## Indications, retrieval rate, and complications of inferior vena cava filters: Single-center experience in Saudi Arabia

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### Abstract:

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**BACKGROUND:** Inferior vena cava (IVC) filter is indicated in patients with acute venous thromboembolism (VTE) in whom therapeutic anticoagulation is contraindicated. While prophylactic insertion of an IVC filter may be considered for patients at high risk of VTE, there are significant differences between clinical guidelines on the role of IVC filters. These discrepancies have arisen predominantly because of the paucity of data on the efficacy and safety of IVC filters. We, therefore, evaluated the indications for filter insertion, the rate of filter retrieval and complications in patients who received IVC filters at King Abdulaziz Medical City (KAMC), Riyadh, Saudi Arabia.

**METHODS:** A descriptive, retrospective review of electronic- and paper-based medical records was performed. Consecutive sampling was used to study all adult patients who received an IVC filter at KAMC between 2007 and 2016 and met the inclusion criteria.

**RESULTS:** A total of 382 IVC filters were inserted. 113 patients (30%) had an acute VTE and a contraindication to anticoagulation while 53 patients (14%) received an IVC filter in the absence of VTE (i.e., prophylactic). Only 124 (32.5%) IVC filters were eventually retrieved. The most common reason for nonretrieval was the need for permanent filtration (155, 60%). Thrombotic complications developed in 72 (19%) patients; nine patients had fatal pulmonary embolism.

**CONCLUSION:** The insertion of IVC filters in this cohort was associated with low retrieval rate and relatively high incidence of thrombotic complications. Follow-up of patients is required to detect IVC filter-related complications and to increase retrieval rate.

#### **Keywords:**

Deep vein thrombosis, inferior vena cava filter, pulmonary embolism, retrievable filters

Venous thromboembolism (VTE) is a common disease that causes substantial morbidity, mortality, and health-care cost.<sup>[1]</sup> Nearly, 2 per 1000 individuals over 45-year-old will develop VTE at some point.<sup>[2]</sup> Of all hospital admissions in the United States, 1% are related to VTE. This amounts to around 900,000 patients per annum.<sup>[3]</sup>

Prevention of serious embolic events, especially pulmonary embolism (PE), is

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one of the most important reasons for treating deep vein thrombosis (DVT) of the lower limbs. Administration of "treatment dose" anticoagulation for at least 6 weeks is currently the standard of care.<sup>[4,5]</sup> This is because the risk of recurrence is highest in the 1<sup>st</sup> week after an acute VTE.<sup>[6]</sup> Anticoagulation reduces the rate of recurrence of VTE to approximately 10% in the 1<sup>st</sup> month, and further reduction occurs with extended treatment.<sup>[7]</sup> The strongest indication for insertion of an inferior vena

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cava (IVC) filter is the presence of a contraindication to anticoagulation in a patient with an extensive acute lower limb DVT.<sup>[4,8,9]</sup> Other indications for IVC filter placement (e.g., prophylaxis in polytrauma patients or adjuvant to anticoagulation for high-risk patients) are controversial. There are significant differences between clinical guidelines on the role of IVC filters in these settings.<sup>[4,8,9]</sup> These discrepancies have arisen predominantly because of the paucity of data on the efficacy and safety of IVC filters.

In 1973, Greenfield inserted the first IVC filter to prevent PE by trapping venous emboli from the lower limbs.<sup>[10]</sup> However, the use of IVC filters did not significantly increase until the development of retrievable filters with a better safety profile in the late 1990s.<sup>[11]</sup> Retrievable IVC filters are preferred over permanent filters as the incidence of complications is thought to increase with the time that the IVC filter remains *in situ*.<sup>[12]</sup>

Unfortunately, the rate of IVC filter retrieval remains disappointing.<sup>[13]</sup> A systematic review of 37 studies by Angel *et al.* reviewed the outcome of 6,834 patients who underwent IVC filter insertion and found that retrieval rate did not exceed 34%.<sup>[14]</sup> Moreover, IVC filters are associated with various mechanical complications (including filter migration, tilting, stenosis, or penetration) as well as thrombotic complications (including filter thrombosis, new or progression of VTE).<sup>[15]</sup> Collectively, these complications raise concerns about the dramatic increase in IVC filter use.<sup>[16]</sup>

There are few data on the recent practice and experience with retrievable IVC filters in Saudi Arabia. We, therefore, evaluated the indications for filter insertion, rate of filter retrieval, and complications of IVC filter in patients at King Abdulaziz Medical City (KAMC), Riyadh, Saudi Arabia.

### **Methods**

A retrospective case series study was performed by case note review at KAMC, Riyadh, Saudi Arabia. All medical records from all patients who had an IVC filter placed between January 2007 and December 2016 at KAMC were reviewed. KAMC is a tertiary referral center with a capacity of 1500 beds and facilities to manage major trauma.

All databases at KAMC were searched thoroughly to identify all patients who received an IVC filter. This search identified 382 patients who had an IVC filter placed. The electronic- and paper-based medical records of these patients were then manually reviewed. Besides the patient demographic data, the data extracted included whether a VTE event had occurred before filter placement, indications for filter placement, filter type, filter retrieval rate, anticoagulation, complications, and follow-up after discharge. Follow-up data were extracted from the time of filter insertion to the last encounter date, death, or end of the study. If the IVC filter was inserted within 30 days of an acute VTE event the indication for filter placement was recorded as "for the acute management of VTE." The extracted data were entered into a secure database that was kept separate from patient identifiers to ensure patient confidentiality was maintained. Ethical approval for this study was obtained from the King Abdullah International Research Center, Riyadh, Saudi Arabia.

### **Statistics**

Categorical variables are presented as frequencies and proportions, and continuous variables as means and standard deviations (SDs). Parametric data were assessed using Students *t*-test; nonparametric data were assessed using the Chi-squared test. P < 0.05 was considered statistically significant. Statistical analysis was performed using IBM SPSS Version 20 (Armonk, NY:IBM Corp., US).

### Results

### **Demographic data**

Between January 2007 and December 2016, 382 patients (225, 58.9% male and 157, 41.1% female) received IVC filters at KAMC [Table 1]. The median age of the patients was 56 years (SD  $\pm$  21, range 18–103 years). The median time of follow-up of this cohort was 303 days (range, 1–3165 days).

### Type of inferior vena cava filter inserted

In this cohort, retrievable IVC filters were placed in all but seven patients (1.8%). The retrievable filters used were Optease (Cordis, California, USA) 303 (79.3%), Denali (Bard Peripheral Vascular Inc, Arizona, USA) 28 (7.3%), Celect (Cook Medical LLC, Indiana, USA) 19 (5%), and Option ELITE (Argon Medical Devices, 2 (0.5%). In 23 cases (6%), the type of retrievable filter inserted could not be identified. All (7) of the permanent

Table 1:	<b>Patients</b>	characteristics	and	type	of	venous
thrombo	embolism	า				

Characteristics	Number of patients (n=382) (%		
Age (years), mean±SD	56±21		
Male sex	225 (58.9)		
VTE diagnosis*			
PE	93 (24.3)		
DVT	189 (49.4)		
PE and DVT*	47 (12.3)		
Non	53 (14)		

\*Those patients presented with PE and DVT. SD=Standard deviation, VTE=Venous thromboembolism, PE=Pulmonary embolism, DVT=Deep venous thrombosis filters inserted were Trapease (Cordis, California, USA). The vast majority of filters were placed infrarenally in the IVC. IVC grams were performed before and after filter insertion, in all cases.

# Requesting specialty and indications for inferior vena cava filter insertion

The placement of IVC filters was requested by physicians from several departments; medicine 152 (39.8%), surgery 136 (35.6%), intensive care 78 (20.7%), and hematology 16 (4.2%). Indications for filter placement are listed in Table 2. The vast majority (329; 86%) of the patients had had a VTE before insertion of the IVC filter. Totally 189 patients (49.4%) presented with DVT, 93 (24.3%) presented with PE and 47 (12.3%) had both PE and DVT at presentation. The rest (53; 14%) had a filter inserted in the absence of a VTE (i.e., prophylactically).

The most common indication for filter insertion was contraindication to anticoagulation (152 patients [40%]; of these, 32 IVC filters were inserted in patients with active bleeding). 113 (30%) patients received their IVC filter as they had an acute VTE (i.e., VTE diagnosed within 30 days of insertion of the IVC filter) and had a contraindication to anticoagulation. A total of 106 patients (28%) had sustained injuries from major trauma before IVC filter insertion. Of these, 63 patients (60%) had then sustained an acute VTE, and 11 (10%) had a history of previous VTE before filter insertion. The other 32 patients (30%) patients who had sustained injuries from major trauma received prophylactic IVC filters.

### **Filter retrieval**

The timing of filter retrieval was primarily determined by the referring physician. Of the 382 filters inserted only 124 (32.5%) were eventually retrieved. The rest of the IVC filters (258) remained *in situ* permanently.

In those patients, whose IVC filter was retrieved, the median time that a filter remained *in situ* was 27 days (range 4–402 days). Of the 124 filters retrieved, 97 (78%) were retrieved during the same admission as their insertion, 27 (22%) filters were removed after discharge from the hospital. The reasons for not removing the filter were need for permanent filter (155, 60%), death before retrieval (52, 20%), patient lost to follow-up (26, 10%), high thrombus burden on the filter (10, 4%), failure of attempted retrieval (9, 3.5%), and unknown 6 (2.4%). However, 41 (27%) patients of those the indication for filter insertion was contraindication to anticoagulation were discharged from the hospital on therapeutic anticoagulation.

### **Complications and follow-up**

Of the 382 patients who received IVC filters, 79 (20.6%) had thrombotic or mechanical complications. 72 (19%)

patients had a thrombotic event during the follow-up. Complications which occurred while the patient's IVC filter was in situ are listed in Table 3. Recurrence or extension of DVT was the most common thrombotic event (28, 39%). The median time to recurrence or extension of DVT was 22 days (1-2200 days). Other thrombotic events included IVC thrombosis (23, 32%), recurrent PE (13, 18%; median time 8 days, range 2-1689 days), and other thrombosis (8, 11%). Of the 72 thrombotic complications, 33 (46%) occurred despite therapeutic anticoagulation and 8 (11%) occurred despite prophylaxis dose of anticoagulation. Of the 72 thrombotic complications, 31 (43%) occurred in patients who were not anticoagulated. Prophylactic IVC filter insertion (i.e., in the absence of a prior VTE) was associated with three thrombotic events. There was no statistically significant difference in the rate of recurrence of PE between patients whose filters were retrieved and patients whose filters remained in situ permanently [Table 4]. Seven patients (1.8%) had one or more filter-related complication. Mechanical complications related to filter insertion included filter

### Table 2: Indications for filter insertion

Indications for filter insertion	Total, <i>n</i> (%)
Acute VTE (<30 days)	258 (67.5)
Contraindication to AC	113 (43.8)
Failure of AC	4 (1.6)
Impeding or recent surgery	28 (10.9)
Adjuvant to AC	38 (14.7)
Trauma	63 (24.4)
Others	12 (4.7)
Nonacute VTE (>30 days)	71 (18.5)
Contraindication to AC	33 (46.5)
Impeding or recent surgery	13 (18.3)
Adjuvant to AC	14 (19.7)
Trauma	11 (15.5)
Non-VTE (prophylaxis)	53 (14)
Trauma	32 (60.4)
Contraindication to AC	6 (11.3)
Recent or impeding surgery	5 (9.4)
Other procedures	6 (11.3)
Others	4 (7.6)

VTE=Venous thromboembolism, AC=Anticoagulation

Table 3: Complications of inferior vena cava filter	Table 3:	Complications	of inferior vena	cava filter
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Complication	n (%)
Thrombotic (total)	72 (19)
Recurrent or extension of DVT	28 (39)
IVC thrombosis	23 (32)
New or recurrent PE	13 (18)
Other thrombosis	8 (11)
Mechanical (total)	7 (1.8)
Filter tilting	6 (86)
IVC occlusion	1 (14)

PE=Pulmonary embolism, DVT=Deep venous thrombosis, IVC=Inferior vena cava

tilting (6, 1.6%). Filter occlusion was reported once (0.3%) on retrieval.

A total of 126 patients (33%) were found to have died during this case note review. Of these, 120 patients (95%) still had their IVC filter *in situ* at the time of death. Of the 124 patients, whose IVC filters were retrieved, only six patients were found to have died during the follow-up. In the cohort who died after insertion of an IVC filter the median survival after filter insertion was 48 days (range 1–2333 days). The most common causes of death were not related to thrombotic or hemorrhagic events (108, 86% of deaths). In this case series, nine patients (7.1% of deaths) had fatal PE.

### Discussion

Although PE is considered a preventable cause of death in hospitalized patients, it remains a major cause of morbidity and mortality.<sup>[17]</sup> It is thought that insertion of an IVC filter can, in some cases, reduce the morbidity and morbidity associated with VTE.<sup>[18-22]</sup> Hence, between January 2007 and December 2016, 382 patients received IVC filters at KAMC.

The insertion of an IVC filter is most strongly indicated in unfortunate patients who simultaneously have an acute VTE and a contraindication to anticoagulation.<sup>[12]</sup> In the present cohort, approximately 40% of the filters were inserted because patients with a VTE had a contraindication to anticoagulation therapy. The majority of the IVC filters in this cohort were inserted within 30 days of diagnosis of the VTE requiring insertion of the IVC filter. Another 40% of the IVC filters in this cohort were inserted into patients who had sustained major trauma or perioperatively for surgery. This second subgroup included patients who required surgery but had recently had a VTE, patients who had sustained major trauma and then developed a VTE, and patients who received prophylactic IVC filters (i.e., in the absence of VTE) after sustaining major trauma. Fifty-three patients (14%) received a prophylactic IVC filter.

In the present cohort, only 124 (32.5%) patients had their filter successfully retrieved. This retrieval rate

Table 4: Rates of development or recurrence of venous thromboembolism in patients whose inferior vena cava filters were retrieved and those whose filters remained *in situ* 

VTE	Filter re	Р	
	Yes (%)	No (%)	
PE	2 (1.6)	11 (4.2)	0.18
DVT	5 (4)	23 (9)	0.08

VTE=Venous thromboembolism, PE=Pulmonary embolism, DVT=Deep venous thrombosis

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is comparable to previous reports.<sup>[14]</sup> For example, an average retrieval rate around 34% was reported in a systematic review,<sup>[14]</sup> and a recent retrospective study found a retrieval rate of 40%.<sup>[23]</sup> Saour et al. retrospectively reviewed the outcomes of 225 patients with lower limb DVT in Saudi Arabia. Of these 225 patients, 77 (34%) received IVC filters (50 permanent and 27 temporary). Only 14 (51.9%) of the 27 temporary filters inserted were eventually retrieved.<sup>[24]</sup> However, their data do not reflect current practice because the vast majority of filters inserted nowadays are retrievable. In the present study, indications for permanent filter, death and loss to follow-up were the most common causes for not retrieving IVC filters. However, one-third of those patients whose IVC filter was inserted for a contraindication to anticoagulation were subsequently discharged from hospital on therapeutic anticoagulation. This suggests that in this subgroup a permanent IVC filter would not have been required. However, the IVC filter was not removed from 132 (87%) of these patients. Complications from IVC filter placement occurred in 79 patients (20%). Of these complications, 72 were thrombotic while seven were mechanical and related to the IVC filter. Overall, 13 (3%) patients in our cohort developed or had recurrent PE despite having an IVC filter in situ. Of these patients, only six patients were not being treated with prophylactic or therapeutic anticoagulation.

No randomized control trials (RCT) have investigated the efficacy and safety of IVC filter use as a sole therapy to prevent PE if anticoagulation is contraindicated.<sup>[12]</sup> The use of IVC filters has been evaluated in two randomized trials. Decousus et al.[15] reported a lower rate of PE in the first 12 days after acute DVT in patients who received an IVC filter and anticoagulation in comparison to anticoagulation alone. At 2 years, there was no reduction in the incidence or recurrence of PE or mortality. However, recurrent DVT was significantly increased in cohort that received an IVC filter. At an 8-year follow-up of this randomized trial, it was found that while the incidence of PE was reduced in the IVC filter group the incidence of DVT was higher and survival was unchanged.<sup>[25]</sup> However, a recent RCT investigated the use of retrievable IVC filters in combination with anticoagulation in patients with PE and DVT.<sup>[26]</sup> This found no benefits in reducing the risk of PE over anticoagulation alone in high-risk PE patients.<sup>[26]</sup> Similarly, a large population-based study of 80,697 patients found that the insertion of an IVC filter in patients with acute VTE and no contraindication to anticoagulation increases the risk of DVT by 50% without a reduction in risk of PE.<sup>[27]</sup> In the present cohort, there was no significant difference in the recurrence rate of VTE whether patients' IVC filters remained in situ or were removed. However, all nine of the patients who died from PE in this series still had their IVC filter *in situ* (six of the patients were not anticoagulated).

Several clinical guidelines including the American College of Chest Physicians and the Society of Interventional Radiology agree that insertion of an IVC filter is indicated if therapeutic anticoagulation is contraindicated in patients with an acute proximal DVT or PE.<sup>[4,8,9]</sup> However, these guidelines contain conflicting statements on other indications for IVC filter insertion (e.g., prophylactic insertion in patients who have sustained major trauma in the absence of a VTE, or as adjuvant to anticoagulation for high-risk patients with VTE). These discrepancies reflect the paucity of high-quality data on the safety, efficacy, and role of IVC filters in these settings.

Mechanical complications related to the presence of the IVC filter *in situ* include incomplete deployment, filter tilting, and fracture.<sup>[28]</sup> In the present cohort, the rates of these mechanical complications were lower than those reported previously; where the incidence of mechanical complications documented in the previous series was around 9%.<sup>[28,29]</sup>

The most common thrombotic complication associated with the IVC filters in our cohort was recurrence or extension of DVT. IVC thrombosis was reported in 23 patients. However, it is difficult to distinguish *de novo in situ* thrombosis within an IVC filter from the successful trapping of an embolus from the lower limbs. Therefore, further research is required to explore the pathophysiology of isolated filter thrombus and its long-term consequences if left untreated, especially in patients with filters that remain *in situ* permanently.

This study has some limitations. Retrospective collection of data was confined to the medical records available at KAMC. Although the vast majority of patients were from Riyadh and eligible for treatment at KAMC, it is possible patients may have received some treatment at other hospitals after discharge. Hence, the actual rate of complications in our cohort may have been higher than was observed.

### Conclusion

Indications for IVC filter insertion vary between guidelines. One-third of the patients in the present cohort had a contraindication for anticoagulation in acute VTE, the most widely acceptable indication. The present data are consistent with previous studies which have reported a low rate of filter retrieval and relatively high filter-related thrombotic complications. Initiatives are required to limit the unnecessary insertion of IVC filters and ensure that there is a regular follow-up for patients with IVC filters to prevent and detect filter-related complications and to retrieve the IVC filter when feasible.

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### **Conflicts of interest**

There are no conflicts of interest.

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