

Indications and Outcomes of Inferior Vena Cava Filter Insertion in a Tertiary Hospital in Metro Manila, Philippines: A Retrospective Cohort Study

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Abstract

INTRODUCTION: Inferior vena cava (IVC) filters entrap emboli from the periphery going to the pulmonary circulation, preventing pulmonary embolism (PE). Studies show that many IVC filter insertions are done for weak or non-guideline-directed indications. This study examined the indications for IVC filter insertion in a tertiary care hospital in Metro Manila, adherence to society guidelines, and clinical outcomes after filter insertion.

METHODS: This study is a retrospective cohort involving patients who received an IVC filter from January 2015 to February 2021. The main outcome was the indication for IVC filter. Other outcomes were strength of recommendation for filter placement and postfilter clinical outcomes: all-cause death, venous thromboembolism-related mortality, PE, and filter-related complications.

RESULTS: Eighty-three patients received IVC filters from January 2015 to February 2021, and 77 were included in the analysis. Sixty-one percent had moderate to strong indications for the procedure, 49% were due to contraindication to anticoagulation. Thirty-nine percent had unclear indications: 16% concomitantly received therapeutic anticoagulation, whereas 11% had isolated distal deep vein thrombosis. Mean follow-up was 170 days. Postfilter clinical outcomes included all-cause death in 12%, venous thromboembolism-related mortality in 1%, and PE in 3%. Filter complications occurred in 4%. Retrievable IVC filters were used in 51% with attempted removal in 4%, 3% of which were successful.

CONCLUSION: The majority of patients receiving IVC filters in our center had strong to moderate indications for the procedure. The use of retrievable filters and consequent retrieval is low and should be encouraged. Venous thromboembolism-related mortality and filter complications were low, comparable to international data.

KEYWORDS: echocardiography, laboratory, reader, resources, sonographer, survey

INTRODUCTION

Background of the Study

Vena caval filters are metal alloy devices that entrap emboli as they migrate from the deep venous system to the pulmonary circulation and can be either permanent, retrievable, or convertible. Inferior vena cava (IVC) filters were originally designed to be permanent and are indicated for patients with long-term risk for venous thromboembolism (VTE) with a contraindication to anticoagulation. However, while preventing pulmonary embolism (PE), the presence of an IVC filter also has risks. Complications occur in 4% to 11% of cases and include those associated with the process of insertion such as bleeding or infection at the puncture site; allergic reactions to contrast or other medications used during placement; malposition of the filter; entrapment of the guidewire within the filter; postprocedure complications related to the access site, such as acute venous thrombosis, hematoma, or arteriovenous fistula; longer-term complications, such as filter erosion, migration, or embolization; and chronic thrombosis or recurrent thromboembolism. To circumvent these risks, retrievable filters were created. Retrievable filters are ideal for patients with only a transient need for an IVC filter such as a temporary contraindication to anticoagulation. Once the risk for VTE is gone or the contraindication to anticoagulation is lifted, the filter can be percutaneously removed. Removal of these filters, however, has its own accompanying risks. In a retrospective study involving 197 patients who underwent insertion of a retrievable IVC filter, filter removal was attempted only in 94 patients. Of these, only 85.1% were successful. Unsuccessful retrievals were due to technical difficulties in removal of the filter or thrombosis of the IVC.

Convertible filters are alternatives to retrievable filters, designed to be deactivated percutaneously to an “open” position when there is no more risk of VTE. Convertible filters theoretically provide an alternative to filter removal as it bypasses the risks associated with the retrieval of the filter. When retrievable or convertible filters are used, there should be a plan regarding when to retrieve the filter when protection against PE is no longer needed or when the contraindication to anticoagulation has abated.

The only widely accepted uses for IVC filters to date are (1) an absolute contraindication to anticoagulation or (2) the occurrence of VTE despite adequate anticoagulation. However, IVC filter insertion may be appropriate as an adjunct to anticoagulation in patients in whom another embolic event would be poorly tolerated (eg, poor cardiopulmonary reserve or severe hemodynamic or respiratory compromise), although clinical data are lacking.

The Society of Interventional Radiology (SIR), in collaboration with the American College of Cardiology (ACC), American College of Chest Physicians (ACCP), American College of Surgeons Committee on Trauma, American Heart Association (AHA), Society for Vascular Surgery (SVS), and Society for Vascular Medicine (SVM), released a guideline for IVC

filter insertion in the treatment of patients with venous thromboembolic disease in September 2020. Based on this guideline, IVC filter is considered for the following populations: (1) patients with acute PE and deep vein thrombosis (DVT) who have a contraindication to therapeutic anticoagulation, (2) patients with objectively confirmed VTE without any modifiable cause for the failure of anticoagulation, and (3) patients with recurrent VTE with poor cardiopulmonary reserve in whom another VTE will lead to deterioration. The guideline also states that, for patients with mitigated risk for VTE who received retrievable or convertible filters, the IVC filter should be removed or converted.

As for the 2019 European Society of Cardiology (ESC) and European Respiratory Society guidelines for acute PE, class IIa recommendation was given to IVC filter insertion for patients with acute PE and absolute contraindications to anticoagulation and for cases with PE recurrence despite therapeutic anticoagulation.

Inferior vena cava filter insertion may also be considered in addition to anticoagulation among patients with massive PE. These are patients with systolic blood pressure <90 mm Hg or poor tissue perfusion or multisystem organ failure plus extensive thrombosis, such as “saddle” PE or right or left main pulmonary artery thrombus.

Other expanded indications for IVC filter insertion as recommended by the SIR in 2016 include (1) ilio caval or large free-floating proximal DVT, (2) inability to achieve/maintain adequate anticoagulation, (3) massive PE with residual DVT in a patient at risk for further PE, (4) chronic VTE with thromboendarterectomy, (5) thrombolysis of ilio caval DVT, (6) VTE with limited cardiopulmonary reserve, (7) recurrent PE with IVC filter in place (filter failure), (8) poor compliance with anticoagulation, and (9) high risk of complication of anticoagulation (e.g., high fall risk).

With the increasing availability and ease of placement of IVC filters worldwide, controversies on the risk-benefit analysis of the procedure have risen because many procedures are done on patients without guideline-directed recommendations for its use. In a statewide study of IVC filter outcomes in New York covering years 2005 through 2014, 91,873 patients received IVC filters. The risk of having an IVC filter-related complication was 1.5% (95% confidence interval [CI], 1.4%–1.6%). An increasing trend of filter removal was observed from 2010 to 2014 (hazard ratio, 2.70; 95% CI, 2.50–2.91) as recommended by international guidelines. Among patients who did not have PE but received an IVC filter as prophylaxis because of elevated VTE risk, the risk of having a PE within 1 year from filter insertion was 2% (95% CI, 1.9%–2.1%).

Because the placement of IVC filters has its accompanying risks, it is of utmost importance to offer the procedure only to patients in whom these are truly indicated as recommended by society guidelines. In our medical center, the number of

IVC filter insertions has likewise increased since the year 2015 as shown in Figure 1. However, there are no data examining the indications of these procedures or their corresponding outcomes, hence this study.

Significance of the Study

This study will help the medical center evaluate the current practice of IVC filter insertion, whether indications for which are in accordance with recommended guidelines, and whether such procedures are beneficial to patients in the real-world setting. With the varying recommendations on IVC filter insertion among the different medical societies, this study will help the medical center draft its own guidelines regarding what will be considered as acceptable indications for IVC filter insertion that would be congruent with international recommendations.

OBJECTIVES

General Objectives

The aims of this study were to describe the current practice of IVC filter insertion in a tertiary care hospital in Metro Manila, Philippines, and assess its clinical outcomes

Specific Objectives

- (1) To determine the frequency of IVC filter insertion in the medical center from January 2015 to February 2021
- (2) To determine the most common indications for IVC filter insertion in the medical center
- (3) To assess the adherence to the ESC, SIR, and joint ACC/ACCP/AHA/SVM guidelines with regard to the indication for IVC filter insertion
- (4) To determine complications encountered during IVC filter insertion
- (5) To determine the occurrence of the following outcomes within 1 year from IVC filter insertion:

- PE (new or recurrent)
- Time of occurrence of PE after IVC filter insertion
- All-cause death
- Death due to VTE
- Time of occurrence of death after IVC filter insertion
- Filter complications:
 - Filter thrombosis
 - Migration of filter
 - Vascular injury
- Filter removal or conversion

METHODOLOGY

Study Design and Population

This is a retrospective cohort study including all adult patients (>18 years old) who received IVC filters in the medical center from January 2015 to February 2021. Patients were included in the study if they were adults older than 18 years, received an IVC filter, and had complete chart records including pertinent laboratory tests and the operative technique during IVC filter insertion. Those with incomplete data were excluded from the study.

Materials and Methods

The list of IVC-related procedures done from January 2015 to February 2021 was obtained from the cardiac catheterization laboratory to generate the master data set. These include IVC filter insertions, removals, conversions, or any reintervention.

For each patient, the medical chart and operative technique were examined, and the following data were extracted using a standardized data collection form: (1) age; (2) sex; (3) baseline medical history and comorbid conditions; (4) date and location of VTE; (5) indication for IVC filter insertion; (6) contraindication to anticoagulation, if any; (7) date of IVC filter insertion; (8)

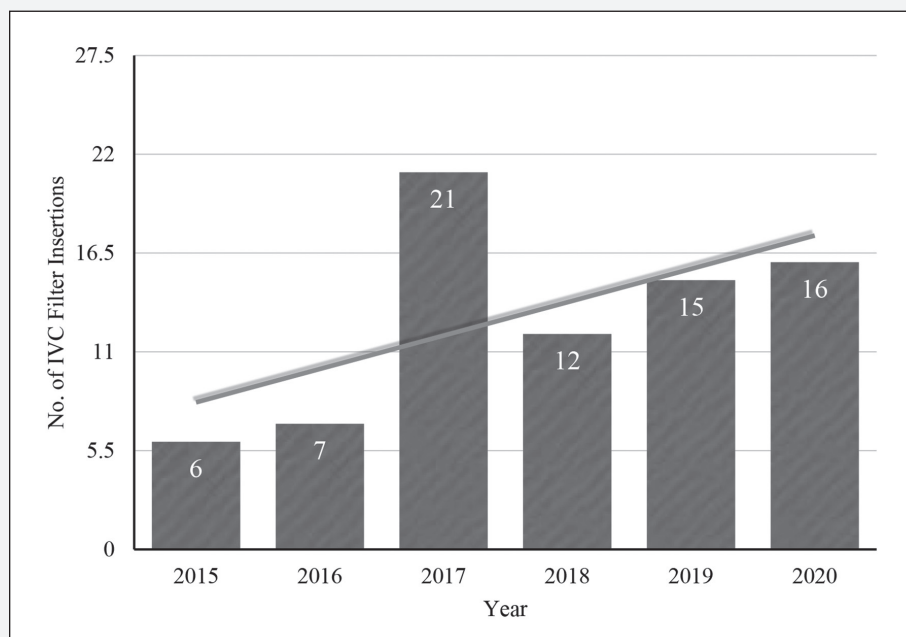


Figure 1. Trend of inferior vena cava filter insertions in the medical center.

brand and type of IVC filter inserted; (9) IVC filter-related complications; (10) date of IVC filter removal/conversion; (11) operator of the IVC-related procedure; and (12) post-filter insertion clinical events including all-cause death, VTE-related death, and new or recurrent PE. The date of the last recorded visit to the medical center was considered as the end of the follow-up period for each patient.

Baseline medical history consisted of the chief complaint and the reason for admission, a history of VTE, active cancer defined as the presence or treatment of cancer within 6 months of the VTE, hypertension, atrial fibrillation or other arrhythmias, ischemic heart disease, heart failure, diabetes mellitus, dyslipidemia, chronic lung disease requiring bronchodilator therapy, renal disease defined as an estimated creatinine clearance of less than 30 mL/min per 1.73 m², liver disease, cerebrovascular disease, thyroid disease, and coagulation disorders.

Patients with PE were further classified as massive PE (systolic blood pressure <90 mm Hg or poor tissue perfusion or multisystem organ failure plus extensive thrombosis, such as “saddle” PE or right or left main pulmonary artery thrombus), submassive high-risk PE (hemodynamically stable but moderate or severe right ventricular dysfunction or enlargement,

coupled with biomarker elevation), submassive low-risk PE (hemodynamically stable with right ventricular dysfunction or biomarker elevation but not both), or small to moderate PE (normal hemodynamics and normal right ventricular size and function).

Any form of bleeding was considered a contraindication to anticoagulation. Recurrent VTE despite adequate anticoagulation was considered if the patient has been receiving an appropriate anticoagulant in its recommended dose for VTE for at least 1 month prior to the occurrence of VTE. A free-floating thrombus was considered if the venous compression or venous duplex study indicated a “free-floating” or “mobile” thrombus in the result. Deep vein thrombosis was considered acute or chronic as indicated in the official venous compression or venous duplex result. It was considered proximal DVT if thrombosis was located in the IVC, external iliac, common femoral, femoral, deep femoral, or popliteal veins. Deep vein thromboses in the tibioperoneal trunk, peroneal, anterior tibial, posterior tibial, and soleal veins were considered distal.

The level of recommendation for filter insertion was classified according to the joint SIR/ACC/ACCP/AHA/SVS/SVM 2020, ESC/European Respiratory Society 2019, and SIR 2016 recommendations as summarized in Table 1.

Table 1. Summary of Guideline Recommendations Regarding IVC Filter Insertion^{6,7}

	SIR/ACC/ACCP/AHA/ SVS/SVM 2020	ESC/ERS 2019	SIR 2016
Strong			
Acute PE with contraindication to anticoagulation	Consider	Class IIa	Classic indication
Moderate			
Acute proximal DVT with contraindication to anticoagulation	Consider	—	Classic indication
Patients undergoing anticoagulation for acute VTE in whom a contraindication to anticoagulation develops	Consider	—	Classic indication
Patients receiving therapeutic anticoagulation for VTE who experiences a recurrent VTE	Not recommended	Class IIa	Classic indication
Patients with acute VTE who are undergoing advanced therapies (ie, catheter-directed thrombolysis, thrombectomy, embolectomy)	Consider	—	Expanded indication
Iliocaval or large free-floating proximal DVT	—	—	Expanded indication
Massive PE with residual DVT in a patient at risk for further PE	—	—	Expanded indication
VTE with limited cardiopulmonary reserve	—	—	Expanded indication
Filter failure	—	—	Expanded indication

(continuation of Table 1)

	SIR/ACC/ACCP/AHA/ SVS/SVM 2020	ESC/ERS 2019	SIR 2016
Not indicated			
Patients with acute VTE who are being treated with therapeutic anticoagulation	Not recommended	Class III	—
Patients on extended anticoagulation for VTE and who have completed the acute phase of treatment in whom a contraindication to anticoagulation develops	Not recommended	—	—
Trauma patients without known acute VTE	Not recommended	—	Prophylactic indication if high risk for VTE
Patients without known VTE undergoing major surgery	Not recommended	—	Prophylactic indication if high risk for VTE
Medical condition with high risk of VTE	—	—	Prophylactic indication if high risk for VTE

ACC=American College of Cardiology; ACCP=American College of Chest Physicians; AHA=American Heart Association; DVT=deep venous thrombosis; ESC=European Society of Cardiology; ERS=European Respiratory Society; PE=pulmonary embolism; SIR=Society of Interventional Radiology; SVM=Society for Vascular Medicine; SVS=Society for Vascular Surgery; VTE=venous thromboembolism.

Table 2. Baseline Characteristics of Patients Who Underwent IVC Filter Insertion*

Characteristics	n = 77
Age, median (range), y	61 (23–96)
Female sex	56 (73)
VTE as reason for admission	
DVT	19 (25)
PE	3 (4)
Previous VTE	10 (13)
Active cancer	42 (55)
Hypertension	39 (51)
Atrial fibrillation	7 (9)
Diabetes	22 (29)
Ischemic heart disease	7 (9)
Dyslipidemia	6 (8)
Chronic lung disease	4 (5)
Renal disease	9 (12)
CVD	
CVD infarct	5 (6)
CVD bleed	3 (4)
Coagulation disorder	
Antiphospholipid antibody syndrome	1 (1)
Factor V Leiden	1 (1)

CVD=cerebrovascular disease; DVT=deep vein thrombosis; IVC=inferior vena cava; PE=pulmonary embolism; VTE=venous thromboembolism.

*Expressed as number (percent) unless otherwise specified.

Table 3. Indications for IVC Filter Insertion

Indications	n (%)
Strong	
Submassive low-risk PE with contraindication to anticoagulation	7 (9)
Submassive high-risk PE with contraindication to anticoagulation	1 (1)
Moderate	
Acute proximal DVT with contraindication to anticoagulation	28 (36)
Patients undergoing anticoagulation for acute VTE in whom a contraindication to anticoagulation develops	2 (3)
Patients receiving therapeutic anticoagulation for VTE who experiences a recurrent VTE	2 (3)
Patients with acute VTE who are undergoing advanced therapies (ie, catheter-directed thrombolysis, thrombectomy, embolectomy)	1 (1)
Iliocaval or large free-floating proximal DVT	6 (8)
Not Indicated	
Acute proximal DVT on therapeutic anticoagulation	12 (16)
Acute distal DVT with contraindication to anticoagulation	11 (14)
Chronic proximal DVT with contraindication to anticoagulation	3 (4)
Submassive low-risk PE on therapeutic anticoagulation	2 (3)
Small to moderate PE on therapeutic anticoagulation	1 (1)

Abbreviations: DVT=deep vein thrombosis; IVC=inferior vena cava; PE=pulmonary embolism; VTE=venous thromboembolism.

Data Analysis

Nominal, binary, ordinal data, and frequencies were expressed in percentages. Time to event was expressed as mean, median, and range.

RESULTS

There were 85 cases of IVC procedures identified from the database of the cardiac catheterization laboratory from January 2015 to February 2021. Eighty-three of the procedures were IVC filter insertions, whereas two were filter removals. Six records were excluded because of incomplete data or the lack of an operative technique, leaving 77 patients for analysis. The baseline demographics of the included patients are presented in Table 2. Most of the patients were female, and active cancer was the most common comorbidity.

The distribution of indications for IVC filter insertion according to the strength of recommendation is summarized in Table 3. Of the 77 patients included in the study, a strong recommendation for IVC filter insertion was present in eight patients (10%). Seven (9%) of these patients had submassive low-risk PE with a contraindication to anticoagulation, whereas one had submassive high-risk PE.

A moderate indication was present in 41 patients (53%), and most of them (28 of 41) had acute proximal DVT with a contraindication to anticoagulation. Overall, this also represents the most common indication for IVC filter insertion in the medical center.

No clear indication for IVC filter insertion was identified in 28 patients (36%). Most of them had acute proximal DVT receiving therapeutic anticoagulation, whereas 11 (14%) of them had isolated distal DVT with bleeding and therefore could not receive anticoagulation.

Inferior vena cava filter insertion characteristics are shown in Table 4. Most of the patients who underwent IVC filter insertion had proximal DVT. The majority of the patients who had PE are under the submassive, low-risk category. The leading contraindication to anticoagulation is gastrointestinal bleeding.

The majority of the IVC filter insertions were done by interventional cardiologists. The use of permanent versus retrievable filters was almost equal. Convertible filters are not yet available in the country. Only three filter retrievals were

Table 4. IVC Filter Insertion Characteristics

Characteristics	n (%)
Location of VTE	
PE only	2 (3)
DVT only with proximal involvement	50 (65)
DVT only with proximal floating thrombus	10 (13)
PE and DVT	10 (13)
Isolated distal DVT	12 (16)
No VTE history	0 (0)
PE category	
Massive	0 (0)
Submassive, high risk	2 (3)
Submassive, low risk	9 (12)
Small to moderate	1 (1)
Contraindications to anticoagulation	
Gastrointestinal bleeding	14 (18)
Genitourinary bleeding	9 (12)
Endotracheal bleeding	4 (5)
Intracerebral hemorrhage	6 (8)
Aortic repair leak	1 (1)
Anticipated surgery	10 (13)
Thrombocytopenia <50,000/ μ L	1 (1)
Operator	
Interventional cardiologist	71 (92)
Interventional radiologist	3 (4)
Thoracic vascular surgeon	3 (4)
Type of IVC filter	
Permanent	38 (49)
Retrievable	39 (51)
Attempted IVC filter removal	3 (4)
Success	2 (3)
Failed	0 (0)
Aborted	1 (1)

DVT=deep vein thrombosis; IVC=inferior vena cava; PE=pulmonary embolism; VTE=venous thromboembolism.

attempted. Two of these were successful, whereas one was aborted because of perioperative findings of new DVTs at the access sites.

Clinical outcomes after IVC filter insertion are shown in Table 5. Mean follow-up was 170 days after IVC filter insertion. Death occurred in nine patients (12%) and was mostly due to pneumonia. There was one death due to massive PE occurring 4 days after IVC filter insertion. There were two cases of PE identified on the first and fourth day after IVC filter insertion. There were three identified filter complications: one was a minor vascular injury, which involved extravasation of contrast into the iliopsoas region and did not require intervention; one was IVC filter thrombosis identified during follow-up imaging; and the last one was IVC filter thrombosis identified at the time of filter retrieval.

Table 5. Clinical Outcomes After IVC Filter Insertion

Outcome	n (%)
All-cause death	9 (12)
Pneumonia	7 (9)
Ruptured aortic aneurysm	1 (1)
VTE-related death	1 (1)
PE	2 (3)
Filter complications	
Vascular injury	1 (1)
Filter thrombosis	2 (3)

IVC=inferior vena cava; VTE=venous thromboembolism.

DISCUSSION

Insertion of an IVC filter is a viable therapeutic option for patients with VTE with a defined set of indications as determined by several international societies. Among the 77 patients who received an IVC filter from January 2015 to February 2021 in our center, 49% were due to contraindication to anticoagulation, which is a generally accepted indication for the procedure. This is higher than a Canadian retrospective cohort in 2016, with only 20% of patients receiving IVC filters because of the same indication. In comparison, the recently concluded PRESERVE (Predicting the Safety and Effectiveness of Inferior Vena Cava Filters) Trial, which investigated the use of IVC filters in 1421 patients in the United States, showed that 81.6% received an IVC filter because of a contraindication to anticoagulation or failed anticoagulation. The most frequent contraindications to anticoagulation encountered in our medical center were gastrointestinal bleeding, genitourinary bleeding, and anticipated surgery. Overall, 61% of the patients in our center had strong to moderate indications for IVC filter insertion.

Of the 39% of patients without clear indications for IVC filter insertion, the majority (16%) had acute proximal DVT who were simultaneously receiving therapeutic anticoagulation. In the prospective PREPIC2 2015 study, 399 patients with unprovoked symptomatic PE with a high risk for recurrent PE were randomized to receive an IVC filter or no filter. Both treatment and control groups received therapeutic levels of anticoagulation. Results showed no clear difference in recurrent PE (fatal and nonfatal) at 3 months (RR, 1.99; 95% confidence interval, 0.5–7.85; $P = 0.33$) and at 6 months (RR 1.74, 95% confidence interval, 0.52–5.86; $P = 0.37$) among patients who received and did not receive IVC filters in addition to anticoagulation. Thus, IVC filters are not indicated for patients who can be given anticoagulation. Similarly, a study among cancer patients with concurrent VTE who received and did not receive IVC filters in addition to anticoagulation showed no difference in recurrent PE (24.8% vs 24%). Therefore, it should be reiterated that patients receiving therapeutic dosages of anticoagulants do not warrant IVC filter insertion.

Another common indication for IVC filter insertion among the patients in the medical center is isolated distal DVT. The treatment of isolated distal DVT varies in different institutions. Clinicians are generally in agreement to anticoagulate patients with symptomatic distal DVT. This indication for anticoagulation merits only a grade 2C or weak recommendation from the ACCP based on low-quality evidence. As for asymptomatic distal DVT incidentally found on venous duplex scan, the general recommendation is forego anticoagulation unless the DVT is documented to extend into or toward the proximal veins. The risk for PE among patients with isolated distal DVT, whether symptomatic or asymptomatic, is reduced to half that of those with proximal vein involvement. In the majority of cases, isolated distal DVT resolves spontaneously. Thus, the insertion of IVC filters to prevent PE in those with isolated distal DVT is not warranted because of the low risk of embolization in this population.

Another population of patients with VTE who are not represented in international guidelines for IVC filter insertion are those with chronic VTE who develop a contraindication to anticoagulation. To date, guidelines have not mentioned anything for or against the insertion of IVC filters in this population.

Among the 77 patients included in this study, 51% received retrievable filters, but only 4% were retrieved, and 3% were successfully removed. This is comparable with other studies reporting filter retrieval rates of only 5% to 45%.^{11,12} In the 2020 SIR/ACC/ACCP/AHA/SVS/SVM recommendation, filter retrieval was already part of the recommendation as soon as the risk for VTE or the contraindication to anticoagulation is mitigated. Therefore, there is a need to encourage the retrieval of filters for patients in our medical center with only transient indications for IVC filter. Moreover, a plan when to remove this filter should be in place at the outset, and its removal facilitated as soon as the need for the filter abates.

Venous thromboembolism–related mortality in our population is low at 1%, whereas PE after filter insertion occurred in only 3%. Pulmonary embolism was documented 1 day after filter insertion in one patient and may have been present even before insertion of the filter. Filter complications were also low at 4%. This is comparable with international data showing filter complications in 4% to 11% of patients, mostly related to the technical difficulties of the procedure.^{1,12}

LIMITATIONS OF THE STUDY

This study is limited by its retrospective study design. Clinical outcomes were based solely on chart review. Thus, the completeness of the outcome data cannot be ascertained.

CONCLUSION

Overall, the majority of patients receiving IVC filters in our medical center had strong to moderate indications for the procedure with a low rate of complications and also a low filter retrieval rate. The creation of an institutional policy regarding filter insertion and subsequent removal are proposed. Because of the limitations of the retrospective study design, a prospective study is suggested to better ascertain the accuracy and completeness of outcome data. Further investigation as to the cause of the low filter retrieval rate in our center is likewise suggested.

ETHICAL CONSIDERATIONS

This study was approved by the scientific and ethical review boards of the Research and Biotechnology Division (SL-21041).

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CONFLICT OF INTEREST

There are no relevant conflicts of interest to disclose.

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