Inferior vena cava filters: a framework for evidence-based use

Amar H. Kelkar and Anita Rajasekhar

Division of Hematology & Oncology, Department of Medicine, University of Florida College of Medicine, University of Florida Health Shands Hospital, Gainesville, FL

Venous thromboembolism (VTE) is a common cause of morbidity and mortality. Although most patients can be managed safely with anticoagulation, inferior vena cava filters (IVCFs) represent an important alternative to anticoagulation in a small subset of patients. IVCF use has expanded exponentially with the advent of retrievable filters. Indications for IVCFs have liberalized despite limited evidence supporting this practice. Because indiscriminate use of IVCFs can be associated with net patient harm, knowledge of the risks and benefits of these devices is essential to optimal evidence-based practice. Patients with acute VTE and absolute contraindications to anticoagulation or major complications from anticoagulation are universally agreed indications for IVCFs. However, the reliance on IVCFs for primary VTE prophylaxis in high-risk patients is not substantiated by the available literature. This review examines trends in IVCF use, practice-based recommendations on IVCF use in various clinical scenarios, complications associated with indwelling IVCFs, and indications for IVCF retrieval.

LEARNING OBJECTIVES

- Review current evidence on therapeutic and prophylactic indications for inferior vena cava filters (IVCFs)
- Summarize immediate, early, and late complications associated with IVCFs
- Discuss considerations for timely IVCF retrieval
- Outline a "best practices" approach to incorporating IVCFs into clinical practice

Introduction

Despite advances in prevention strategies, venous thromboembolism (VTE) remains a leading cause of preventable hospital mortality.[1] In most patients, pharmacologic and/or mechanical thromboprophylaxis are sufficient to prevent VTE. For acute VTE, anticoagulation remains the treatment of choice without need for additional interventions. However, in patients with active bleeding or high risk of bleeding, inferior vena cava filters (IVCFs) are used to mechanically interrupt the inferior vena cava (IVC), thereby preventing pulmonary embolism (PE). Unlike anticoagulation, IVCFs neither treat VTE nor prevent deep vein thrombosis (DVT) or in situ PE.

Designing an IVCF that can be deployed safely, traps thrombi, preserves laminar flow, and minimizes the inherent thrombogenicity of an intravascular device is challenging. IVC interruption advanced over the course of 100 years from surgical IVC ligation to percutaneous placement of permanent filters (eg, Greenfield filter). In 2003, the first retrievable inferior vena cava filter (rIVCF) was approved for patients at risk for VTE with short-term contraindication to anticoagulation. rIVCFs have largely supplanted permanent inferior vena cava filters (pIVCFs), although there is no evidence that they are either safer or more effective.[1] IVCF use has increased due to liberalized indications, bedside placement techniques, increased numbers of specialists with skills of insertion, improved detection of PE with modern imaging, and the unconfirmed belief that rIVCFs are safer than older pIVCFs. Therapeutic indications for IVCFs have increased linearly, whereas placement for prophylactic indications has increased supralinearly.[2] Globally, the United States surpassed the 5 largest European nations in IVCF insertion by 25-fold despite similar annual VTE mortality.[2] Herein, we present safety and efficacy data surrounding IVCFs in common clinical scenarios, complications of IVCFs, considerations for timely IVCF retrieval, and a holistic approach for how to incorporate IVCFs into practice (Figure 1; Table 1).

Indications for IVCF placement

IVCF placement can be grouped into 2 categories: (1) therapeutic indications for known VTE and (2) prophylactic

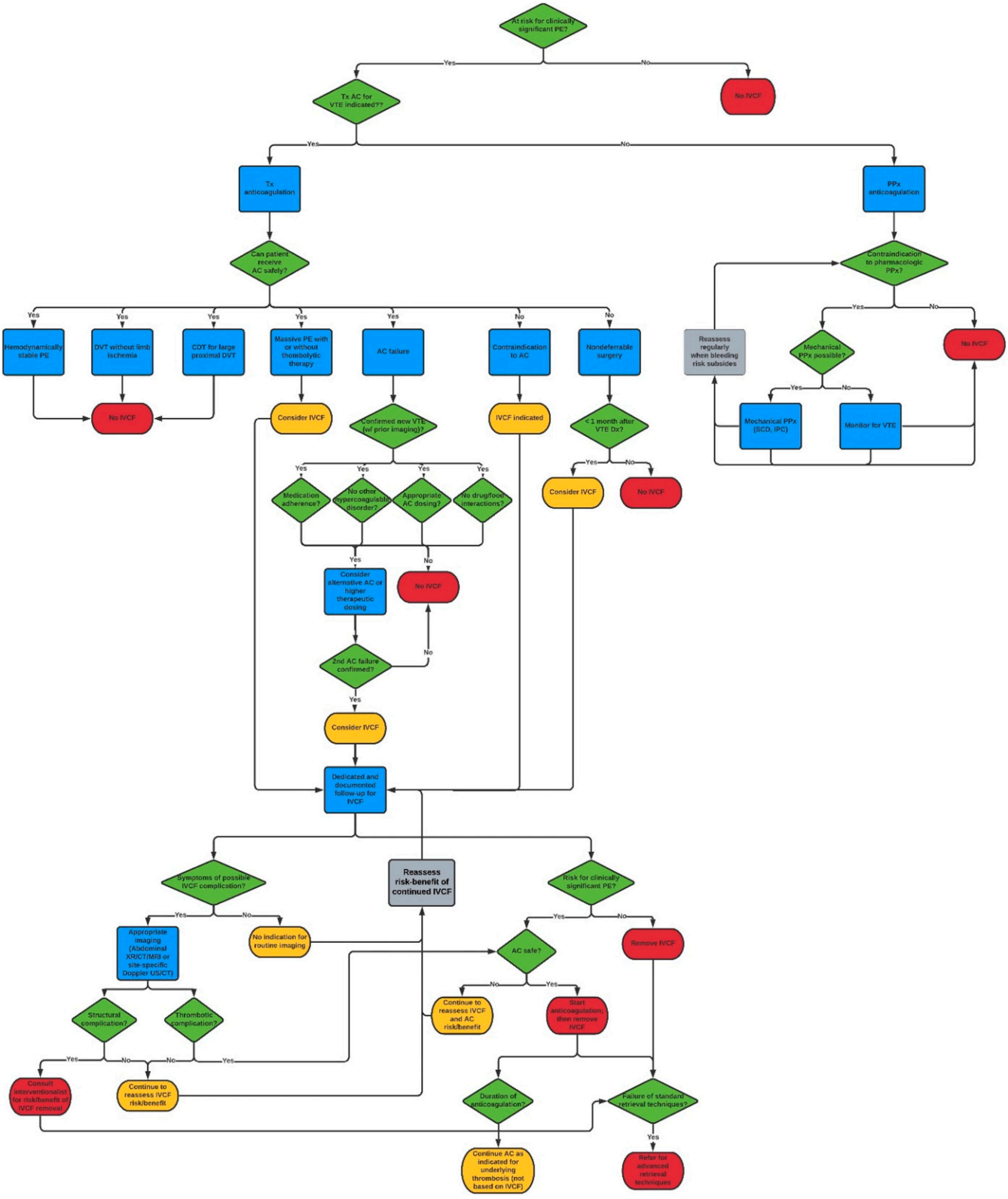

Figure 1. IVCF decision tree. AC, anticoagulation; CT, computed tomography; IPC, intermittent pneumatic device; MRI, magnetic resonance imaging; PPx, prophylaxis; SCD, sequential compression device; Tx, treatment; US, ultrasound; XR, x-ray.

Table 1. Dos, doubts, and don'ts of IVCFs

Do
• Evaluate risks/benefits of AC before considering IVCF placement
• Assess regularly the safety of resuming prophylactic or therapeutic AC in those with initial CI
• Place rIVCF in patients with acute VTE and absolute CI to AC (eg, active major bleeding or major complication while receiving AC)
• Screen for modifiable reasons of AC "failure" in suspected recurrent VTE before considering rIVCF placement
• Document systematic follow-up plan for retrieval at the time of rIVCF insertion
• Schedule periodic assessments for filter integrity and complications
• Report IVCF complications to FDA MAUDE database
• Remove rIVCF as soon as PE risk subsides and/or AC can be resumed safely
• Refer to center with expertise in advanced retrieval techniques if standard techniques fail
Doubt
• Benefit of routine IVCF placement for extended indications (CDT for DVT, massive PE, surgery requiring interruption of AC, free-floating DVT)
• Benefit of long-term AC for the sole purpose of an indwelling IVCF
Don't
• Place IVCFs for primary VTE prophylaxis in high-risk patients (trauma, bariatric surgery, spinal cord injury, high-risk orthopedic surgery)
• Place IVCFs in exquisitely hypercoagulable patients (eg, cancer, APLS) with acute VTE outside of classic indications
• Use permanent IVCFs because most patients have only temporary CI to AC

AC, anticoagulation; APLS, antiphospholipid syndrome; CDT, catheter-directed lysis; CI, contraindication; FDA MAUDE, US Federal Drug Administration Manufacturer and User Facility Device Experience.

indications for patients labeled "high risk" for VTE. Because of a dearth of high-quality studies, recommendations from clinical practice guidelines are incongruent, leading to wide practice variation (Table 2).[3-15]

IVCFs for therapeutic indications

Case 1

A 63-year-old-man presents 2 days after a fall with headache, vision changes, and nausea. Computed tomography of his head reveals an acute, moderate-sized right subdural hematoma (SDH) without midline shift. Two days after admission, he complains of right leg tenderness and is diagnosed with an acute right iliofemoral vein DVT. The result of computed tomography with pulmonary angiography is negative for pulmonary embolism. An IVCF is considered.

The standard of care in patients with acute VTE is therapeutic anticoagulation.[8] However, when anticoagulation is contraindicated, such as in major bleeding or emergent surgery, anticoagulation may be delayed or interrupted. Estimated rates of recurrent VTE without anticoagulation are 40% in the first month and 10% in the second and third month after the diagnosis of acute VTE.[16] Large observational studies evaluating the benefit of IVCFs in patients with acute VTE and contraindications to anticoagulation have reported conflicting results, and no prospective studies have been performed.[17,18] Nevertheless, as in case 1, therapeutic IVCF placement for acute VTE with contraindication to anticoagulation is the only consensus indication for routine IVCF placement.[4-9,11,13-15] In some cases in which therapeutic anticoagulation is temporarily contraindicated, prophylactic dose anticoagulation with titration to a therapeutic dose may be preferable to IVCF placement.

Data on the use of IVCFs in patients with known VTE come predominantly from 2 randomized controlled trials (RCTs) that explored IVCFs as an adjunct to therapeutic anticoagulation (Table 3).[19-21] In PREPIC, patients randomized to a pIVCF compared with no filter had a sustained reduction in PE at the cost of long-term increase in DVT and no change in mortality. This benefit would likely be diminished with currently recommended durations of anticoagulation for similar high-risk patients.[19,20] In PREPIC 2, the low rate of recurrent PE observed in the nonfilter group is consistent with successful contemporary therapeutic anticoagulation.[21] Taken together, the results of PREPIC and PREPIC 2 do not provide justification for routine IVCF placement for VTE that can be treated with anticoagulation.

Extended IVCF indications in patients with VTE

Cancer-associated thrombosis

Malignancy is an independent risk factor for VTE. The increasing incidence of VTE is possibly due to longer survival of patients with cancer, administration of prothrombotic systemic therapies, and improved VTE diagnostic measures. The high frequency of recurrent VTE and bleeding cannot be explained by over- or under-anticoagulation.[13] Low-molecular-weight heparins or direct oral anticoagulants are the preferred anticoagulants for cancer-associated thrombosis.[22] A meta-analysis found no difference in recurrent VTE in patients with cancer receiving an IVCF as an adjunct to anticoagulation.[23] A small RCT explored the benefits of an IVCF in addition to fondaparinux compared with fondaparinux alone in patients with cancer with acute DVT and reported higher DVT resolution rates in the nonfilter arm without any difference in PE, DVT, or 90-day mortality.[24] Furthermore, because the hypercoagulable state of cancer affects all vascular beds, regional therapies, such as IVCFs, are likely insufficient for prevention of recurrent thrombosis and may instead be thrombogenic. Nevertheless, patients with cancer are twice as likely as patients without cancer to receive an IVCF, and retrieval rates are lower.[25] Evidence-based guidelines recommend against the routine

Table 2. Comparison of clinical practice guidelines for IVCF indications

Proposed indications	EAST, 2002[3]	BSH, 2006[4]	AHA, 2011[5]	ESC, 2014[6]	ACCP, 2012[7]/ 2016[8]	ISTH, 2013[9]	ESA, 2018[10]	ACR, 2019[11]	ASH, 2019[12]	ASCO, 2019[13]	NICE, 2020[14]	SIR, 2020[15]
Acute VTE without CI to AC	NR	Not supported (grade A, level 1b)	NR	Not supported (class III, level A)	Not supported (grade 1B)	Not supported	NR	NR	NR	NR	Not supported	Not supported
VTE and CI to AC	NR	Supported (grade B, level III)	Supported (class I, level B)	Supported (class IIa, level C)	Supported (grade 1B)	Supported if high-risk PE	NR	Supported	NR	Supported if life-threatening acute VTE (within 4 wk). Moderate recommendation, low-quality evidence	May be appropriate	Supported
Acute VTE and major complication of AC	NR	NR	Supported (class I, level B)	NR	NR	Supported	NR	Supported	NR			Supported
Recurrent VTE despite appropriate AC ("failure of AC")	NR	May be appropriate after alternative AC discussed (grade C, level IV)	May be appropriate (class IIa, level C)	Supported (class IIa, level C)	NR	NR	NR	Supported	NR	May be appropriate. Weak recommendation, low-quality evidence	May be appropriate after other options explored	Not supported
CTEPH	NR	NR	NR	Not supported	NR	NR	NR	May be appropriate if CI to AC	NR		NR	NR
Nondeferrable surgery requiring AC interruption with recent history of VTE (<1 mo)	NR	May be appropriate (grade C, level IV)	NR	NR	NR	NR	May be appropriate (grade 2C)	NR	NR	Not supported. Moderate recommendation, low-quality evidence	NR	NR
Thrombolysis for DVT	NR	Not supported (grade C, level IV)	Not supported (class III, level C)	NR	NR	NR	NR	May be appropriate	NR		NR	May be appropriate
Poor cardiopulmonary reserve (eg, massive PE)	NR	NR	May be appropriate (class IIb, level C)	Not supported	May be appropriate	NR	NR	May be appropriate	NR		NR	May be appropriate
Free-floating iliofemoral or IVC thrombus	NR	Not supported (grade B, level III)	NR	Not supported	NR	NR	NR	May be appropriate	NR		NR	NR
Patient with cancer with acute VTE as an adjunct to AC	NR	Not supported	NR	May be appropriate if AC CI	NR	Not supported	NR	Not supported	NR		NR	NR
Primary prophylaxis trauma	Supported if PP CI (level III)	NR	NR	NR	Not supported (grade 2C)	NR	May be appropriate if PP/MP CI (grade 2C)	May be appropriate	Not supported		NR	Not supported
Primary prophylaxis bariatric surgery	NR	NR	NR	NR	Not supported (grade 2C)	NR	May be appropriate if PP/MP CI (grade 2C)	May be appropriate	Not supported		NR	Not supported
Primary prophylaxis high-risk orthopedic surgery	NR	NR	NR	NR	Not supported (grade 2C)	NR	May be appropriate if PP/MP CI (grade 2C)	May be appropriate	Not supported		NR	Not supported

AC, anticoagulation; ACCP, American College of Chest Physicians; ACR, American College of Radiology; AHA, American Heart Association; ASCO, American Society of Clinical Oncology; ASH, American Society of Hematology; BSH, British Committee for Standards in Haematology; CI, contraindicated; CTEPH, chronic thromboembolic pulmonary hypertension; EAST, Eastern Association for the Surgery of Trauma; ESA, European Society of Anaesthesiology; ESC, European Society of Cardiology; ISTH, International Society on Thrombosis and Haemostasis; MP, mechanical prophylaxis; NICE, National Institute for Health and Care Excellence; NR, not reported; PP, pharmacologic prophylaxis; SIR, Society of Interventional Radiology.

Table 3. RCTs on efficacy and safety of IVCFs

	Study/year	Population	Intervention	Comparator	Outcome in IVCF group vs non-IVCF group (ratios presented with 95% CI)
Therapeutic trials	Decousus, PREPIC 1998,[19] 2005[20]	Acute proximal DVT ± PE	Permanent IVCF + therapeutic AC	Therapeutic AC	12 d PE, 1.1% vs 4.8% OR, 0.22 (0.05-0.90); *P* = .03 2 y Symptomatic PE, 3.4% vs 6.3% OR, 0.5 (0.19-1.33); *P* = .16 DVT, 20.8% vs 11.6% OR, 1.87 (1.10-3.20); *P* = .02 8 y Symptomatic PE, 6.0% vs 15.0% HR, 0.37 (0.17-0.79); *P* = .008 DVT, 35.7% vs 27.5% HR, 1.52 (1.02-2.27); *P* = .042 No difference in mortality at 12 d, 2 y, 8 y
	Barginear, 2012[24]	Patients with cancer with acute DVT ± PE	Permanent IVCF + therapeutic AC	Therapeutic AC	2 mo DVT, 64% vs 58%; *P* = .63 PE, 24% vs 24.8%; *P* = NS DVT resolution, 37.5% vs 61%; *P* = .02 No difference 90-d mortality or major bleeding
	Sharifi, 2012[30] PEVI-CDT	Proximal DVT undergoing PEVI	PEVI + IVCF + AC	PEVI + AC	24 h after PEVI Iatrogenic symptomatic PE, 1.4% vs 11.3%; *P* = .048 No difference in mortality
	Mismetti, PREPIC2 2015[21]	Symptomatic PE and lower-limb vein thrombosis + additional risk factor for severity	Retrievable IVCF + therapeutic AC	Therapeutic AC	3 mo Recurrent PE, 3% vs 1.5%; RR, 2.00 (0.51-7.89); *P* = .50 6 mo Recurrent PE, RR 1.75 (0.52-5.88); *P* = .54 No difference in recurrent DVT, major bleeding, or mortality at 3 or 6 mo
Prophylaxis trials	Rajasekhar, 2011[39]	High-risk trauma without VTE	Retrievable IVCF + pharmacologic prophylaxis	Pharmacologic prophylaxis	6 mo PE, 0 vs 1 DVT, 1 vs 0 No difference in mortality
	Ho, 2019[40]	High-risk trauma without VTE and CI to AC	Retrievable IVCF	No IVCF	90 d Composite symptomatic PE or death 13.9% vs 14.4%; HR, 0.99 (0.51 to 1.94); *P* = .98 Mortality, 13.1% vs 9.3%; RR, 1.41 (0.69-2.87)

AC, anticoagulation; CDT, catheter-directed lysis; CI, confidence interval; HR, hazard ratio; OR, odds ratio; RR, relative risk.

use of IVCFs in cancer-associated thrombosis outside of classic indications.[9,13]

Anticoagulation failure

Recurrent VTE while receiving therapeutic anticoagulation is uncommon and often represents inadequate treatment or noncompliance. Patients with suspected recurrent VTE should continue therapeutic anticoagulation without IVCF placement, ensuring attention to proper dosing, malabsorption issues, medication adherence, and potential drug or food interactions that may reduce anticoagulant efficacy. Current and past imaging should be compared to distinguish acute from chronic thrombosis. In confirmed anticoagulation failure, it is preferable to use alternative anticoagulants or dose escalation.[8] In such

cases, hypercoagulable conditions, such as active malignancy, antiphospholipid syndrome, heparin-induced thrombocytopenia, paroxysmal nocturnal hemoglobinuria, or myeloproliferative syndromes, should be explored.[26] In prothrombic conditions, IVCFs will not prevent recurrent VTE and may serve as a thrombotic stimulus. Data from the PREPIC and PREPIC2 provide ample evidence that supplementing anticoagulation with IVCFs did not improve outcomes.[19-21] Recurrent lower-extremity DVT or non–catheter-related upper-extremity DVT in the same location, especially in young patients, should prompt evaluation for vascular anomalies such as May-Thurner syndrome (abnormal compression of the left common iliac vein by the right iliac artery) or Paget-Schroetter syndrome (thoracic outlet syndrome). In these anatomic variants, thrombolysis, pharmacomechanical thrombectomy, endovascular stenting, and decompressive surgery are preferred interventions over IVCFs, which can exacerbate the underlying chronic obstruction to venous flow.[26]

Interruption of anticoagulation

IVCFs have been proposed for major surgery requiring interruption of anticoagulation. Clinicians must determine if the surgery is urgent or elective and the necessary duration off anticoagulation. If surgery can be delayed to allow completion of 3 months of therapeutic anticoagulation or if anticoagulation will be held for only a short period of time (eg, <48 hours for a low–bleeding risk procedure), aggressive pharmacologic prophylaxis with dose escalation to therapeutic doses may be preferred over an IVCF. If the surgery cannot be deferred in the setting of recently diagnosed DVT (≤30 days), an rIVCF can be considered.[4,10] The rationale for this approach is based on the estimated 40% risk of VTE recurrence in the first month after diagnosis.[16] If an rIVCF is placed, a systematic plan should be delineated before insertion to ensure timely removal and avoid filters being left indwelling permanently. Beyond 30 days, VTE recurrence risk is reduced, and thus the risks of IVCF at that point likely outweigh the benefits.

Other extended indications

Patients with massive PE (large-volume PE accompanied by hemodynamic instability) are considered at high risk for fatal recurrent PE and thus are potential candidates for rIVCFs. The concern is that additional PE could lead to poor outcomes due to limited cardiopulmonary reserve. However, most patients with massive PEs will receive emergent systemic or catheter-directed thrombolysis (CDT) and promptly experience reduced thrombus burden, questioning the utility of an IVCF at that point. Large registry studies have provided mixed results but overall have demonstrated short-term survival benefit in patients with massive PE, regardless of thrombolytic use.[27] However, given the inherent selection and survival biases of registry studies, we cannot currently recommend routine use of rIVCFs as short-term adjuncts to anticoagulation and thrombolysis.[5,8,15,27]

IVCF deployment before CDT has been suggested as an appropriate indication. Retrospective studies of CDT combined with IVCFs showed no difference in PE or mortality compared with CDT alone, but increased complications were noted in patients who had filters placed.[28,29] Conversely, the FILTER-PEVI RCT demonstrated that IVCFs lowered the incidence of immediate post-procedural symptomatic PE without mortality benefit compared with patients receiving anticoagulation alone.[30] The authors advised a selective approach to filter placement in those with specific predictors of PE. IVCFs have also been considered for proximal free-floating DVT; however, anticoagulation alone is sufficient for treatment.[4,6]

IVCFs for primary prophylaxis

IVCF placement for primary VTE prophylaxis is controversial but accounts for more than half of IVCFs placed in the United States.[31] The rationale for inserting a prophylactic IVCF is to offer mechanical protection against PE during the limited high-risk period when pharmacologic prophylaxis may be contraindicated.

Case 2

A 42-year-old morbidly obese woman (body mass index, 55 kg/m^2) presents for elective gastric bypass surgery. She has no personal or family history of VTE. The surgeon asks whether a rIVCF preoperatively for VTE prophylaxis is appropriate.

VTE is an important cause of preventable postoperative mortality after bariatric surgery owing to obesity, immobility, surgery, and possible underdosing with standard pharmacologic prophylaxis. The reported incidence of DVT is 1% to 3% and that of PE is 0.3% to 2%, but mortality with PE may be as high as 40%.[32] Incidence of PE is highest within 1 month after bariatric surgery and may occur despite pharmacologic prophylaxis. A practice pattern survey revealed that 28% of respondents used IVCFs routinely before bariatric surgery.[33] No RCTs of prophylactic IVCFs in this population exist, leading to incongruent guideline recommendations.[7,12,15] A National Inpatient Sample study and a meta-analysis reported no difference in PE, increased rates of DVT, and increased risk of mortality, calling into question empiric placement of IVCFs before bariatric surgery.[32,34] Therefore, in case 2, aggressive pharmacologic prophylaxis rather than an IVCF should be used for prevention of postoperative VTE.

A similar lack of benefit of prophylactic placement of IVCFs is apparent in other high-risk surgical patients. In major trauma, VTE occurs in up to 58% of patients without thromboprophylaxis.[35] Although pharmacologic prophylaxis is effective and unanimously recommended by evidence-based guidelines, many patients with trauma have ongoing or perceived risk of bleeding and are not considered to be candidates for initial anticoagulation, owing to their underlying injuries.[3,7,12] Conflicting guidelines on IVCF use in patients with trauma has led to inconsistent practice patterns.[3,7,10-12] Three meta-analyses and 2 RCTs did not demonstrate a reduction in fatal PE or death with prophylactic IVCF placement in patients with trauma (Table 3).[36-40] In recent years, IVCF use in patients with trauma has declined without an increase in PE rates, further supporting a restrictive strategy.[41] For additional information on IVCF use in trauma, refer to the evidence-based minireview in Hematology 2020.[42]

Prophylactic IVCFs also have unproven benefit perioperatively in patients undergoing spinal surgery, total hip arthroplasty, or total knee arthroplasty and are therefore not recommended.[7,11,12,15] Importantly, IVCF insertion may lead to a delay in initiation of pharmacologic prophylaxis.

IVCF-related complications

Case 3

A 39-year-old man presents with abdominal pain and melena. He has a history of rIVCF placement 7 years ago for primary VTE prevention after a motor vehicle accident. The IVCF was never removed. Computed tomography of his abdomen and pelvis

Table 4. Complications associated with IVCFs

	Complications	Definition*	Reported Rates*	Comments
Immediate	Insertion problems	Incomplete filter opening, filter tilt more than 15 degrees from the IVC axis, misplacement of filter outside the intended area, or prolapse of filter components	5%-23%	Filter tilt may contribute to impaired filtration efficiency and increased difficulty with removal.
	Pneumothorax	Pneumothorax developing after filter insertion due to filter or guidewire complications	0.02%	
	Air embolism	Air embolism of the pulmonary arteries developing after filter insertion	0.2%	
	Carotid artery puncture	Carotid artery puncture developing after filter insertion due to filter or guidewire complications	0.04%	
	Arteriovenous fistula	Arteriovenous fistula developing after filter insertion due to filter or guidewire complications	0.02%	
	Insertion site hematoma	Hematoma developing at the venotomy site after filter insertion	0.6%	
Early	Insertion site thrombosis	Thrombus developing at the venotomy site after filter insertion	0-25%	
	Infection	Infection developing at or from the venotomy site after filter insertion		
Late	Filter migration	Movement of the filter >2 cm from its initial placement position	0-18%	In extreme migration, embolization of the entire filter or strut components to a distant anatomic location have been reported (0.1%).
	IVC penetration or perforation	Filter component extending >3 mm beyond the caval wall or into an adjacent structure	0-41%	Limited IVC wall penetration is required to secure the struts of an IVCF at the desired location during deployment. Risk can be reduced by using fluoroscopy during interventional radiology procedures and straight-tipped guidewires. Conical devices are associated with higher IVC perforation.
	Filter/IVC thrombosis	Acute or chronic thrombus in the IVC or filter after filter insertion	2%-30%	Thrombus can be related to new local thrombus, trapped embolus within IVCF, or extension of a distal DVT proximally. Histopathologic evidence of thrombus is evident on removed IVCFs within 2-11 d after placement. Risk increases with time. Cylindrical or umbrella-shaped filters have more IVC occlusion. For diagnosis, contrast-enhanced CT is most useful, whereas ultrasound has limited value. Venography should be limited to when catheter-directed intervention is pursued.
	Recurrent DVT	Thrombosis of proximal lower extremities after filter insertion	5%-35%	
	PE	Thrombosis of pulmonary arteries after filter insertion	0.5%-6%	
	Post-thrombotic syndrome	Post-thrombotic syndrome of the proximal lower-extremity vessels developing after filter insertion	15%-40%	
	Filter tilting or fracture	Filter tilting or fracture occurring after filter insertion		
	Entrapment of guidewire	Entrapment of guidewire after filter insertion		

CT, computed tomography.
*Definitions and reported rates modified from BSH 2006,[4] Angel 2011,[31] and Caplin 2011.[43]

Table 5. IVCF research portfolio and priorities

Ongoing studies and outcomes
• PRESERVE (NCT02381509) - Prospective observational study of safety and effectiveness of 6 commercially available permanent and retrievable IVCFs
• RIPT (NCT03070834) - RCT comparing rIVCF vs no rIVCF for primary VTE prophylaxis in trauma
• Safety and Efficacy Study of Fitaya Vena Cava Filter (NCT03691753) - RCT comparing implantation success and prevention of VTE between 2 rIVCFs
• EPICT (NCT04066764) - RCT in patients with IVCF comparing VKA vs DOAC for prevention of VTE and filter-related thrombosis
• FILTER (NCT01158482) - Prospective observational study of outcomes of IVCF placement and removal procedure
• Inferior Vena Cava Filters: Analysis of a Database (NCT04330170) - Retrospective observational cohort study of IVCF occlusion and filter removal rates
• REFiVeC (NCT02757001) - Prospective observational registry evaluating successful planned retrieval and adverse events during dwell time
• Bioconvertible Sentry IVC Filter (NCT04208139) - Prospective observational study of patency and thrombus formation of a bioabsorbable filter
Future research priorities (When RCTs are not feasible/ethical, then prospective observational studies should be undertaken.)
• Does rIVCF vs no rIVCF prevent post-procedural PE in patients undergoing advanced therapies (eg, thrombolysis for massive PE or phlegmasia cerulea dolens)?
• Does rIVCF vs no rIVCF prior to urgent/emergent major surgery in patients with acute VTE (<1 mo) improve postoperative PE rates?
• Does rIVCF vs no rIVCF in high-risk patients without VTE and contraindication to pharmacologic/mechanical VTE prophylaxis affect mortality or symptomatic PE rates?
• Does change in AC (dose or drug) vs rIVCF in patients with confirmed recurrent VTE despite therapeutic AC reduce recurrent VTE or mortality rates?
• Standardized criteria for optimal retrieval strategies (including time frame for retrieval and preprocedure imaging)
• Cost-effectiveness studies in patients with therapeutic or prophylactic IVCFs
• Multi-institutional clinical IVCF registry for systematic and standardized reporting of efficacy, safety, and complications
• What is the most effective system-, provider-, and patient-focused structured follow-up program that maximizes IVCF retrieval rates?
• In patients with IVCFs left indwelling long term, does extended duration AC vs no AC reduce thrombotic IVCF complications?

AC, anticoagulation; DOAC, direct oral anticoagulant; VKA, vitamin K antagonist.

reveals IVCF tines extending beyond the wall of the IVC into the lumen of the duodenum. Esophagogastroduodenoscopy confirms that the IVCF perforated the distal duodenum with evidence of recent bleeding. General surgery is consulted for laparotomy with IVCF removal.

Recognizing the paucity of evidence showing benefit of IVCFs in most circumstances, providers must consider the mounting evidence for adverse events with these devices. Complications may occur in the immediate post-procedural period, early after IVCF placement, or years later (Table 4). Immediate and early complications are uncommon, and fatal complications are rare, occurring in only 0.12% of insertions.[43] Late complications are more common, particularly when filters are left indwelling beyond when risk–benefit analysis favors removal. Recurrent DVT, even in patients who are receiving anticoagulation, may reflect filter-mediated changes in venous flow, the underlying hypercoagulable condition of the patient, or a synergistic effect of both. Furthermore, PE can still occur despite the presence of an IVCF due to thrombus extension proximally off the device.

From 2009 to 2012, 1606 IVCF-related adverse events were reported to the US Food and Drug Administration Manufacturer and User Facility Device Experience database on IVCF complications.[44] These rates likely underestimate the true incidence of complication rates because reporting is voluntary. Published rates of specific IVCF complications are disparate due to variance in filter types, follow-up duration, complication definitions, use of concurrent anticoagulation, and use of screening imaging. Thrombotic and device-related adverse events are 6 times more likely to be reported with indwelling rIVCFs than with pIVCFs (86.8% vs 13.2%; $P < .0001$).[44] Optimal management of nonthrombotic device-related complications is unknown. Management decisions should be made in collaboration with the interventionalist on a case-by-case basis, weighing risks of intervention vs continued monitoring in asymptomatic patients.

Retrieval

Case 1b

The patient in case 1 with acute SDH and acute lower-extremity DVT has an rIVCF placed. He recovers gradually from SDH without operative intervention. Two weeks later, neurosurgery is comfortable with initiating anticoagulation. The patient remains stable after initiation of therapeutic anticoagulation without any signs of recurrent bleeding.

Over 50% of IVCFs are placed for temporary prevention of VTE, but only 12% to 45% are retrieved.[45] This reflects a combination of overconfidence in the long-term safety of indwelling rIVCFs, lack of provider and patient education on the importance of retrieving filters, and loss to follow-up.[31,45] When attempted, >90% of IVCF retrievals are successful in the first month. At 12 months, the success rate drops to 37%.[31] Procedural factors associated with retrieval failure include prolonged dwelling time, advanced patient age, filter tilting, adherence to the IVC

wall, or large clot volume within the filter.[31] Clinical factors that influence the rate of IVCF retrieval include comorbidities, concurrent anticoagulation, insurance coverage, primary indication for placement, and documented plans for removal.[45] The urgency of early retrieval was highlighted in a 2014 US Food and Drug Administration safety alert.[46] Though no guidelines recommend a specific time frame for removal, a decision analysis study found that retrieval between 29 and 54 days after insertion was optimal.[47] Notably, an IVCF left indwelling permanently is not of itself an indication for indefinite anticoagulation.[4,7] The underlying thrombotic event and perceived bleeding risk should guide duration of anticoagulation.

To improve provider- and system-related factors associated with low retrieval rates, providers have focused on increased clinician education and oversight, novel technical aspects of retrieval, and streamlining systems-based approaches for patient follow-up.[44,48] Poor patient education is a barrier to IVCF removal. In one qualitative study 12% of patients interviewed were not aware of having an IVCF, 77% did not know an IVCF can be removed, and 79% were not aware of long-term risks of IVCFs, highlighting patient education and engagement as an important strategy to improve retrieval rates.[49] Ultimately, the decision to retrieve an IVCF should be based on the patient's current risk of thrombosis and bleeding risk with anticoagulation. In case 1b, the patient has initiated anticoagulation for DVT without progression of SDH; therefore, IVCF retrieval should be planned. Optimizing appropriate IVCF removal requires a collaborative approach with multidisciplinary providers and shared decision making with the patient.

Conclusion

Despite the availability of safe and effective anticoagulants, a small group of patients with acute VTE and absolute contraindication to anticoagulation will continue to require IVCFs. However, for extended indications, there is insufficient evidence to support routine IVCF use. If IVCFs are employed, close follow-up is vital with attention to resumption of anticoagulation when safe, monitoring for filter complications, and IVCF removal when no longer needed. Further research is essential to address these popular, but overall unsubstantiated, devices (Table 5). Until well-designed trials are available, IVCFs will remain a contentious topic. Clearly, a "more is better" approach is not appropriate when incorporating IVCFs into clinical practice, and therefore clinicians must assimilate the available evidence to make case-by-case decisions.

Conflict-of-interest disclosures

A.R. has served on advisory boards for Alexion, Baxter, Bayer, Kedrion Biopharma, and Octapharma Plasma. A.H.K. declares no competing financial interests.

Off-label drug use

None disclosed.

Correspondence

Anita Rajasekhar, University of Florida – Shands Hospital, 1600 SW Archer Rd, Gainesville, FL 32610; e-mail: rajasa@medicine.ufl.edu.

References

1. Rajasekhar A, Streiff MB. Use of vena cava filters and venous access devices. In: Kitchens CS, Kessler CM, Konkle BA, Streiff MB, Garcia DA, eds. Consultative Hemostasis and Thrombosis. 4th ed. Philadelphia, PA: Elsevier Inc.; 2019:594-636
2. Wang SL, Lloyd AJ. Clinical review: inferior vena cava filters in the age of patient-centered outcomes. *Ann Med*. 2013;45(7):474-481.
3. Rogers FB, Cipolle MD, Velmahos G, Rozycki G, Luchette FA. Practice management guidelines for the prevention of venous thromboembolism in trauma patients: the EAST practice management guidelines work group. *J Trauma*. 2002;53(1):142-164.
4. Baglin TP, Brush J, Streiff M; British Committee for Standards in Haematology Writing Group. Guidelines on use of vena cava filters. *Br J Haematol*. 2006;134(6):590-595.
5. Jaff MR, McMurtry MS, Archer SL, et al; American Heart Association Council on Arteriosclerosis, Thrombosis and Vascular Biology. Management of massive and submassive pulmonary embolism, iliofemoral deep vein thrombosis, and chronic thromboembolic pulmonary hypertension: a scientific statement from the American Heart Association. *Circulation*. 2011;123(16):1788-1830.
6. Konstantinides SV, Torbicki A, Agnelli G, et al; Task Force for the Diagnosis and Management of Acute Pulmonary Embolism of the European Society of Cardiology (ESC). 2014 ESC guidelines on the diagnosis and management of acute pulmonary embolism. *Eur Heart J*. 2014;35(43):3033-3080.
7. Guyatt GH, Akl EA, Crowther M, Gutterman DD, Schuünemann HJ; American College of Chest Physicians Antithrombotic Therapy and Prevention of Thrombosis Panel. Executive summary: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines [published correction appears in *Chest*. 2012;141(4):1129; published correction appears in *Chest*. 2012;142(6):1698]. *Chest*. 2012;141(2 suppl):7S-47S.
8. Kearon C, Akl EA, Ornelas J, et al. Antithrombotic therapy for VTE disease: CHEST Guideline and Expert Panel Report. *Chest*. 2016;149(2):315-352.
9. Farge D, Debourdeau P, Beckers M, et al. International clinical practice guidelines for the treatment and prophylaxis of venous thromboembolism in patients with cancer. *J Thromb Haemost*. 2013;11(1):56-70.
10. Comes RF, Mismetti P, Afshari A; ESA VTE Guidelines Task Force. European guidelines on perioperative venous thromboembolism prophylaxis: inferior vena cava filters. *Eur J Anaesthesiol*. 2018;35(2):108-111.
11. Minocha J, Smith AM, Kapoor BS, et al; Expert Panel on Interventional Radiology. ACR Appropriateness Criteria® radiologic management of venous thromboembolism-inferior vena cava filters. *J Am Coll Radiol*. 2019;16(5 suppl):S214-S226.
12. Anderson DR, Morgano GP, Bennett C, et al. American Society of Hematology 2019 guidelines for management of venous thromboembolism: prevention of venous thromboembolism in surgical hospitalized patients. *Blood Adv*. 2019;3(23):3898-3944.
13. Key NS, Khorana AA, Kuderer NM, et al. Venous thromboembolism prophylaxis and treatment in patients with cancer: ASCO clinical practice guideline update. *J Clin Oncol*. 2020;38(5):496-520.
14. National Institute for Health and Care Excellence (NICE). Venous thromboembolic diseases: diagnosis, management and thrombophilia testing. NICE guideline [NG 158]. 26 March 2020.
15. Kaufman JA, Barnes GD, Chaer RA, et al. Society of Interventional Radiology clinical practice guideline for inferior vena cava filters in the treatment of patients with venous thromboembolic disease: developed in collaboration with the American College of Cardiology, American College of Chest Physicians, American College of Surgeons Committee on Trauma, American Heart Association, Society for Vascular Surgery, and Society for Vascular Medicine. *J Vasc Interv Radiol*. 2020 Oct;31(10):1529-1544. doi:10.1016/j.jvir.2020.06.014.
16. Kearon C, Hirsh J. Management of anticoagulation before and after elective surgery. *N Engl J Med*. 1997;336(21):1506-1511.
17. Zektser M, Bartal C, Zeller L, et al. Effectiveness of inferior vena cava filters without anticoagulation therapy for prophylaxis of recurrent pulmonary embolism. *Rambam Maimonides Med J*. 2016;7(3):e0019.
18. Turner TE, Saeed MJ, Novak E, Brown DL. Association of inferior vena cava filter placement for venous thromboembolic disease and a contraindication to anticoagulation with 30-day mortality. *JAMA Netw Open*. 2018;1(3):e180452.
19. Decousus H, Leizorovicz A, Parent F, et al; Prévention du Risque d'Embolie Pulmonaire par Interruption Cave Study Group. A clinical trial of vena caval filters in the prevention of pulmonary embolism in patients with proximal deep-vein thrombosis.*N Engl J Med*. 1998;338(7):409-416.
20. PREPIC Study Group. Eight-year follow-up of patients with permanent vena cava filters in the prevention of pulmonary embolism: the PREPIC (Prevention du Risque d'Embolie Pulmonaire par Interruption Cave) randomized study. *Circulation*. 2005;112(3):416-422.
21. Mismetti P, Laporte S, Pellerin O, et al; PREPIC2 Study Group. Effect of a retrievable inferior vena cava filter plus anticoagulation vs anticoagulation alone on risk of recurrent pulmonary embolism: a randomized clinical trial. *JAMA*. 2015;313(16):1627-1635.

22. Ay C, Beyer-Westendorf J, Pabinger I. Treatment of cancer-associated venous thromboembolism in the age of direct oral anticoagulants. *Ann Oncol*. 2019;30(6):897-907.
23. Rojas-Hernandez CM, Zapata-Copete JA, García-Perdomo HA. Role of vena cava filters for the management of cancer-related venous thromboembolism: systematic review and meta-analysis. *Crit Rev Oncol Hematol*. 2018;130:44-50.
24. Barginear MF, Gralla RJ, Bradley TP, et al. Investigating the benefit of adding a vena cava filter to anticoagulation with fondaparinux sodium in patients with cancer and venous thromboembolism in a prospective randomized clinical trial. *Support Care Cancer*. 2012;20(11):2865-2872.
25. Abtahian F, Hawkins BM, Ryan DP, et al. Inferior vena cava filter usage, complications, and retrieval rate in cancer patients. *Am J Med*. 2014; 127(11):1111-1117.
26. Schulman S. How I treat recurrent venous thromboembolism in patients receiving anticoagulant therapy. *Blood*. 2017;129(25):3285-3293.
27. Zuin M, Rigatelli G, Zonzin P, Roncon L. Inferior vena cava filters in hemodynamically unstable patients with acute pulmonary embolism: how often are they used? Data from multicenter prospective registries on acute pulmonary embolism. *Cardiovasc Intervent Radiol*. 2019;42(8):1073-1079.
28. Avgerinos ED, Hager ES, Jeyabalan G, Marone L, Makaroun MS, Chaer RA. Inferior vena cava filter placement during thrombolysis for acute iliofemoral deep venous thrombosis. *J Vasc Surg Venous Lymphat Disord*. 2014;2(3):274-281.
29. Akhtar OS, Lakhter V, Zack CJ, et al. Contemporary trends and comparative outcomes with adjunctive inferior vena cava filter placement in patients undergoing catheter-directed thrombolysis for deep vein thrombosis in the United States: insights from the National Inpatient Sample. *JACC Cardiovasc Interv*. 2018;11(14):1390-1397.
30. Sharifi M, Bay C, Skrocki L, Lawson D, Mazdeh S. Role of IVC filters in endovenous therapy for deep venous thrombosis: the FILTER-PEVI (filter implantation to lower thromboembolic risk in percutaneous endovenous intervention) trial. *Cardiovasc Intervent Radiol*. 2012;35(6):1408-1413.
31. Angel LF, Tapson V, Galgon RE, Restrepo MI, Kaufman J. Systematic review of the use of retrievable inferior vena cava filters. *J Vasc Interv Radiol*. 2011;22(11):1522-1530.e3.
32. Kaw R, Pasupuleti V, Wayne Overby D, et al; Cardiovascular Meta-analysis Research Group. Inferior vena cava filters and postoperative outcomes in patients undergoing bariatric surgery: a meta-analysis [published correction appears in Surg Obes Relat Dis. 2014;11(1):268-269]. *Surg Obes Relat Dis*. 2014;10(4):725-733.
33. Pryor HI II, Singleton A, Lin E, Lin P, Vaziri K. Practice patterns in high-risk bariatric venous thromboembolism prophylaxis. *Surg Endosc*. 2013;27(3): 843-848.
34. Reddy S, Zack CJ, Lakhter V, et al. Prophylactic inferior vena cava filters prior to bariatric surgery: insights from the National Inpatient Sample. *JACC Cardiovasc Interv*. 2019;12(12):1153-1160.
35. Geerts WH, Code KI, Jay RM, Chen E, Szalai JP. A prospective study of venous thromboembolism after major trauma. *N Engl J Med*. 1994;331(24):1601-1606.
36. Rajasekhar A, Lottenberg R, Lottenberg L, Liu H, Ang D. Pulmonary embolism prophylaxis with inferior vena cava filters in trauma patients: a systematic review using the Meta-analysis of Observational Studies in Epidemiology (MOOSE) guidelines. *J Thromb Thrombolysis*. 2011;32(1):40-46.
37. Haut ER, Garcia LJ, Shihab HM, et al. The effectiveness of prophylactic inferior vena cava filters in trauma patients: a systematic review and meta-analysis. *JAMA Surg*. 2014;149(2):194-202.
38. Shariff M, Kumar A, Adalja D, Doshi R. Inferior vena cava filters reduce symptomatic but not fatal pulmonary emboli after major trauma: a meta-analysis with trial sequential analysis [published online ahead of print, 27 March 2020]. *Eur J Trauma Emerg Surg*. doi:10.1007/s00068-020-01350-z.
39. Rajasekhar A, Lottenberg L, Lottenberg R, et al. A pilot study on the randomization of inferior vena cava filter placement for venous thromboembolism prophylaxis in high-risk trauma patients. *J Trauma*. 2011;71(2): 323-329.
40. Ho KM, Rao S, Honeybul S, et al. A multicenter trial of vena cava filters in severely injured patients. *N Engl J Med*. 2019;381(4):328-337.
41. Cook AD, Gross BW, Osler TM, et al. Vena cava filter use in trauma and rates of pulmonary embolism, 2003-2015. *JAMA Surg*. 2017;152(8): 724-732.
42. Kelkar AH, Rajasekhar A. Do prophylactic inferior vena cava filters in trauma patients reduce the risk of mortality or pulmonary embolism? *Hematology Am Soc Hematol Educ Program (2020)*. 2020 (1):1-4. DOI: 10.1182/hematology.2020000169.
43. Caplin DM, Nikolic B, Kalva SP, Ganguli S, Saad WE, Zuckerman DA; Society of Interventional Radiology Standards of Practice Committee. Quality improvement guidelines for the performance of inferior vena cava filter placement for the prevention of pulmonary embolism. *J Vasc Interv Radiol*. 2011;22(11):1499-1506.
44. Andreoli JM, Lewandowski RJ, Vogelzang RL, Ryu RK. Comparison of complication rates associated with permanent and retrievable inferior vena cava filters: a review of the MAUDE database. *J Vasc Interv Radiol*. 2014;25(8):1181-1185.
45. Mission JF, Kerlan RK Jr, Tan JH, Fang MC. Rates and predictors of plans for inferior vena cava filter retrieval in hospitalized patients. *J Gen Intern Med*. 2010;25(4):321-325.
46. U.S. Food and Drug Administration. *Removing Retrievable Inferior Vena Cava Filters: FDA Safety Communication*. Washington, DC: US Food and Drug Administration; 2014. http://wayback.archive-it.org/7993/20170722215731/https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm396377.htm. Accessed 7 May 2020.
47. Morales JP, Li X, Irony TZ, Ibrahim NG, Moynahan M, Cavanaugh KJ Jr. Decision analysis of retrievable inferior vena cava filters in patients without pulmonary embolism. *J Vasc Surg Venous Lymphat Disord*. 2013; 1(4):376-384.
48. Goodin A, Han Q, Raissi D, Brown JD. A review of interventions to increase vena cava filter retrieval rates. *Ann Vasc Surg*. 2018;51:284-297.
49. Aurshina A, Brahmandam A, Zhang Y, et al. Patient perspectives on inferior vena cava filter retrieval. *J Vasc Surg Venous Lymphat Disord*. 2019;7(4): 507-513.

DOI 10.1182/hematology.2020000149