the medical population.\textsuperscript{68,69,100,155-159}

Table 3 shows the most current evidence-based recommendations from a variety of expert groups and consensus committees. These include the recent 2008 updates to the American College of Chest Physicians guidelines for both prophylaxis and treatment of VTE. Although the recommendations and supporting evidence vary widely between groups, a common theme is the cited lack of adequate prospective and controlled data to make evidence-based decisions regarding placement of a VCF in all situations. The only Level I recommendation identified is that VCF is not indicated in the patient with venous thromboembolic disease who can be anticoagulated.\textsuperscript{68} The majority of groups agree that venous thromboembolic disease in patients who cannot be anticoagulated have a significant anticoagulation-related complication, or fail anticoagulation, are acceptable reasons to consider VCF placement. Even in these situations they do not make a strong recommendation in favor of VCF placement, but leave it as an option to be considered. In the 2 guidelines focusing solely on trauma patients, no firm conclusions could be drawn, but they advised that VCF should be “considered” only in high risk trauma patients, especially those who have a contraindication to standard prophylactic dose anticoagulation.\textsuperscript{100,157,159} Again, these were noted to be Level III recommendations that are not supported by strong scientific data. Only 1 guideline addressed cancer patients with DVT or PE and recommended against routine use of VCF unless another indication was present.\textsuperscript{68}

Table 2 provides a list of the most commonly cited indications for VCF placement, divided into a small list of widely accepted indications and a longer list of indications that are considered relative or controversial. The accepted indications all fall into the “therapeutic” category for VCF placement, whereas most of the relative and controversial indications involve placement of a VCF for PE prophylaxis. Of this entire list of potential indications, there is only 1 that is based on Level I prospective randomized data, as discussed in the next section. The remainder of this
article focuses on the particular scenarios that are most likely to be encountered by the practicing surgeon or surgical intensivist.

**Additional Expert Guidelines**

In addition to the evidence-based consensus statements listed above, there are several noteworthy expert or society guidelines for VCF use available. Although a variety of medical and surgical practitioners are now involved in VCF placement, this procedure has traditionally been performed by specialists in interventional radiology. In 2003, the Society of Interventional Radiology Standards of Practice Committee published a set of quality improvement guidelines for the placement of VCF. They listed 5 accepted indications for VCF placement: (1) presence of DVT or PE and a contraindication, complication, or failure of anticoagulation; (2) massive PE with residual DVT and at risk for further PE; (3) free floating iliofemoral or IVC thrombus; (4) DVT with severe cardiopulmonary disease; and (5) poor compliance with anticoagulation. Additional indications were listed for high risk trauma patients (closed head injury, spinal cord injury, multiple long bone or pelvic fractures) and high risk medical or surgical patients. In addition to these standard indications, this group also outlined the indications for placement of the filter in the suprarenal position. These included (1) renal vein thrombosis; (2) IVC thrombosis extending to or above the renal veins; (3) placement during pregnancy or in women of childbearing age; (4) thrombus extending above a previously placed filter; (5) PE after gonadal vein thrombosis; and (6) anatomic variants of the IVC or renal veins. Relative contraindications to VCF placement were uncorrectable coagulopathy and bacteremia or untreated infection. They also warned about using strict indications in pediatric and young adult patients due to concerns about the long-term effects and durability of these devices.

It is important to note that the above guidelines were written specifically for the placement of permanent filters. With the explosion in the use and expanding indications seen with the introduction of retrievable filters, additional guidelines were needed. In 2006, the Society of Interventional Radiology Multidisciplinary Consensus Conference published an updated set of guidelines for the use of retrievable and convertible filters. Table 4 shows the key points of consensus from this conference. These are notable for the statement that there are no unique indications for placement of a retrievable filter and that the primary treatment and prophylaxis of VTE should be pharmacologic. Figure 6 shows the proposed algorithm for deciding on filter placement and for choosing between an optional (retrievable) or permanent filter. It also lists the
indications and contraindications for VCF placement. It should be noted that several indications that were categorized as “accepted” in the previous guidelines\textsuperscript{160} (such as iliocaval or free-floating DVT) were downgraded to “relative indications” in the more current guidelines.\textsuperscript{38}

In addition to these broad and generic guidelines, there have been several expert panel or consensus conference statements published that focus on specific patient populations or demographics. Several of these are of particular interest to the surgeon or surgical intensivist, such as trauma and burns, oncology, or the critically ill. These guidelines are discussed in more detail in the subsequent sections focused on specific surgical patient populations. Although each of these patient populations has specific and different sets of risk factors for VTE and anticoagulation, the same general set of indications for VCF placement described above should apply universally.

**Indications in Specific Surgical Patient Populations**

*Trauma.* Multiple series have examined the role of prophylactic and therapeutic VCF placement in the “high risk” trauma patient.\textsuperscript{52,95,97,151,161-169} These series vary widely in their definitions of “high risk criteria,” as well as patient demographics, indications for placement, type of filter, length of follow-up, methods for determining rates of complications, DVT, and PE. Trauma patients remain 1 of the highest risk groups for development of VTE, with a reported incidence of DVT as high as 50% and PE as high as 32%.\textsuperscript{157,159} Prolonged immobility, venous

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**TABLE 4. Key points of consensus**

1. The primary means of therapy and prophylaxis of VTE are pharmacologic
2. No unique indications for optional vena cava filters exist that are distinct from permanent vena cava filters
3. Some patients with indications for vena cava filters have limited periods of risk of clinically significant PE and/or contraindication to anticoagulation and may not require permanent protection from PE with a vena cava filter
4. Patients with filters in situ should be managed with pharmacologic methods according to their VTE status and risk of anticoagulation as soon as safe and feasible
5. There are no absolute indications for discontinuation of filtration unless the filter itself is a source of documented major morbidity that will be relieved by retrieval or conversion
6. Discontinuation of filtration should only occur when the risk of clinically significant PE is reduced to an acceptable level and is estimated to be less than the risk of leaving the filter in situ
7. The quality of literature on optional vena cava filters is not sufficient to support evidence-based recommendations at this time

Reprinted with permission from Kaufman et al.\textsuperscript{38}
stasis and injury, a proinflammatory hypercoagulable state, and the high risk of bleeding all contribute to the increased risk of VTE and the overall poor results with standard thromboprophylaxis seen in severely injured trauma patients.99,170-173 This lack of effective VTE prophylaxis options was emphasized in the 2002 Eastern Association for the Surgery of Trauma (EAST) guidelines, with no Level I recommendations provided for preventing DVT and/or PE in trauma patients identified.157

Severely injured patients, particularly those with hemorrhage and the need for massive transfusion, are typically thought of as hypocoagulable and have therapy aimed at improving their clotting function. This was thought to be due simply to depletion of clotting factors, which was transient and easily corrected with the administration of plasma products and control of exacerbating factors such as acidosis and hypothermia.

FIG 6. Society of Interventional Radiology proposed algorithm for vena cava filter placement and list of indications for filter placement. P = permanent filter; O = optional filter. (Reprinted with permission from Kaufman et al.38)
More recent research has revealed that the coagulopathy of trauma is an incredibly complex and heterogenous process, which typically involves a mix of hypo- and hypercoagulation states that produce a high risk of clot formation as well as hemorrhage.\textsuperscript{94,174-177} There also appears to be a reproducible temporal pattern in the coagulopathy of trauma, with the initial early hypocoagulable state transitioning to a more prothrombotic milieu, which may be difficult or impossible to recognize clinically. These factors coupled with the presence of endothelial injury, bony fractures, immobility, and stasis produce one of the highest risk populations for the formation of venous thrombosis.

Adding to the already high baseline risk of VTE in the severely injured patient is the difficulty in the administration and efficacy of mechanical and chemical VTE prophylaxis. Mechanical prophylaxis, typically with lower extremity compression devices, is usually applied in a delayed fashion and may be limited by extremity injuries, casts, or external fixation devices. Patient and nursing compliance is also a demonstrated problem with mechanical compression devices.\textsuperscript{178} The use of chemical prophylaxis with unfractionated or LMWH compounds has become a standard component of VTE prophylaxis for trauma patients, but in many cases the administration of these agents is delayed or withheld due to concerns about bleeding. Even if standard chemoprophylaxis is administered in a timely manner, there may be factors in trauma patients that promote resistance or failure of these agents. Several series have investigated the impact of trauma on multiple components of the coagulation system. Systemic levels of AT III, a key cofactor required for the effectiveness of heparin compounds, have been found to decline after trauma.\textsuperscript{179-181} In 1 series, more than 60% of adult trauma patients were found to have low levels of AT III and the decrease in levels appears to correlate with injury severity and physiologic derangement.\textsuperscript{181} These complex coagulation changes may explain both the high rate of VTE and the high failure rates of standard VTE prophylaxis that have been demonstrated in the severely injured trauma population.\textsuperscript{99,173} In a prospective study of 200 critically injured patients who were evaluated with routine duplex ultrasound surveillance, Velmahos and colleagues\textsuperscript{173} found a high incidence of DVT (13%) despite a program of aggressive combined mechanical and chemical prophylaxis. They identified no difference in the rate of DVT between patients who received mechanical compression devices only and patients who received LMWH and mechanical prophylaxis. In a subsequent meta-analysis of 73 relevant articles, there was no proven benefit of any form of VTE prophylaxis.
(mechanical, UFH, LMWH) compared with no prophylaxis among trauma patients.159

Multiple risk factors for VTE in trauma patients have been described, including advanced age, female gender, obesity, high Injury Severity Score, head injury, spinal cord or vertebral injury, pelvic and long bone fractures, venous injury, and multiple transfusions.54,163,182-184 Many of these reports suffer from small numbers of patients with VTE or incomplete analysis of the independent contribution of each factor to the risk for VTE. However, on careful meta-analysis of available data, it appears that only spinal cord and vertebral column injuries are strong independent predictors (Level I recommendation) of VTE, while other described risk factors are of marginal or questionable value for reliably identifying a truly “high risk” patient that could benefit from VCF placement.100,157,159 The high risk of VTE with spinal cord injury is even more concerning in light of the results of a prospective randomized trial comparing UFH + pneumatic compression devices with enoxaparin for prophylaxis in the acute injury phase (Journal of Trauma, SCITI group 2003). The incidence of combined VTE events in both treatment arms was greater than 60%, with up to an 18% incidence of PE.

In a 1997 practice pattern survey of 210 US trauma surgeons (87% from Level I trauma centers), there was overwhelming agreement for VCF placement only in the setting of the traditional indications such as PE while therapeutically anticoagulated (93% agreed) and DVT with a contraindication to anticoagulation (89% agreed).185 For all other indications, including standard high risk trauma criteria, agreement was 50% or less. However, there was a statistically significant trend toward increased filter use for 9 of 10 relative indications when given the option of choosing a removable VCF. This study also revealed the wide range of VCF use, with 61% of centers inserting 0 to 1 filters per month, and 13% inserting more than 4 filters per month. In a subsequent analysis of the National Trauma Data Bank and a survey of 131 participating trauma centers, 86% of VCF appeared to have been placed for prophylactic indications, and 12% were placed in patients without any identifiable VTE risk factors.54 Among survey respondents, only 16% stated they would place a VCF for prophylactic indications, with the majority using mechanical compression devices only. However, Fig 4 demonstrates that most of the increased use of VCF in trauma patients is attributed to placement for prophylactic indications.

The most recent consensus guidelines focused solely on the trauma patient were published in 2008 by the Inflammation and the Host Response to Injury Collaborative Research Project investigators.186 They
identified the “high risk” trauma patient as those expected to be hospitalized for at least 48 hours and having one or more of the following risk factors: pelvic or lower extremity fracture requiring operation, spinal cord injury, complex lower extremity venous injury, significant head injury, immobilization for >48 hours, history of VTE or known hypercoagulable state, body mass index (BMI) >30, age >50, Injury Severity Score >15, and pregnancy. They cited the standard therapeutic indication for VCF placement in the trauma patient with a demonstrated DVT or PE and a contraindication to anticoagulation. For prophylactic VCF placement, they developed an algorithm for filter placement in high risk trauma patients (as defined above) with a potential contraindication to LMWH and who had either (1) spinal cord injury with paraplegia or quadriplegia; (2) complex pelvic fracture with associated long bone fractures; (3) multiple long bone fractures; or (4) a contraindication to LMWH expected to exceed 72 hours.

**Surgical Oncology.** Patients with active malignant disease have long been recognized as a high risk population for developing venous thromboembolic disease and complications.\(^{187-190}\) This increased risk can be attributed to various combinations of the prothrombotic state induced by malignant disease, venous stasis due to mass effect of solid tumors, and the frequent presence of other risk factors (ie, age, immobility) seen in this patient population.\(^{191-193}\) There is a mounting body of very interesting evidence that anticoagulants may possess a variety of beneficial effects in the cancer patient independent of their impact on VTE. Several components of the clotting cascade and other vascular factors appear to play critical roles in tumor growth and differentiation, local invasion, and distant metastasis.\(^{194}\) Anticoagulants such as LMWH appear to exert a variety of antineoplastic effects by interfering with tumor angiogenesis and the ability of the tumor cells to adhere, invade, and metastasize.\(^{194,195}\) In a recent meta-analysis of randomized controlled trials in cancer patients, anticoagulant administration was found to be associated with a significant reduction in overall mortality (odds ratio 0.90 for 1-year mortality).\(^{91}\)

In addition to the well-described baseline risk of VTE in cancer patients, several of the newer antitumor agents that may be administered perioperatively appear to increase the incidence of VTE. Although VTE has been a well-described risk associated with thalidomide,\(^{196}\) these patients are rarely encountered by surgeons. Several other agents, however, are being increasingly used in solid-tumor patients who often require surgical intervention. A meta-analysis of data from trials with the antiangiogenic agent bevacizumab demonstrated a relative risk of 1.3 for VTE events.\(^{197}\)
In addition to venous thrombosis, bevacizumab has also been associated with life- or limb-threatening arterial thromboses.\textsuperscript{198} Another series has demonstrated that the matrix metalloproteinase inhibitor prinomastat was associated with a doubling of the hazard ratio for VTE among lung cancer patients.\textsuperscript{199}

Any patient with malignancy is at risk for the development of life-threatening VTE, but there are multiple modifiable and nonmodifiable risk factors that must be taken into account when making decisions regarding the optimal strategy for prophylaxis and treatment. Khorana and Connolly\textsuperscript{200} identified multiple factors that are predictive of VTE in this population. The clinical risk factors included the primary tumor site, stage, time from diagnosis, comorbid conditions, chemotherapy, antiangiogenic therapy, and need for hospitalization. The biomarker risk factors identified were elevated platelet or leukocyte count, tissue factor, soluble p-selectin, and D-dimer level. Incorporating these into a validated risk model was shown to be highly predictive of VTE in cancer patients\textsuperscript{201} and may be helpful for guiding decisions about VCF placement.

Aggressive mechanical and chemical prophylaxis is clearly warranted in hospitalized cancer patients, particularly in those with the added risk of undergoing a surgical procedure. The surgeon must consider not only the factors described for other patient populations, but also must take into account the nature and severity of the malignant process, quality of life, and the estimated duration of survival. In addition to the often poor prognosis associated with the index cancer, there is increasing evidence that the occurrence of VTE in cancer patients is an independent factor predicting a significantly worse short- and long-term prognosis.\textsuperscript{194} Any decision regarding prophylactic VCF patient in the cancer patient must take into account the significantly altered risk and benefit profile, which make this population unique from most others.

Among cancer patients with diagnosed VTE, treatment failures and VTE recurrence can be seen in 10%-20\% of cases despite standard anticoagulation therapy and appear to be significantly higher with oral therapy (coumadin) compared with LMWHs.\textsuperscript{202,203} This high failure rate ofchemoprophylaxis has resulted in some authors including malignancy as an indication for VCF placement in patients undergoing major surgical procedures.\textsuperscript{204-207} However, several series have questioned the validity of malignancy as an indication for VCF placement,\textsuperscript{202,208-210} with 1 series demonstrating a doubling of the mortality rate among cancer patients undergoing VCF placement.\textsuperscript{211}

In recognition of the high risk of VTE in this patient population, multiple society guidelines have been published regarding the prophyl-
Axixs and treatment of VTE in cancer patients. A subsequent working panel representing members from each of these societies (Italian Association of Medical Oncology, National Comprehensive Cancer Network, American Society of Clinical Oncology, French National Federation of the League of Centers Against Cancer, European Society of Medical Oncology) was convened and published a joint consensus statement that covers both the prophylaxis of VTE and the treatment of established VTE in cancer patients. For the prevention of VTE in the surgical cancer patient, the group consensus was for universal chemical prophylaxis with a heparin product (either unfractionated or LMWH). In addition, there was broad agreement that this prophylaxis should be continued for up to 4 weeks following major abdominal or pelvic surgery based on several studies demonstrating improved outcomes with this approach. No mention is made of VCFs as a primary preventive or “prophylactic” measure for the cancer patient. The only consensus indication for VCF placement in these guidelines is a therapeutic indication in the patient with documented VTE. There was broad agreement for VCF use in cancer patients with VTE and a contraindication to anticoagulation or for recurrent PE despite adequate anticoagulation. One of the individual societies, the National Comprehensive Cancer Network, added the additional indications of “cardiopulmonary dysfunction severe enough to make any new PE life-threatening or multiple PE with chronic pulmonary hypertension.”

Obesity and Bariatric Surgery. With the rapidly spreading “obesity epidemic” and explosion in bariatric surgical procedures worldwide, there has been increasing awareness and debate concerning prevention and management of VTE in the obese surgical patient. Multiple studies have found obesity to be a strong independent risk factor for the development of DVT, as well as fatal and nonfatal PE. In a prospective study of over 100,000 females, obesity (BMI >29 kg/m²) was found to be 1 of the strongest independent risk factors for PE, with an adjusted relative risk of 2.9. This risk, combined with the added risk of surgery and difficulties in proper dosing of chemoprophylaxis in obese patients, makes them particularly susceptible to VTE-related morbidity and mortality. However, despite the recognized association of obesity and VTE risk, multiple series of bariatric surgical patients have been published demonstrating a very low incidence of perioperative thromboembolic events. In a prospective study of 126 patients undergoing either open or laparoscopic gastric bypass, universal pre- and postoperative duplex ultrasound demonstrated only 1 DVT (0.79%) and there were no PEs.
Efforts to combat the high rate of DVT and PE in this patient population have led some authors to recommend routine preoperative prophylactic IVC filter placement for select patients undergoing bariatric surgery. In 1 retrospective review of 3861 bariatric procedures there was a low overall incidence of PE identified (0.85%), but the mortality rate in this group was 27%. A prophylactic VCF was used in 145 of these patients, with 3 postoperative PEs identified (2.1%) in the filter group. Nonetheless, the authors’ conclusions recommend VCF use in patients who are superobese and who have limited mobility. Ferrell and colleagues retrospectively analyzed 586 patients undergoing gastric bypass and identified 12 who had a VCF placed; 6 of these were prophylactic and 6 were placed for postoperative complications. Despite the identified “technical challenges” of VCF placement in these patients, there were no long-term complications identified and the authors recommend VCF placement for patients with elevated VTE risk factors or patients with prolonged immobility and ICU stay due to complications. In another study of 5554 bariatric operations, risk factors for postoperative VTE were identified and recommended as indications for VCF; these included venous stasis disease, BMI greater than 60, truncal obesity, and obesity hypoventilation syndrome. DeMaria and colleagues recently performed an analysis of 2,075 consecutive bariatric surgery patients to develop a simple scoring system to predict mortality risk. Their final scoring system included a novel “pulmonary embolus risk” component that included 4 risk factors: prior VTE, prior VCF placement, right heart failure, and obesity hypoventilation syndrome. This component of the scoring system had an associated odds ratio of 2.62 for perioperative mortality. It should be noted that VCF placement itself was identified as a factor predictive of perioperative mortality in this patient population. Several recent retrospective studies using similar “high risk” criteria for patients undergoing bariatric surgery have demonstrated a high technical success rate and a significantly decreased incidence of PE with VCF placement, with 1 series demonstrating a 0% rate of PE in patients who received a prophylactic VCF.

Intensive Care Unit. Critically ill or injured patients represent another high risk population for venous thromboembolic events and may be the highest risk surgical population. In addition to their high disease or injury acuity, ICU patients have a multitude of additional factors that increase the risk of venous thrombosis. They are typically less mobile than ward patients and may be kept fully immobilized with heavy sedation or even chemically paralyzed for prolonged periods to time. This population also tends to be older and have a greater number of
comorbidities, particularly cardiovascular, which can contribute to venous stasis and a prothrombotic state. They are much more likely to have an indwelling central venous catheter, which can result in alterations in venous flow, vein stenosis, and adherent clot.\textsuperscript{135,235} All of these increase the risk of DVT formation at the catheter site or distally. Diagnosis may be hindered by the fact that these catheter-associated DVTs are often in the upper venous system, which is typically not included in routine ultrasound surveillance.\textsuperscript{61} In addition, placement of a VCF in the typical location (IVC) will not prevent PE from upper extremity or central venous sources.\textsuperscript{66}

The absolute risk of VTE in ICU patients is difficult to characterize due to the heterogeneity of the population and to wide variations in the screening and diagnostic protocols used in different centers. ICU patients have reported rates of VTE ranging from 10\% to 100\% in select high risk populations.\textsuperscript{236} Velmahos and colleagues\textsuperscript{173} performed a prospective study of trauma ICU patients with weekly duplex surveillance for DVT. There were 26 patients identified with at least 1 DVT (13\%), and most of these (58\%) were diagnosed within 2 weeks of injury. The only risk factors identified for DVT were the severity of injury to the chest and extremities and the need for high-level ventilatory support. There was a 31\% mortality rate among the group with DVT. In a prospective study of 190 surgical ICU patients, the incidence of confirmed DVT was found to be 10.5\%, and the only independently predictive factor was a prolonged length of ICU stay.\textsuperscript{237} An analysis of data from the prospective randomized Xigris and Prophylactic Heparin Evaluation in Severe Sepsis (XPRESS) trial demonstrated a 5\% incidence of VTE in critically ill patients by day 6 of study enrollment, most of which were clinically silent. The only independently validated predictor of VTE was a prior history of VTE (odds ratio, 3.66). Interestingly, only 50\% of patients were receiving chemical prophylaxis at the time of study enrollment.

Although ICU patients are at extremely high risk for DVT and PE, they may also be among the most difficult patient populations to administer appropriate and effective chemoprophylaxis. These patients often have a complex mix of coagulopathy and hypercoagulable states that can confound decision-making relating to administration of anticoagulants. Alterations such as the depleted levels of AT III may decrease or negate the efficacy of standard heparin anticoagulation.\textsuperscript{179,180,238} Dosing at both prophylactic and therapeutic levels of anticoagulant agents is extremely difficult in these patients due to unpredictable alterations in the volumes of distribution, drug metabolism, and plasma protein binding.\textsuperscript{239-241} They also frequently have significant organ dysfunction, particularly hepatic...
and renal, that make appropriate dosing of these agents problematic or unobtainable.\textsuperscript{242,243} One of the most common issues encountered is the difficulty in using LMWH in patients with significant renal dysfunction.\textsuperscript{244} Finally, these agents are typically administered via the subcutaneous route and depend on adequate tissue perfusion for appropriate and timely systemic absorption. ICU patients have several factors that may impact this, such as massive tissue edema, decreased cardiac output, use of vasoconstrictor agents, and poor peripheral tissue perfusion. There is a growing body of literature in the ICU population demonstrating the poor absorption and unreliable systemic levels achieved when administering medications via the subcutaneous route.\textsuperscript{245} Changing to an intravenous route or close monitoring of systemic efficacy, such as following antifactor Xa levels for LMWH administration, should be considered in the critically ill ICU patient.\textsuperscript{246-248}

In general, the same indications for VCF placement described for other surgical populations apply to the ICU population. This is such a heterogeneous population that it is difficult to make broad statements or guidelines, and practices will vary widely by the type of ICU, the type of providers, and the type of patients admitted to the unit. Patients with the risk factors listed above, such as prior VTE, increased age, obesity, prolonged mechanical ventilation, malignancy, chemical or spinal paralysis, or the inability to administer adequate chemical prophylaxis, should be considered for possible VCF placement. In a study of 209 ICU patients (53% surgical), there were an average of 4.4 risk factors for VTE identified per patient. The majority (57%) received mechanical prophylaxis alone, and only 3% underwent prophylactic VCF placement.\textsuperscript{249} In a recent review article on the management of VTE in the ICU, the only indication discussed for VCF placement was the therapeutic indication in the patient with a PE who cannot be anticoagulated. In this scenario a removable filter was recommended, along with resumption of anticoagulation as soon as possible and subsequent filter removal.

A final additional consideration in the critically ill patient is the risk of transport to the interventional radiology suite or operating room for VCF placement. It is well known that transport of critically ill patients carries a risk of morbidity or even death, and some patients may be too ill to be safely moved. In addition, they may require specialty beds or positioning, such as rotational therapy for respiratory distress, or reverse Trendelenburg positioning for elevated intracranial pressure. These factors should be considered when considering VCF placement. Several authors have described bedside ICU techniques for VCF placement using either ultrasound or fluoroscopy.\textsuperscript{250-253} In addition to the reported high success
rate, this technique has the advantage of avoiding transport-associated morbidity and appears to offer significant cost savings. 252

“Contraindication” to Anticoagulation

One of the most frequently cited reasons for considering or placing a VCF is a contraindication to anticoagulation. 54,161,185 In the surgical and trauma populations this is most commonly due to the fear of perioperative hemorrhage or to injuries that are high risk for bleeding, such as intracranial hemorrhage, solid organ injuries, or severe pelvic and extremity fractures. 96 In a set of recently published guidelines from a multicenter consensus panel, there were 5 factors identified as potential contraindications to LMWH in their proposed algorithm. These included: (1) severe head injury with intracranial hemorrhage or craniotomy; (2) epidural catheter or hematoma; (3) ongoing hemorrhage or significant coagulopathy; (4) nonoperative management of an intraabdominal solid organ injury; or (5) spinal column fracture. 186 However, they noted that there is significant controversy regarding the degree to which these factors are absolute contraindications to beginning appropriate VTE prophylaxis and state that this should be left to “physician discretion.”

In other surgical populations there is often fear of an increased risk of bleeding complications with anticoagulants or the anticipated need to hold anticoagulation for prolonged periods around the time of operation. Similarly, in the ICU population anticoagulants are often held due to fear of bleeding complications from the multiple invasive procedures performed such as central line placement, bronchoscopy, tube thoracostomy, etc. Although these are certainly valid concerns in many patients, it is the authors’ experience that these decisions are often made based on an exaggerated estimate of the bleeding risk associated with pharmacologic anticoagulants, especially when considering prophylactic dose regimens. Prophylactic dose UFH and LMWHs have both been demonstrated to be safe and effective in patients undergoing surgery for cancer, orthopedic surgery, polytrauma, and neurosurgery/neurotrauma and can usually be started within 24 to 48 hours of injury or surgery. 233,254-258 There has been little to no strong evidence of complications associated with early use of chemical prophylaxis in these populations, but strong data that withholding therapy results in increased rates of DVT and PE.

Even among patients with intracranial hemorrhage or solid organ injury being managed nonoperatively, prophylactic dose anticoagulation can usually be started safely after an initial observation period and with no signs of ongoing hemorrhage. 233,254,256,259 Historically, both trauma surgeons and neurosurgeons have been reluctant to administer any type of
chemical anticoagulant to trauma victims with any degree of intracranial hemorrhage. This practice is now being questioned in light of accumulating data regarding the incidence of VTE and the risks of anticoagulation in this patient population. A prospective study of VTE in trauma patients by Geerts and colleagues found a 40% incidence of DVT among brain-injured patients who were not given chemical prophylaxis and called for increased vigilance and attention to VTE prophylaxis.\textsuperscript{81} Reiff and colleagues analyzed all traumatic brain injuries over a 7 year time period at a level 1 trauma center. They demonstrated a 3- to 4-fold increase in DVT associated with brain injury. In addition, they found no increased incidence of bleeding progression or adverse outcomes among those who received early pharmacologic prophylaxis, and called for more aggressive use of chemoprophylaxis with head injury.\textsuperscript{98} Several other groups have examined this issue and reported similar findings supporting the safety of prophylactic LMWH even with mild to moderate brain injury.\textsuperscript{93,96} In these patients we would recommend development of a protocol for early initiation of chemical prophylaxis in select patients with brain injury rather than proceeding directly to prophylactic VCF placement.

Similar data are now accumulating for trauma patients with multisystem injuries, spinal cord injuries, or solid organ injuries that are managed nonoperatively. Alejandro and colleagues analyzed 188 patients with blunt splenic injury, including 50 patients who received LMWH within 48 hours of injury.\textsuperscript{259} There was no difference in the incidence of blood transfusions or failure of nonoperative management among the patients who received early chemical prophylaxis. Cothren and colleagues analyzed data at a Level 1 trauma center using a once-daily LMWH protocol in 743 high risk and severely injured patients.\textsuperscript{254} They demonstrated that this regimen was both effective (3.9% DVT and 0.8% PE incidence) and well tolerated (3% unexplained transfusions) among both multisystem trauma patients and those with intracranial hemorrhage. A prospective randomized trial of chemoprophylaxis in the acute injury phase of spinal cord injury demonstrated very low rates of adverse events with either UFH or LMWH.

Although injury severity appears to directly correlate with the risk of VTE, there seems to be increased reticence to begin appropriate prophylaxis in these patients. In a recent multicenter prospective cohort study of seriously injured trauma patients with an ICU stay longer than 7 days, only 25% had prophylaxis initiated within 48 hours, and 25% had no prophylaxis for at least 1 week after injury. A delay in initiating appropriate VTE prophylaxis was associated with a risk ratio of 3.0 (95%
CI 1.4-6.5) of DVT or PE. Factors that were associated with delay in starting appropriate anticoagulation were head injuries and the need for massive transfusion. As these authors rightly noted, there is a clear risk to delaying appropriate prophylaxis in this group of high risk patients, while data regarding the risks of initiating early prophylactic therapy remain unclear or speculative. It is the authors’ opinion that although “contraindication to anticoagulation” is frequently cited as a definitive indication for VCF placement in high risk trauma and surgical patients, a substantial portion of this group can receive appropriate chemoprophylaxis safely and effectively.

### Procedures and Techniques for Filter Placement

The incidence of VTE has remained fairly constant over the last 3 decades; however, the use of IVC filters has increased markedly during this time frame. The likely explanation is the expansion of the relative indications mentioned above for the insertion of a VCF and the improved filter technology. In addition, rather than only vascular specialists and radiologists placing these devices, other specialists such as cardiologists, trauma surgeons, and critical care physicians have learned the technique of placement. Once the indication for insertion of an IVC filter has been met, the planning is straightforward. Traditionally, the filters have been placed in an interventional suite but more recently it has also been described at the bedside using fluoroscopy or ultrasound for guidance.

When planning for filter placement in the interventional suite, the patient’s renal function can be assessed by evaluation of the creatinine level. If the creatinine is elevated, then hydration measures, use of half-strength contrast, and potentially using carbon dioxide imaging can be considered. Other laboratory tests include a coagulation profile with an activated PTT and PTT. If a patient is receiving intravenous heparin, it can either be continued or held once in the angiography suite; this decision is generally at the discretion of the provider since many times “hold the IV heparin” may lead to prolonged periods of inadequate anticoagulation. In addition, if there is a potential for difficult access, the heparin can be discontinued once in the angiography suite.

From prior imaging such as CT, the caliber of the IVC can be measured and any anomaly of the vena cava identified. Most IVC diameters are 20 mm, but in a small percentage of patients it may measure up to 30 mm (megacava). The diameter is extremely important since most IVC filters can be employed in an IVC less than 30 mm but only 1 can be placed in a megacava (Bird’s Nest Filter, Cook Medical, Inc, Bloomington, IN). If there is no cross-sectional imaging of the abdomen, the IVC can be
measured during the preplacement cavagram. The location of the DVT, if known, is important since an iatrogenic PE can occur from passing the filter through the thrombus. Finally, noting the body habitus of the patient is important since it may be easier to access the internal jugular vein in an obese patient versus the femoral vein or vice versa in a trauma patient with a cervical collar and immobilization.

There are now numerous filters available (Table 1) and each has its own kit for deployment. Although the profiles for these devices may vary (6-12 Fr), the technique for deployment is fairly standard for placement under fluoroscopic guidance—obtain venous access in the common femoral vein or internal jugular vein using a standard angiographic needle. The preferential site is usually the right since this offers the most direct route to the IVC. Ultrasound-guided venous access can be very beneficial especially in the anticoagulated or obese patient (Fig 7). A wire is then passed into the vena cava under fluoroscopic guidance. A sheath is then placed over the wire into the IVC (most of the current devices are packaged in kits with the sheaths and device). A cavagram using digital subtraction imaging and IV contrast is then performed to identify the renal veins with the sheath or imaging catheter centered in the IVC using the L3 or L4 vertebra as a landmark (Fig 8). The filter is then usually deployed in the infrarenal IVC, between the renal veins and the iliac veins (Fig 9).

IVC filter placement under fluoroscopy and with contrast is the gold standard and using this technique is fairly straightforward. In many cases, it

**FIG 7.** Ultrasound-guided venous access. Note the clear visualization of the access needle in the vessel lumen.
may not be advantageous to transfer a patient such as a trauma patient or unstable patient on the ventilator to the imaging suite. In addition most angiographic suites have weight limits (often 200 kg) that cannot be exceeded, making it unavailable for the superobese (BMI greater than 50
kg/m²). Therefore, other modalities have been employed such as bedside insertion of IVC filters.

**Bedside Placement Techniques**

**Portable Fluoroscopy.** The technique mentioned above for standard IVC placement can be employed at the bedside as well. The main requirement for this technique versus placement in an angiographic suite is the need for a fluoroscopy-ready bed for which a portable fluoroscopy unit with digital subtraction imaging can be used. Other considerations are the room size; its potential safety for use of radiation in doses larger than standard x-rays; and the need for personnel to be trained in radiation safety and to wear protective gear. The obvious rate-limiting step with this technique is the availability of a portable fluoroscopy unit that will be allowed to be transported from the operating room to the ICU and ensure that the staff in this setting is trained to use this unit. The modality may be ineffective in visualizing the IVC in the superobese.

**Transabdominal Ultrasound.** As the noninvasive imaging has evolved in vascular surgery, the use of transabdominal US as well as intravascular ultrasound (IVUS) has been employed as the sole imaging modality in placing IVC filters. The reported benefit is in a patient who is not a candidate for anticoagulation alone and is also at risk for transportation to the interventional suite. The obvious limitation of using these imaging modalities is the familiarity and expertise of the practitioner in interpreting these images. For US, a patient must be thin enough to allow visualization of the IVC in the transverse and longitudinal axis (Fig 10).
Passman and colleagues have been advocates for early adoption of bedside filter placement and found for US-guided placement that the stainless steel Greenfield filter (Boston Scientific, Natick, MA) and the Tulip-Gunther filter (Cook Medical, Inc, Bloomington, IN) are the most easily visualized of the filters. One of the benefits of US is that the IVC is visualized and can be measured very accurately. The technique described by Passman and colleagues for placing an IVC filter with US is as follows: using ultrasound guidance, access is obtained in the femoral vein or jugular vein using standard Seldinger techniques and a sheath is placed in the vein. Next, a 0.035-inch guidewire is passed into the IVC under US-guidance and the tract is dilated to allow placement of the sheath to the renal veins. In the case of the Greenfield filter, which is preloaded in the delivery catheter, it is advanced to the right renal vein and IVC junction, which is visualized in the transverse plane (Fig 10). Using a combination of transverse and longitudinal views, the filter is deployed below the right renal vein (Figs 11 and 12). After deployment, US imaging is then obtained to confirm the proper positioning of the filter in the IVC along with abdominal radiographs. The key landmark is the right renal vein, which is usually lower than the left renal vein. Once identified, the filter is placed below this level. Again, familiarity with this imaging modality and identifying the exact patient who will benefit from this technique are paramount to success.

Intravascular Ultrasound-Guided Placement. One of the benefits of IVUS placement is that other than venous access it is not affected by body habitus and can be employed in the superobese patients as well. In addition, most filters can be placed with this method as well. The technique for placing an IVC filter with IVUS has been described with
dual venous access technique and a single venous access technique.\textsuperscript{261,265,266} The dual venous technique is performed as follows: first, access is obtained in both femoral veins and a 9-Fr sheath is placed in the left femoral vein. The filter will be placed into the IVC from the right access site and therefore the sheath size will depend on the device used. The IVUS catheter is then advanced into the right atrium and slowly withdrawn so the hepatic veins, the right and left renal veins, and posterior situated right renal artery are identified (Fig 13). The infrarenal IVC is then measured via the IVUS catheter and the device is advanced via the right femoral sheath. With the IVUS catheter in place visualizing the renal veins, the device and deployment catheter are advanced to just below the renal veins. The IVUS catheter is then withdrawn below the filter and the filter is deployed. IVUS is then employed to visualize the strut position against the wall. Post-procedure abdominal radiograph is obtained to confirm position and alignment. The single venous access technique is as follows: first, a single femoral vein puncture is made preferably on the right as described above, followed by placement of a 9-Fr sheath. Next, the IVUS catheter is then placed over the 0.035-inch guidewire to the right atrium as described above and the key landmarks are again identified. Techniques vary at this point, but the 1 described by Rosenthal and colleagues\textsuperscript{267} is a useful and straightforward approach. The 9-Fr sheath that is part of the filter’s kit for the Celect filter (Cook, Inc) is advanced over the IVUS catheter, which is placed at the base of the

**FIG 12.** Ultrasound view of deployed filter in the inferior vena cava (IVC). (Reprinted with permission from Passman et al.\textsuperscript{264})
renal veins. The sheath’s radiopaque bands then would cover the IVUS catheter tip, causing the renal vein image to lose its brightness. This technique can be repeated to confirm the location of the veins. The IVUS catheter is then removed and the filter is placed within the sheath in its deployment catheter. The filter catheter is then secured and the 9-Fr sheath is pulled back to the proximal marker on the sheath and deployed. IVUS can be reintroduced to look at the position of the struts against the wall and a completion abdominal radiograph is also obtained.

Numerous groups have reported excellent results with US and IVUS and Passman and colleagues\textsuperscript{264} have described refinements in the technique of placing IVC filters in critically ill patients at the bedside. Their group reported on 486 bedside filters deployed via IVUS (435 filters) and US (51 filters). Technical success with US-guided filter placement was

\begin{figure}[h]
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\includegraphics[width=\textwidth]{figure13.png}
\caption{Intravascular ultrasound (IVUS) view of relevant anatomy during IVC evaluation. (A) Cavo-atrial junction. (B) Vena cava at the level of the hepatic veins. (C) Left and right renal vein junction with the vena cava. (D) Vena cava below the renal veins. IVC = inferior vena cava. (Reprinted with permission from Passman et al.\textsuperscript{264})}
\end{figure}
observed in 97.7% of patients when the IVC visualization was adequate. The technical success rate of IVUS placement was 96.1% and all failures were with a single venous access technique that led to misidentification of venous anatomy and iliac vein deployment. Twelve patients had inadequate placement of the filter on postoperative radiography (10 patients from the US and 2 from the IVUS). They believe that the low risk of malpositioning is acceptable in this patient population and when a patient cannot tolerate transport to the angiography suite.

Rosenthal and colleagues\textsuperscript{268} reported on 93 trauma patients who underwent bedside placement of IVC filters via the single access technique described above with IVUS. They reported technical success in 91 patients (97.8%) and no procedural complications. They preface their results by encouraging fluoroscopic imaging in conjunction with IVUS imaging in the initial placement of filters early in the operator’s experience, as have others.

\textbf{Alternative Placement Locations}

The preferred anatomic location for placement of a VCF is immediately below the renal veins in the IVC as described above. This location is preferred to provide protection from all lower extremity emboli while also avoiding any possible injury or thrombosis involving the renal veins. However, certain situations or anatomic anomalies may call for placement in alternative locations. The most common alternative location used is in the suprarenal IVC. Anatomic abnormalities such as anomalous takeoff of the renal veins or the circumaortic left renal vein may necessitate placement of the filter above the renal veins, due to inadequate length of the infrarenal portion or the presence of collateral pathways for emboli that could circumvent an infrarenal filter. Other factors such as vena cava thrombus, narrowing, pelvic masses, or pregnancy have also been described. In a 20-year single-center experience, 70 patients had suprarenal filters placed with good technical results and a low complication profile, comparable to results with infrarenal filters.\textsuperscript{269} The authors identified no problems with renal vein thrombosis or decline in renal function.

The 2 other alternative locations for VCFs that may be encountered are in a duplicated vena caval system or in the SVC. Duplicated IVC is a rare anomaly that results in an accessory vena cava to the left of the aorta and typically draining the left iliac system. Since this duplicated system typically connects with the main caval system at a level above the renal veins, a filter in the typical infrarenal position will not provide adequate protection from lower extremity or pelvic emboli. Multiple case reports
have described the successful placement of dual VCFs in this situation. Important factors to note are that this will usually require access via the left femoral vein, and the duplicated cava is often significantly smaller in diameter than the main vena cava. SVC filters are becoming more commonly used with the increased recognition of the role that upper extremity DVT plays in pulmonary and systemic embolization. As opposed to IVC filters, these are almost always placed for the indication of a known upper extremity thrombus and not for prophylactic indications. The internal jugular veins are the usual access point and the techniques for placement are otherwise similar to that previously described. The best long-term follow-up data for SVC filters were reported by Usoh and colleagues, with 154 patients over an 11-year period. All SVC filters were deployed successfully with no cases of caval occlusion, filter migration, or pneumothorax.

**Retrievable Filter Placement**

Retrievable filters were developed for use in patients who do not require long-term caval interruption but are not good candidates for anticoagulation. Examples of these patients are the trauma patient who cannot be anticoagulated but has had a PE or is at high risk for a PE. Superobesity has been demonstrated to be an independent risk factor for PE and patients undergoing laparoscopic gastric bypass with DVT prophylaxis has not decreased the incidence of PE. In addition, Gargiulo and colleagues demonstrated a decrease in PE in patients with a BMI greater than 55 kg/m² from 2.1% to 0% and the PE-related mortality from 1.6% to 0% with VCF placement. Decousus and colleagues performed a randomized prospective study and identified that patients with a proximal DVT and IVC filter in place had a lower rate of PE versus those that underwent anticoagulation alone for the first 12 days but no difference at 2 years. Therefore, there may be short-term benefits to IVC filter placement and retrievable filters are an attractive option.

The issue that often arises is that although the retrieval technical success rate is high, the overall retrieval rate is low due to continued need for the filter and loss of follow-up. Each of the currently available retrievable filters (Table 1) has its own set of instructions for removal, but a common theme among all of these is the fact that the initial indication should be scrutinized for placement of a temporary filter and if that indication is no longer present then retrieval can be accomplished. The retrieval procedure generally involves capturing the “hook” and resheathing the filter (Fig 14). One of the most important aspects of retrieving the filter is the initial placement.
FIG 14. (A) Retrieval of filter. Placement of sheath near filter. (B) Docking with retrieval hook. (C) Resheathing of filter followed by removal.
because any tilt or angulation of the filter may make the retrieval procedure complicated or impossible.\textsuperscript{272}

Each of the temporary filters has its own optimal timing of removal and there have been reports of filters being removed more than 1 year after implantation. Often because of endothelialization and thrombus formation, it may not be safe to remove a filter and techniques such as repositioning and replacement of filters have been offered as a solution to allow for later retrieval.\textsuperscript{273,274}

Given the above-mentioned findings, the “retrievable” filter often becomes left in place as a permanent filter. In addition to the retrievable filters, which may be left in permanently, 1 newer device has been investigated as a purely temporary filter only. The Tempofilter II (B. Braun, Melsungen, Germany) has been developed as a long duration temporary caval filter. It is inserted and withdrawn using a tethered catheter with a subcutaneous anchoring device that does not require a retrieval kit and has been validated for use for 3 months. The explantation technique involves simply pulling the tether catheter in the neck. This filter was able to be removed in 101 of 102 surviving patients and left in 1 patient with a poor prognosis. If longer duration of cava filtration is required, then this filter must be removed and a permanent filter placed.\textsuperscript{275}

These devices are not currently FDA approved or available for use in the USA.

Although there are no Level 1 evidence-based guidelines available regarding the timing and optimal procedure for the removal of a VCF, the Society of Interventional Radiology has published a set of consensus guidelines on the use of retrievable filters.\textsuperscript{38} The algorithm for VCF removal begins with an assessment of the current risk for PE. If this is acceptably low based on the patient’s medical conditions, status of VTE, and ability to administer anticoagulation, then you must consider whether there is a benefit to removal of the filter. If the patient has a short life expectancy (less than 6 months) or will likely require a filter in the foreseeable future, then the device should not be retrieved. If there is an expected benefit to removal, then the patient can then proceed through the technical steps of removal. This should include an evaluation for current DVT (usually by duplex) and the status of any current anticoagulation. If this is acceptable, then the final evaluation should be a high quality cavagram to evaluate for the presence and amount of any filter thrombus. If the filter has a significant clot burden, then removal should not be attempted.

Continued efforts to improve the design of retrievable filters will likely lead to further increases in their use. Improved filter materials, design, and
delivery systems should result in technically easier placement procedures, improved efficacy, and decreased short- and long-term complications. Obviously, as an increased number of these filters are placed and not removed, the long-term complications and efficacy of these devices will be clarified. Future research of retrievable filters should include the development of valid in vitro and animal models to study the impact of filter placement, validation of the indications for placement and removal, prospective studies of outcomes, and cost-effectiveness analyses.38

**Anticoagulation in the Vena Cava Filter Patient**

One controversial area of ongoing debate is whether the presence of a VCF itself should be considered an indication for initiation or continuation of either prophylactic or therapeutic anticoagulation. Although the VCF does appear to offer some protection from PE, it should not be considered an adequate stand-alone method for VTE prophylaxis or treatment. There is still a demonstrated incidence of breakthrough PE in patients with a VCF in place and the presence of the filter also appears to increase the risk of DVT formation. Unless there is a true contraindication to anticoagulation, appropriate prophylactic or therapeutic anticoagulation should still be administered based on the risk for or presence of VTE. However, once there is no longer a standard indication for anticoagulation, the responsible physician is faced with the question of whether to keep the patient on an anticoagulant for the duration the filter is in place. Another dilemma that may be faced is when the VCF was placed due to some contraindication to anticoagulation (intracranial hemorrhage, gastrointestinal bleeding) that has now resolved. Should the patient now have to be placed on anticoagulation to mitigate the thrombotic risks of the filter itself? This problem has been partially addressed by the advent of retrievable filters, but as previously noted more than 50% of these devices are never retrieved and thus become permanent. As with most aspects of VCF, there are no prospective controlled data addressing this issue. Expert opinions and the available data vary widely on this controversy, and an excellent overview can be found in the review by Gomes and colleagues.276 Table 5 outlines the main arguments for and against the administration of chronic anticoagulation to patients with VCF.

In a 2001 study of 465 filter patients with a mean follow-up of 9 years, there was no significant difference in the rates of recurrent DVT, PE, or stasis ulceration between patients who received chronic anticoagulation and those who did not.277 However, there was a significant increase in mortality rate and the need for lower extremity stockings among patients not receiving anticoagulation. Dovrish and colleagues278 also found an
improved survival rate with anticoagulation in VCF patients but no difference in recurrent VTE. Several small and retrospective series have found benefits of chronic anticoagulation with filters, including fewer VTE events\textsuperscript{279} and a lower incidence of caval thrombosis,\textsuperscript{280} whereas others have found no such benefit.\textsuperscript{281,282} A recent meta-analysis on this topic in 2008 combined 14 articles with 1369 subjects to analyze the impact of anticoagulation on the rates of VTE after filter placement.\textsuperscript{283} They found a trend toward improved VTE rates with anticoagulation (12.3\% vs 15.8\% without anticoagulation, odds ratio, 0.64), but this failed to reach statistical significance.

Until there are better quality data available regarding this issue, the role of chronic anticoagulation with VCFs must be based on individual circumstances, risk factors, and practice patterns. There is widespread agreement that appropriate anticoagulation should be initiated as soon as possible in all filter patients based on either the risk for VTE or a diagnosed VTE, and that retrievable filters should be used and removed when possible.\textsuperscript{38,160,276,283} Beyond this, there is no solid evidence that routine continuation of anticoagulation has any benefits that outweigh the risks of serious bleeding events. However, there are clearly several thrombotic risks associated with VCFs that should be factored into this decision. In the patient with established VTE, postphlebitic symptoms, or poor cardiopulmonary reserve, the risk of recurrent VTE or severe adverse symptoms is elevated and may outweigh the risks of anticoagulation.

**TABLE 5.** Arguments for and against chronic anticoagulation for patients with a vena cava filter

<table>
<thead>
<tr>
<th>For anticoagulation</th>
<th>Against anticoagulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients already have proven VTE or high risk for VTE</td>
<td>High risk periods are often transient or resolve</td>
</tr>
<tr>
<td>VCF appear to increase the incidence of DVT risk of access-site thrombosis from placement or retrieval</td>
<td>Data on increased DVT rate is not definitive</td>
</tr>
<tr>
<td>Risk of vena cava thrombosis</td>
<td>Unclear significance of access-site DVT</td>
</tr>
<tr>
<td>Risk of PE from filter thrombus or occlusion</td>
<td>Vena cava thrombosis rare with newer devices</td>
</tr>
<tr>
<td>VCF creates some obstruction of flow in the vena cava</td>
<td>Low risk of PE with VCF in place</td>
</tr>
<tr>
<td>Intravascular foreign body present</td>
<td>Flow characteristics highly variable between devices</td>
</tr>
<tr>
<td>Long-term risks of newer filter devices unclear</td>
<td>No proven benefit of chronic anticoagulation</td>
</tr>
<tr>
<td></td>
<td>Risk of serious or fatal bleeding with anticoagulation</td>
</tr>
</tbody>
</table>

VTE, venous thromboembolism; VCF, vena cava filter; DVT, deep venous thrombosis; PE, pulmonary embolus.
Assessment, Reporting, and Patient Follow-Up

Immediately following placement of a VCF, the responsible physician should document the key elements of the procedure and the device information for future reference. This should include the type of filter and filter-specific identification number, the method and results of preplacement vena cava imaging, the access-site location, and the site of filter deployment. There are published guidelines from the Vena Cava Consensus Conference participants outlining the recommended reporting and follow-up standards for VCF, with a set of supplemental guidelines published for retrievable filters. They outlined the following 3 criteria for successful placement: (1) delivery system advanced to the intended placement location; (2) filter deployed and fixed at that level (no migration, embolization, or caval penetration); and (3) the filter is configured appropriately to prevent PE (fully open, adequate distribution, no tilting). Any deviation from these criteria or other complications should be noted in the permanent record. With the advent of retrievable filters, it is particularly important to note any placement-related factors that could impact the retrieval process such as incomplete deployment or significant filter tilt. The manufacturers recommended that maximum implantation time for that particular device should also be documented to guide the timing of possible future retrieval.

Although reliable follow-up has been notoriously difficult to obtain in many of these patient populations (ie, trauma), all patients with a VCF should have routine dedicated follow-up as outlined in the above cited guidelines. The key elements of this follow-up are the clinical examination and the performance of objective testing. Clinical examination should include obtaining a history about anticoagulation use or complications, performing a thorough physical examination including evaluation of the lower extremities for postphlebitic signs, and lower extremity venous duplex imaging. The minimum suggested objective testing includes dedicated imaging of the filter to evaluate position, patency, and presence of any thrombus. This may be accomplished by contrast cavography, ultrasound, CT scan, or magnetic resonance imaging. For patients with a retrievable filter, follow-up evaluation should also include a determination of the ongoing VTE risk and the appropriate timing for filter removal. This is critical to ensuring timely and appropriate filter removal and minimizing the number of patients who end up with a permanent VCF simply because they were lost to follow-up.
Clinical outcomes and results following VCF placement will be highly dependent on multiple factors such as the patient population, indication for placement, technique of placement, filter type and location, use of concurrent anticoagulation, and the nature and intensity of surveillance and follow-up. Although it is a commonly held misconception that VCFs are completely protective for PE, this has not been borne out by clinical experience. There is no question that patients with VCFs remain at risk for PE141,155,156,286; the only debate is whether there is a significant benefit in PE reduction with filters and whether this benefit outweighs the risks of placement. The main outcomes that should be assessed to determine if there exist any benefits of VCF are mortality and the incidence of initial or recurrent PE after filter placement.140

Although there remains significant debate about the indications and the risk-to-benefit ratio associated with VCFs, most available data support the efficacy of VCFs in reducing the incidence of PE across a wide variety of medical and surgical patients. The questions that remain unanswered are whether these devices result in any significant decrease in preredlated or all-cause mortality and whether the associated short- and long-term risks outweigh the potential benefits. This analysis will vary significantly based on the risk of the patient population being studied and the local proficiency with VCF placement. As with all other aspects of VCFs, the current literature is limited by the lack of adequate prospective and controlled data to make valid comparisons and conclusions.

The data from the only currently available prospective randomized trial of VCF versus standard management in patients with a diagnosed DVT did demonstrate a benefit of VCF in reducing the short- and long-term benefits of VCF.
risk of PE. Within the first 12 days after randomization, the incidence of PE was 1.1% in the filter group compared with 4.8% in the no-filter group (odds ratio 0.22, \( P = 0.03 \)).\textsuperscript{152} Longer term follow-up data from this trial (8 years) demonstrated a significant reduction in symptomatic PE from 15.1% to 6.2% (hazard ratio 0.37, \( P = 0.008 \)) associated with VCF use.\textsuperscript{153} Multivariate analysis demonstrated that VCF placement remained an independent predictor associated with decreased PE incidence. Although there was a demonstrated reduction in PE events, it should be noted that the authors concluded against routine use of VCF due to the associated complications and the failure to impact mortality. It is also important to remember that the patients in this study all received concurrent therapeutic anticoagulation, which limits the general applicability of the findings.

The incidence of recurrent symptomatic PE and several defined complications from summary data for a variety of VCFs is shown in Table 6. The majority of studies demonstrate an incidence of symptomatic PE in 2% to 4% of VCF patients, while the incidence of asymptomatic PE remains unknown but is undoubtedly higher. Although no recurrent PE events were reported for several of the newer devices, these data are limited by the small numbers and very short length of follow-up provided (2.3-6 months). Considering the lack of long-term follow-up in most series and the high percentage of patients who are lost to follow-up, the true incidence of new or recurrent venous thromboembolic events after placement of a VCF remains unknown. This is a particular concern for those patients who have permanent filters placed and can be expected to have a lifelong risk of cumulative events.

An additional efficacy measure that must now be included in the

<table>
<thead>
<tr>
<th>DVT</th>
<th>IVC thrombosis</th>
<th>Postphlebitic syndrome</th>
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<tbody>
<tr>
<td>5.9% (0-18)</td>
<td>3.6% (0-18)</td>
<td>19% (0-47)</td>
</tr>
<tr>
<td>22.7% (0-36)</td>
<td>6.5% (1-31)</td>
<td>14.4% (9-20)</td>
</tr>
<tr>
<td>6% (0-20)</td>
<td>3.9% (0-15)</td>
<td>14% (4-41)</td>
</tr>
<tr>
<td>8.9% (8-11)</td>
<td>7.7% (4-18)</td>
<td>12.9% (6-44)</td>
</tr>
<tr>
<td>32% (0-32)</td>
<td>11.2% (0-28)</td>
<td>41% (24-59)</td>
</tr>
<tr>
<td>7.3%</td>
<td>1.7%</td>
<td>2% (ulceration)</td>
</tr>
<tr>
<td>45.7%</td>
<td>2.8%</td>
<td>NR</td>
</tr>
<tr>
<td>10.3%</td>
<td>0%</td>
<td>NR</td>
</tr>
<tr>
<td>NR</td>
<td>9.6%</td>
<td>NR</td>
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analysis of VCF outcomes is the incidence of new or recurrent VTE during or after removal of a retrievable filter. The incidence of recurrent PE with the filter in place appears to be no different for retrievable filters compared with permanent devices. Although the most touted aspect of these filters is the ability to remove the device at some future time and avoid the lifelong risks associated with VCF, this creates the additional hazard of premature removal, with resultant PE. Another suboptimal situation may occur when the clinical condition of the patient changes after filter removal, placing them again at high risk for VTE with the requirement for repeat filter placement. With the increased use of retrievable VCF, there are now short to moderate follow-up data available. A prospective multicenter study of a mixed group of medical and surgical patients who received the G2 removable VCF demonstrated a recurrent PE rate of 2%, with no events occurring in the 30 days immediately after removal.287 In another recent study of 76 patients who underwent removal of a VCF, there was a redevelopment or worsening of VTE in 5 patients (6.6%).288 This included 2 recurrent pulmonary emboli, both of which were fatal.

The general efficacy and outcomes with modern VCFs may be misleading when making decisions about their use in individual patients or specialized patient populations. There appear to be significant disparities in the associated outcomes and complication rates with VCF between different patient populations. This is likely due to differences in their overall health status, presence of comorbid conditions, presence and degree of coagulation disorders, and risk for VTE events. There are several surgical populations that are among the highest risk groups for VTE and that represent a large portion of current VCF use worldwide.

**Trauma Patients**

Analysis of results for VCF placement in trauma patients is mainly limited by the lack of adequate control groups for comparison, with most series using unmatched cohorts or historical data for comparison. A meta-analysis of 73 articles on trauma patients was performed that included 6 VCF articles with 3210 patients.100 The authors found a PE incidence of 0.2% with VCF compared with 1.5% among controls without a VCF and 5.8% for historic controls but drew no firm conclusions due to the heterogeneity of the data. Rodriguez and colleagues289 compared 40 critically injured patients who received a prophylactic VCF to 80 matched historic controls. Only 1 patient (3%) with a VCF developed PE compared with 14 (18%) in the control group, 4 of
these being fatal PE. Similar reductions in the incidence of PE with filter use compared with control populations or historical data have been reported in other series. Rogers and colleagues reported on 132 trauma patients receiving prophylactic VCF with 5-year follow-up data. They found a 2.3% incidence of PE after filter placement and a mortality rate of 4.4%, with 1 fatal PE. Carlin and colleagues compared a group of 122 trauma patients who received a therapeutic VCF with 78 patients receiving prophylactic filters. They found a mortality rate of 11% for therapeutic VCF and 3% for prophylactic, and an incidence of recurrent PE of 18% in the therapeutic group versus 0% in the prophylactic group. In addition, they associated a 50% reduction in their overall incidence of PE over a 10-year period with a significant increase in use of VCF.

Several more recent series focused on trauma patients have reported similar results with both permanent and retrievable filters. In a study with nearly 9-year follow-up of 90 patients with permanent VCF for trauma, the recurrent PE rate was only 2% and there were few device-related complications. Of interest, the majority of patients reported significant limitations in mobility, which would place them at continued high risk for VTE. Toro and colleagues examined 102 consecutive trauma patients with filters placed for severe pelvic or acetabular fractures. At 4-year follow-up, they identified no hospital readmissions for recurrent DVT or PE among this high risk cohort. Another series demonstrated a PE rate of only 2% among the high risk cohort of patients with acute spinal cord injury who were managed with prophylactic VCFs. In summary, most series report a decreased incidence of all PE and fatal PE using VCF in appropriately selected patients, but there remains a lack of rigorous control groups for comparison.

**Retrieveable Filters in Trauma Patients**

The large majority of experience with retrievable VCF in surgical patients has been in the setting of major trauma. As stated previously, trauma surgeons are more likely to place a VCF if given the option of a retrievable filter, and retrievable filters are being used increasingly in many trauma centers. Meier and colleagues analyzed the results of prophylactic retrievable VCF placement in 35 trauma patients. Filters were retrieved in 86% of patients, and 36% demonstrated trapped clot or thrombus within the device. The incidence of PE was 3%, which occurred in 1 patient 5 days after VCF removal, and the mortality rate was 3%. A more recent series analyzed 187 retrievable VCF placed at the ICU bedside in critically injured patients. The majority (93%) was placed
without complication and there were only 2 documented PE identified. Several other series have reported a high technical success rate and low incidence of PE among high risk trauma patients who received a retrievable VCF.297-299

In a multicenter study by the American Association for the Surgery of Trauma, 446 patients received a retrievable VCF, with the majority (76%) being placed for prophylactic indications.161 In this large series, the retrieval rate was only 22%, and only one half of patients had postdischarge follow-up reported. The reported rate of “breakthrough” PE in these patients was low at 0.5% but should be interpreted with caution due to the poor follow-up and the lack of routine imaging protocols. Although these filters seem to represent an attractive option for the high risk trauma patient, they create additional difficult decisions such as the timing of removal and ensuring adequate follow-up and surveillance. The highest risk for PE is in the early postinjury period, but there remains a significant risk for late PE occurring weeks after injury, which must be considered when timing the removal of a VCF.297,300

Cancer and Surgical Oncology Patients

The prevention and management of VTE in the cancer patient remains problematic, particularly in the perioperative period. VTE has also been found to adversely impact progression-free and overall survival in patients with advanced malignancy.301 In response to concerns about the safety and effectiveness of standard anticoagulant therapy in the cancer patient,202,203,302 many have recommended the consideration of VCF placement in this population.205,208,303,304 The results with VCF use in this population have been highly variable, but most data have shown that although VCFs appear to prevent PE events, they confer no definable survival benefit. The perioperative placement of VCF among women with gynecologic cancer and VTE was analyzed in a series of 39 patients and found to have no complications and no patient developed VTE complications after surgery.305 However, patients in this series were also given LMWH and there was no control group for comparison. Similar findings were reported in a series of 50 patients with cancer and leg DVT, with a 2% incidence of breakthrough PE.306

Several authors have examined the overall survival among patients with cancer and VTE who received a VCF. Ghanim and colleagues307 found no significant difference in overall or in-hospital mortality among 175 patients with brain tumors and VTE managed with VCF or anticoagulation only, with median survival of 21 and 11 weeks, respectively. A study of 166 cancer patients undergoing VCF placement for therapeutic or
prophylactic indications demonstrated a median survival time of only 10 months, confirming the overall poor outcomes in this patient population. A series of 116 patients undergoing active treatment of malignant disease found a low procedural complication rate and a low recurrent PE rate of 3% following VCF placement. However, only 14% of patients were alive at 1 year, leading the authors to conclude that VCF in these patients may be of little clinical benefit. In a retrospective case-control study, Schunn and colleagues demonstrated that VCF in cancer patients appeared to be effective at preventing PE, but there was no survival benefit when compared with a matched control population. Similar results have been reported in several other series. Chau and colleagues used a Markov model of cost-effectiveness comparing VCF or anticoagulation in patients with malignant brain tumors and DVT. They demonstrated that VCF was not cost-effective in this patient population, but when the model was adjusted to reflect the anticipated 5-year survival for a breast cancer population, VCF appeared to be more effective and less expensive than anticoagulation alone. From the available data, it appears that VCF placement will be most effective in cancer patients with proven VTE who have good functional status and longer predicted survival times and should be discouraged in patients with advanced disease.

**Bariatric Patients**

There are relatively few studies detailing the outcomes from VCF use in the bariatric population, and these are limited to case reports and case series. Despite the association of obesity and VTE, the incidence of perioperative PE among patients undergoing bariatric surgery has been found to be extremely low with modern care. However, PE remains the most common cause of sudden postoperative death among this patient population, prompting many to investigate the role of VCF. Piano and colleagues analyzed outcomes from a protocolized approach using a retrievable VCF in 59 patients undergoing bariatric surgery who met high risk criteria. All filters were placed immediately before operation and removal was attempted at 4 weeks postoperatively. There was 1 postoperative PE (1.7%) in a patient who was not receiving chemical anticoagulation and no fatal PE or deaths. In another series of patients undergoing open gastric bypass, there were 58 prophylactic VCFs placed with 100% technical success rate, and no postoperative PE or death in patients with VCF. This was in comparison with a historic control PE rate of 13% and mortality rate of 10%. These authors recommended VCF placement...
for patients with a BMI greater than 55. These results have been similar to that reported in several other smaller series.\textsuperscript{230,312}

More recently, Vaziri and colleagues\textsuperscript{313} reported their results with VCF in 30 bariatric surgical patients with prior VTE. They placed a retrievable VCF immediately before operation and 90% underwent a follow-up venogram. There was a 21\% incidence of recurrent DVT and 15\% incidence of filter-related thrombus, but no PE or deaths. In addition, 70\% of the devices were removed successfully after recovery from surgery. Another group analyzed their results with a simplified VTE prophylaxis program that included preoperative VCF placement in high risk patients (heart failure, prior VTE, or BMI >50).\textsuperscript{230} Among the 150 patients analyzed, there were no VTE events in the perioperative period, and an estimated reduction of the risk of VTE to less than 2\%. Although most of these series in bariatric surgery support the use of VCF in select high risk patients, interpretation of the results is limited by the lack of prospective data, adequate control populations, standardized approach to chemoprophylaxis, and the small numbers available for analysis. Given the relative infrequency of all PE and fatal PE after bariatric surgery,\textsuperscript{271} much larger trials will be required to provide any meaningful data regarding the indications and efficacy of VCF in this patient population.

**Intensive Care Unit Population**

The critically ill or injured ICU patient is 1 of the highest risk groups for DVT or PE, and one of the groups that is least able to tolerate the physiologic insult. Broad statements about the indications and efficacy of VCF use in this patient population are difficult due to the heterogeneity of the patients and their underlying risk factors for VTE. However, as with most groups at high risk of VTE despite appropriate prophylaxis or with contraindications to standard treatment, there has been a demonstrated interest in the use of VCFs in the ICU. This interest and use has increased with the development of techniques that now allow bedside placement of the device under US or fluoroscopic guidance and is even being performed by medical intensivists.\textsuperscript{314,315}

In 1995, Khansarinia and colleagues\textsuperscript{165} analyzed 108 critically injured patients with a prophylactic VCF placed following injury and compared them to 216 matched controls. There were no PE in the filter group, and VCF placement was associated with a significant reduction in both PE and prerelated deaths (both $P < 0.05$). Tola and colleagues\textsuperscript{314} analyzed 25 bedside ICU placements of prophylactic VCF in critically injured patients and found no postprocedure complications or filter-related mortality. In addition, they demonstrated that placement in the ICU was...
significantly faster and less expensive than placement in the operating room (savings of $1844 per filter) or the radiology suite (savings of $2245 per filter). In another cohort of critically ill surgical patients undergoing prophylactic VCF due to contraindications to anticoagulation, there were no documented incidents of new or recurrent VTE after filter placement.\textsuperscript{97} Paton and colleagues\textsuperscript{234} reported a prospective 9-year experience with 403 bedside VCF placed in the ICU by general surgeons. They noted a DVT incidence of 8.5\% and a recurrent PE incidence of less than 1\%. They also noted the elimination of contrast-induced nephropathy using carbon dioxide contrast in high risk patients.

More recently, Oshima and colleagues\textsuperscript{316} analyzed the effect of VCF in a group of critically ill ICU patients with proven DVT. They placed a temporary VCF in 12 patients, 7 of whom had already experienced a PE, and demonstrated no further pulmonary events as well as improvement or resolution of the DVT in all patients. There were 2 minor complications and filters were removed in 11 of the 12 patients. Rosenthal and colleagues\textsuperscript{268} examined their results with bedside ICU placement of retrievable VCF in 187 multitrauma patients. Complications occurred in 7\% and included 6 filter misplacements (iliac vein), 2 access-site DVTs, and 5 groin hematomas. There was a 1\% incidence of recurrent PE and 82 (44\%) of the filters were retrieved successfully.

**Arguments Against Vena Cava Filter Efficacy and Use**

Although most series cited above have concluded that VCF placement offers a benefit in reduction in PE and PE-related morbidity and mortality, there remains a significant amount of skepticism and ongoing debate. Despite demonstrating a decrease in early and long-term PE with VCF use in patients with a known DVT, the PREPIC investigators concluded against routine use of filters due to the lack of mortality benefit and the associated complications.\textsuperscript{152,153} Among the previously listed expert guidelines and opinions for thromboprophylaxis, there is universal agreement regarding the lack of solid efficacy data for VCFs, particularly for prophylactic indications. Multiple arguments have been advanced against the routine use of VCFs, including the associated complication rates, the lack of clear efficacy data, the existence of alternative treatment modalities, and the increased costs associated with this technology. Additional concerns with the increasing use of retrievable filters have been raised regarding the lack of objective data for the timing of filter removal, the incidence of PE after removal, and the difficulty in achieving reliable follow-up for removal of the devices.
One of the most concerning factors in this debate is the observation of increased venous thrombotic events among patients with VCF. The only prospective randomized trial of VCF demonstrated a slight reduction in early (within 12 days) PE, but this was accompanied by a doubling of the incidence of lower extremity DVT.\textsuperscript{152} In a second report from this group with 8-year follow-up, the increased incidence of DVT among filter patients persisted despite being chemically anticoagulated. Multivariate analysis identified the presence of a VCF as an independent risk factor for DVT, with a hazard ratio of 1.5 compared with patients with no filter.\textsuperscript{153} A large population-based study using discharge data from California hospitals found that there was no reduction in rehospitalization for PE among patients who received a VCF compared with those with no filter, but that the VCF group had a significantly higher hospital readmission rate for DVT.\textsuperscript{317} In a study of a high risk cohort of trauma patients with spinal cord injury, the incidence of DVT was 5.2% without a filter and increased to 20.4% among those with a VCF.\textsuperscript{295} In addition, there was only 1 PE among the entire cohort and this was in a patient with a VCF.

Other series have challenged the assertion that VCF are superior to standard chemical and mechanical VTE prophylaxis. Spain and colleagues\textsuperscript{318} found a low rate of DVT and PE among 2868 trauma patients, 280 of whom were deemed “high risk” for VTE, despite the use of only 1 prophylactic VCF over the 2-year study period. There were no diagnosed PE in the low risk group and no deaths attributable to PE in the high risk group, leading them to conclude that routine VCF use is a waste of resources with little benefit. Antevil and colleagues\textsuperscript{164} demonstrated a 3-fold increase in VCF use after introduction of a retrievable filter at their institution, but no significant differences were seen in the incidence of PE or filter-related complications. In addition, only 21% of retrievable filters were removed successfully, which agrees with data from a multicenter trial of retrievable VCF.\textsuperscript{161} More recently, Cherry and colleagues\textsuperscript{319} analyzed 244 prophylactic VCF placements in trauma patients over a 3-year period. Despite the nearly 5-fold increase in the use of VCF at that institution, there was no change in the incidence of PE (0.7%-0.4%).

Another important factor to consider is the cost associated with VCF placement. Although standard mechanical and chemical prophylaxis is relatively cheap and cost-effective,\textsuperscript{320} there is a significantly higher cost and resource use required for filter placement. In addition to the costs associated with the device, the equipment, and the personnel required to place a VCF, the increased use of retrievable filters now introduces the added cost of a second procedure for removal. Chiasson and colleagues\textsuperscript{321} performed an economic analysis of 3 strategies for VTE prophylaxis in
trauma patients with contraindications to anticoagulation. Their model determined that prophylactic VCF use would result in no improvement in mortality or quality of life but was associated with the highest costs of the 3. Another cost-effectiveness analysis found that routine screening US was significantly more cost-effective than prophylactic VCF use among high risk trauma patients.168 The high costs and lack of proven benefit for routine prophylactic VCF use compared with standard prophylactic measures has also been questioned in the population of patients with acute spinal cord injury.322

Retrievable filters appear to have the same efficacy and complication rates as permanent filters while they are in situ. However, there are no objective or reliable guidelines available to determine the optimal timing of removal of these devices. This can result in the device being left in situ well after the period of risk has resolved, or the device may be removed while the patient remains at continued risk for VTE. The issue of breakthrough and recurrent PE with retrievable filters is discussed in the following section on complications. One of the common criticisms of the use of retrievable VCF is the poor rate of follow-up and subsequent filter removal in most series that have been reported. Although several of these devices may not be amenable to removal due to filter thrombus or device tilt,287,323 the most common reason cited for failure to remove them is patient lost to follow-up.161 The American Association for the Surgery of Trauma multicenter study of retrievable VCF demonstrated that only 28% of patients underwent an attempt at filter removal and only 22% ultimately had the device removed.161 The most common reason for failure to remove the filter was found to be loss of the patient to follow-up (31%), followed by persisting VTE risk due to immobility (30%). The most significant factor associated with device removal was whether the service that placed the device was responsible for follow-up.

Other single-center series have reported similarly poor retrieval rates as low as 4%,324 with multiple centers reporting retrieval rates of less than 50%.325-328 The most recent single-center series in trauma patients found that only 30% of retrievable filters were removed, and the most common reason was loss of follow-up due to transfer of the patient to extended care or rehab.329 Other reasons for failure to remove the VCF include a continued risk of VTE or inability to administer anticoagulation, the presence of significant filter thrombus, or technical failure due to filter tilt or tissue ingrowth. Filter thrombus has been demonstrated in up to 25% of attempted retrievals.323,330 In a series of 33 VCF that were unable to be removed, 21 were due to
filter tilt and 12 were due to prolonged dwell time with excessive tissue ingrowth.\textsuperscript{268} The result of these practices is to negate the potential option and benefits of removing the VCF, which has ironically become the most important factor in many physicians’ decision to use these devices.\textsuperscript{185} With the expanding use of retrievable filters at many centers, there remains significant debate about their utility, the optimal timing of removal, and the amount and duration of follow-up that will require further prospective data to answer.\textsuperscript{150,161,297}

**Complications Associated With Vena Cava Filters**

There are a variety of complications that have been described with the currently available devices for VCF. Complications associated with VCFs can be divided into short-term and long-term. Short-term complications are typically associated with the placement procedure and can involve injury or complications at the access site vessel, the site of filter placement, or any location in between. Longer term complications typically arise from the effect of the filter locally or in the proximal veins, or problems with the filter migrating and/or fracturing. It is difficult to understand the true incidence and importance of many of these complications due to the significant variation in patient populations, filter types, comorbid disease burden, and variability in follow-up intensity and duration. Other factors that may influence the type and incidence of complications include the filter material and design, the route and technique of placement, the indication for placement, and the category of filter used (retrievable versus permanent). Although the current literature suggests that retrievable filters have a comparable complication profile to permanent ones, there is significantly less long-term follow-up available for analysis. In addition, retrievable filters have the added issues revolving around the timing of removal, with the resultant potential for complications involving the removal procedure or subsequent PE after filter removal. Table 6 summarizes the overall reported complication rates with VCF, and Fig 15 summarizes selected complication rates for permanent (Fig 15A) and retrievable (Fig 15B) filters in the trauma population. As with any procedure, correct placement or removal of an IVC filter is predicated on preoperative planning and a solid grasp of deployment techniques for the particular filter. As opposed to open procedures where recovery can usually be accomplished via standard methods, there are limited “rescue” options for endovascular procedures.
A

<table>
<thead>
<tr>
<th>Study</th>
<th>Filter Type</th>
<th>No. Patients</th>
<th>Insertion Complications*</th>
<th>Filter Migration</th>
<th>Cava Occlusion</th>
<th>IVC Penetration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Greenfield et al. 2000</td>
<td>53% - Titanium GF 47% - Stainless Steel GF</td>
<td>385 - Initial 293 - Follow-up</td>
<td>24/385 (6%) 6/293 (2%) 7/293 (2.4%) 2/290 (0.6%)</td>
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<td>Patton et al. 1996</td>
<td>100% - Titanium GF</td>
<td>110 - Initial 30 - Follow-up</td>
<td>6/110 (5.4%) 1/110 (0.9%) 9/110 (8.2%)</td>
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<td>Langan et al. 1999</td>
<td>Stainless Steel (not reported %)</td>
<td>167 - Initial 75 - Follow-up</td>
<td>3/187 (1.6%) 0/75 (0%) 0/70 (0%) 1/70 (1.4%)</td>
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<tr>
<td>Rogers et al. 1998</td>
<td>Titanium GF 16% - Stainless Steel GF 8% - Vena Tech Filter 6% - Bird’s Nest Filter</td>
<td>122 - Initial 47 - Follow-up</td>
<td>4/122 (3.3%) - 1/47 (2%)</td>
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</tr>
<tr>
<td>Rodríguez et al. 1996</td>
<td>100% - Titanium GF</td>
<td>40 - Total</td>
<td>- - 4/40 (10%)</td>
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TOTAL 39/914 (4.8%) 7/473 (1.5%) 12/469 (2.5%) 3/363 (0.8%)

*Insertion Complications: Hematoma, Insertion Site DVT, Arterial Puncture, Pneumothorax, Misplaced IVC Filter, Deployment Errors, Puncture Site Infection
Note: GF = Greenfield Filter

B

<table>
<thead>
<tr>
<th>Study</th>
<th>Filter Type</th>
<th>No. Patients</th>
<th>Duration of Insertion (mean (days) (range))</th>
<th>Insertion Complication*</th>
<th>Filter Migration</th>
<th>IVC Penetration</th>
<th>Cava Occlusion</th>
<th>Failed Retrieval Rate</th>
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<td>19 (5-25)</td>
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<td>Gunther Tulip</td>
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<td>0</td>
<td>0</td>
<td>1/25 (4%)</td>
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<td>Gunther Tulip</td>
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<td>14 (3-39)</td>
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<td>0</td>
<td>0</td>
<td>1/40 (2.6%)</td>
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<td>Hoff et al. 2004</td>
<td>Gunther Tulip</td>
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<td>0/35</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0/18</td>
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TOTAL 224 6/224 (2.6%) 1/224 (0.4%) 0 2/114 (2.6%)

* Insertion Complications: Hematomas, Insertion Site DVT, Arterial Puncture, Pneumothorax, Misplaced IVC Filter, Deployment Errors, Puncture Site Infection

FIG 15. Overview of selected complication rates from the literature for both permanent (A) and retrievable (B) vena cava filters. (Adapted with permission from Datta I, Ball CG, Rudmik L, et al. Complications related to deep venous thrombosis prophylaxis in trauma: a systematic review of the literature. J Trauma Outcomes Manag 2010;4:1.)

Misplacement

A cavagram is essential for identifying key landmarks such as the renal veins and allowing correct placement of an IVC filter. There are numerous reports of filters placed in the aorta, the iliac veins, and even the mesenteric veins. The common factor in all of these misplacements is in failure to perform an adequate cavagram or misinterpreting the cavagram. In the case of cannulation of the mesenteric veins, a jugular approach may lead to cannulation of the hepatic veins and into the portal system. In addition to vascular misplacements, recently a report of placement of a filter into the spinal canal has been reported.
In this case, the cavagram was performed by removing the wire from the sheath and then replacing the wire and advancing the sheath over it. After puncture of the vena cava, the sheath was likely pushed into the vertebral foramina.\textsuperscript{332}

The misplacements above reveal that even with digital subtraction imaging with intravenous contrast mistakes do occur. If a sheath is being used for the cavagram and the landmarks cannot be visualized, placing a multi-side hole catheter (pigtail catheter) and using the power injector can often provide excellent imaging. If performing the procedure under transabdominal US or with IVUS, one must be familiar with these techniques as stated above and clearly visualize the landmarks for correct placement.

**Recurrent or “Breakthrough” Pulmonary Embolus**

Table 6 illustrates the various rates of recurrent PE with the different filters in use. It is critical for the managing physician to realize that VCFs do not provide complete protection from subsequent PE. This could be due to primary failure of the filter, embolization of filter thrombus, or embolization from another location such as the upper extremities. The rates vary by report for each filter but generally are low, but these PEs are often fatal. For example, the reported mortality with a recurrent PE in the Venatech filter is up to 50% and with the Bird’s Nest Filter is 90%.\textsuperscript{281,333}

In the 8-year follow-up report from the prospective randomized trial of VCF in patients with DVT (PREPIC trial), there was a documented incidence of 6.2% for recurrent PE in the group with filters in place.\textsuperscript{152}

Twenty percent of these recurrent PE were fatal. A recent analysis of trauma patients who received permanent VCF found a 2.1% incidence of recurrent PE at 105 months of follow-up. Greenfield and colleagues analyzed their prospective database of 2109 consecutive permanent filters and found a recurrent PE incidence of 2%.\textsuperscript{277} Of interest, in this large series, the rates of recurrent PE and DVT were not impacted by the concurrent use of anticoagulation.

Another issue that is becoming more recognized is the risk of PE during or after the retrieval of a removable VCF. The decision about when to remove the VCF is highly subjective and there are no reliable guidelines or objective variables to use in making this decision. PE in this situation can result from dislodgment of clot during the removal procedure or from embolization of a new or existing DVT after the protective filter has been removed. Mahrer and colleagues\textsuperscript{334} analyzed their experience with 37 trauma patients referred for removal of a VCF. They identified significant thrombus in the filter in 8 (22%), which required aborting the attempt at
removal. In the largest published series of retrievable VCF there was noted to be a 2% incidence of “breakthrough” PE while the filters were in place.\textsuperscript{161} In addition, among patients who had a therapeutic filter placed and underwent successful retrieval there was a 6% incidence of nonfatal PE during the follow-up period.

**Perforation**

IVC perforation from filter placement is not uncommon but is not clinically relevant in most instances. The Birds Nest Filter was reported to have caval wall penetration in 83% of cases.\textsuperscript{333} Filter angulation or tilting is often the cause of perforation and is commonly due to undersizing the IVC. Duodenal perforations as well as aortic perforation have been documented with perforation of the IVC.\textsuperscript{335,336} Perforations of the duodenum are usually symptomatic but may be an unusual source of abdominal pain. Duodenocaval fistula is a late complication of IVC filters but can present with life-threatening bleeding. Penetration into the aortic wall may lead to pseudoaneurysm formation and can also lead to mural thrombus formation with distal embolization.\textsuperscript{337}

**Caval Thrombosis**

The reported incidence of caval thrombosis is less than 10% with the newer devices (Fig 15, Table 6) and remains asymptomatic in most patients. It may be difficult to ascertain whether the thrombosis is caused by the filter or the initial DVT. There is continued debate about whether caval thrombosis is related to the presence of a foreign body and obstruction to flow, thus representing a complication of the filter, or whether this is due to the accumulation of emboli caught by the filter, and thus filter success. However, caval thrombosis can cause significant morbidity including lower extremity swelling and edema, renal failure (suprarenal thrombosis), and systemic or pulmonary embolization. Thrombosis of the SVC is of particular concern and can result in the life-threatening sequelae of acute SVC syndrome.

**Migration**

Filters that are not sized appropriately are the cause of migrations. These filters can migrate to the right atrium and ventricle as well as the PA. The Greenfield filter, which has been in existence since 1973 and has been studied more than any other filter, was found to have a migration rate of 3 mm or more in 8% of patients when respiratory variation was considered.\textsuperscript{338} Another cause of migration is placement of central lines or guidewires dislodging a successfully placed IVC. If component fracture
occurs, a filter may migrate many years after placement. Migration of the filter to the cardiac or pulmonary systems requires immediate intervention to remove the device and prevent further complications. This can be attempted by an endovascular approach but may require an open thoracotomy or sternotomy.

**Postthrombotic Syndromes**

There appears to be an increased incidence of proximal vein thrombotic complications (mainly DVT) associated with VCFs. Although the assumption is that this is due to filter-induced changes in venous flow and stasis, others have suggested that this may be due to the patient’s systemic condition and not related to the filter. It does appear that patients with a VCF have roughly double the incidence of DVT compared with patients without VCF. These may be asymptomatic, but frequently result in signs and symptoms of postthrombotic syndrome that can range from mildly irritating to limb-threatening. A recent systematic review of the literature on this topic analyzed 11 articles including over 1500 patients with a mean follow-up of 4.5 years. They found a pooled incidence of edema of 43% and chronic skin changes of 12%. Interestingly, the incidence of these findings was significantly lower among patients who had a VCF placed for prophylactic indications (20% edema, 8% skin changes) compared with those placed for therapeutic indications (51% edema, 14% skin changes). It is unclear at this time whether factors such as compression stocking use or concurrent anticoagulation with VCF will impact the incidence or severity of postthrombotic syndrome.

**Access Site Thrombosis**

Since the newer devices have a lower profile (6-12 Fr) compared with the older filters available (24-28 Fr), the incidence of insertion site thrombosis occurs in only 10% of cases. The incidence appears to be higher in patients with a contraindication to anticoagulation or a known hypercoagulable state. Treatment should be standard anticoagulation if possible and most of these occlusions can be expected to recanalize and resolve. All attempts should be made to minimize vessel manipulation, injury, and the duration of postprocedure compression. As opposed to arterial access, minimal pressure and duration are required for hemostasis of a femoral vein puncture.
Renal Vein Occlusion

Optimal placement of IVC filters is below the renal veins, but suprarenal filters can be placed with similar efficacy as infrarenal filters. However, the potential for renal vein thrombosis should be monitored. This is of particular concern in patients with known hypercoagulable states (such as cancer), preexisting renal dysfunction, or prior renal vein thrombosis. In a series of 13 cancer patients with filters placed in the suprarenal vena cava, there were 2 cases of fatal renal vein thrombosis identified. In addition to these factors, if the patient has a solitary functioning kidney, then a suprarenal filter is not appropriate.

Other Complications

A variety of additional complications can occur with VCFs. Guidewire entrapment in the filter may occur during the placement of a central line or other intravascular procedure. These may be impossible to remove and may require repeat endovascular or open procedures for retrieval. Other mechanical problems with the filter can include strut fracture or filter tilt, which can predispose the device to migration, perforation, or thrombosis. These complications are fortunately uncommon with modern devices, occurring in less than 5% of patients with long-term follow-up. Finally, infection is an extremely rare event with IVC filters but may necessitate prolonged antibiotics, filter removal, or even surgical thrombectomy and drainage.

Recent Developments and Future Directions

Prospective and Controlled Studies

Despite the lack of controlled data and high level evidence-based guidelines for the use of VCFs, they are being increasingly used in a variety of patient populations. This is primarily based on expert opinion, interpretation of uncontrolled data from small series, industry marketing tactics, and the frustration with the failure of currently available methods for the prevention and treatment of VTE. The most important advance that can come about in the near future related to this technology is the design, execution, and reporting of prospective and controlled trials of VCFs. This should include separate analyses of their use in both prophylactic and therapeutic indications, with and without accompanying anticoagulation, and with permanent and retrievable devices. Only then will we be able to make safe, effective, and well-informed decisions about which patients will benefit from...
filter placement and the optimal strategies for managing patients with a filter in place.

**Venous Thromboembolism Chemoprophylaxis and Treatment**

There is much new and ongoing research focused on the development of new agents for chemoprophylaxis and treatment of VTE that could obviate the need for VCFs in some patients. The development of the LMWH agents and fondaparinux has been a great advance, but these agents are limited by their route of administration, efficacy, and limitations with renal dysfunction. Newer agents that target specific elements of the coagulation cascade such as thrombin (dabigatran, etexilate) or factor Xa (rivaroxaban, apixaban) are in advanced stages of development. These can be administered orally, provide reliable and effective levels of anticoagulation, and require no laboratory monitoring in most situations. Validation of these agents as safe and effective alternatives may obviate the need for VCF in some patients, although they will continue to be contraindicated in several surgical populations due to concerns for hemorrhage.

In the setting of acute DVT the use of catheter-directed thrombolysis is becoming more popular and may be used in conjunction with or in place of VCFs. This technique is commonly employed for iliofemoral DVT by passing a wire across the thrombus, placing an infusion catheter with side-holes, and infusing a thrombolytic directly into the thrombus. By employing this method, the amount of thrombolytic given is less than with systemic dosing and several series have reported excellent success rates. The potential benefits of complete clot lysis, the lower incidence of postphlebitic syndrome, and reduced chances for potential PE must be weighed against the potential bleeding complications that may occur with thrombolytics.

**Advanced Filter Design**

There have already been significant advances in the materials and design of modern VCFs. Continued advances in the materials, design, and delivery systems for VCFs may further improve their efficacy and decrease the incidence of complications or adverse effects. There have been significant improvements in the size of the devices and delivery systems to allow placement with less vessel injury and the use of alternative access sites. Advanced imaging for placement and evaluation of these devices such as intravascular US or real-time 3-dimensional US is already being reported. Improvements to the filter
design that minimize or eliminate the problems of filter tilt and tissue ingrowth will decrease the incidence of technical failure during the retrieval process. The development of newer materials for filter construction, such as bioabsorbable or dissolvable frames, may even completely obviate the need for a removal procedure and the long-term risks of a permanent device.

Ensuring Follow-Up and Filter Removal

One of the glaring problems that has been widely identified with the management of retrievable VCFs is the frequent lack of follow-up and failure to remove the device despite no indication for permanency. This is particularly difficult in mobile, transient, uninsured, or less reliable patient populations. The American Association for the Surgery of Trauma multicenter study of retrievable VCF demonstrated that only 28% of patients underwent an attempt at filter removal and the most common reason for this was loss of the patient to follow-up. This concerning finding has been duplicated in multiple other series. It appears that the most important factor for ensuring appropriate follow-up and removal of the device is that the service placing the VCF has an established system and responsibility for patient follow-up and device removal. Johnson and colleagues reported their success in achieving 85% follow-up of military patients who had a retrievable filter placed by having the responsibility for both placement and removal assumed by their vascular surgery service. Ko and colleagues demonstrated the impact of initiating a protocolized process for follow-up and retrieval at their Level 1 trauma center. Their retrieval attempt rate improved from 42% before the protocol to 95% after the protocol. Any facility that is involved in the placement of retrievable VCF should develop a policy and protocol that facilitates follow-up and evaluation for removal, and that identifies the personnel or group responsible for ensuring this happens.

Summary and Conclusions

Surgical populations remain among the highest risks for DVT, PE, and the long-term consequences of VTE. Although VCFs have become an accepted method of preventing new or recurrent PE among at-risk patient populations, there remain little prospective and controlled data to verify and quantify their utility. The advent of retrievable filters has made this technology more attractive to many physicians but also introduces an additional set of variables and decisions that must be considered. Most guidelines agree that the only well-supported indication for placement of a VCF is in the patient with established VTE who cannot be safely
anticoagulated or has failed an adequate trial of anticoagulation. For all other indications, there is significant controversy and disagreement regarding the role of VCFs in surgical patients. This is most commonly encountered with the prophylactic use of VCF in high risk trauma patients, which has become standard practice at many trauma centers despite the lack of supporting data. Until the results of well-controlled trials for this indication become available, we recommend that VCF use should only be used within a well-defined protocol and with strict adherence to the guidelines for placement and follow-up outlined above. We believe that a significant portion of the current VCF use in surgical patients could be avoided by more liberal use of appropriate chemical prophylaxis with little to no adverse effect. However, for well-selected patients the use of a VCF may provide the only effective means of preventing a significant or fatal pulmonary embolic event. There is a particularly alarming rate of poor follow-up for retrievable filters that should be amenable to focused quality improvement initiatives and protocols.

REFERENCES


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