ORIGINAL ARTICLE

Retrospective analysis of the use of inferior vena cava filters in routine hospital practice

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Introduction: Characteristics and outcomes of patients undergoing inferior vena cava (IVC) filter insertion are not well reported. Particularly, the role of long term anticoagulation in these patients is unclear.

Aims: (1) To describe in a cohort of patients undergoing IVC filter insertion, underlying diseases, indications for filter insertion, complications, and survival. (2) To determine the effect of long term anticoagulant treatment on thromboembolism and patient survival.

Study design: A retrospective analysis of 109 consecutive patients undergoing IVC filter insertion in two university hospitals.

Results: Average age was 67.4 years. Median duration of follow up was two years. Indications for IVC filter insertion were: contraindication to anticoagulation (n=61, 56%), prophylactic insertion (n=29, 27%), thromboembolism while receiving adequate anticoagulation (n=17, 15%), and non-compliance with anticoagulation (n=2, 2%). Insertion related complications were groin haematoma in four patients (3.5%) and localised infection at the puncture site in one patient (0.9%). Fifty six patients (51.4%) died during the study period. Of these, 22 received long term anticoagulants and 34 did not. Overall and thrombosis free survival was greater in the anticoagulant treated group (median survival not reached) than in the untreated group (median survival=12 months). Patients not receiving long term anticoagulation after IVC filter insertion were nearly 2.5-fold more likely to die or experience venous thromboembolism.

Conclusion: IVC filter insertion was a safe procedure and was performed for appropriate indications in the patients studied. In patients surviving for longer than 30 days, prolonged administration of oral anticoagulants was associated with improved survival with no significant increase in haemorrhagic complications.

Interruption of the inferior vena cava (IVC) using an endovascular filter is performed to prevent pulmonary embolism in patients in whom anticoagulation is contraindicated or has proved ineffective. An IVC filter may be inserted in patients with current venous thromboembolic disease or in patients at high risk for venous thromboembolism (VTE) in whom even prophylactic doses of anticoagulants pose an unacceptable haemorrhagic risk.^{1,2} The latter group includes patients with traumatic brain injury or extensive pelvic or long bone fractures.³ The role of IVC filters in the management of VTE has never been studied in a randomised controlled fashion, thus recommendations regarding the proper use of these devices have been developed based on observed common practice.

An important complication of IVC filters is thrombosis of the device and the potential for pulmonary embolism from this source.⁴ The frequency of this complication and the role of long term anticoagulation in its prevention are currently unknown. In this study we retrospectively analysed a cohort of patients in whom an IVC filter was inserted. Indications for IVC insertion, complications associated with the procedure, long term thromboembolic complications, and patient survival are reported. The possible salutatory effect of anticoagulation on VTE and death and bleeding complications are discussed.

Vena cava filters are inserted for a number of indications. Although guidelines for their use have been developed, a number of clinical situations exist for which there is no clear consensus regarding IVC filter insertion.^{5–7} Patients treated by a number of specialties may be referred for IVC filter insertion, thus collation of outcome data regarding all patients undergoing this procedure may tend to be incomplete. Furthermore, the necessity for long term

anticoagulation after IVC filter insertion has not been studied prospectively and probably for this reason use of long term anticoagulation is based on the decision of individual physicians. To better understand the current practices surrounding IVC filter use in our hospitals, we undertook the current retrospective study in which all patients undergoing IVC filter insertion in two teaching hospitals during a four year period were studied.

METHODS

All patients in whom an IVC filter was inserted in the Meir Hospital, Kfar Saba and Beilinson Hospital, Petach Tikva, during the period 1 January 2000 to 31 December 2003 were identified using the hospitals' computer code system for invasive procedures. The patients' hospital and clinic charts were reviewed and their primary care physicians were interviewed by one of us (ZD). Data regarding patient characteristics, the indication for IVC filter insertion, immediate and long term complications, concomitant illnesses and drug treatments, long term anticoagulation, and mortality were recorded (table 1).

Statistical analysis was performed using GraphPad Prism version 4 (San Diego, CA). Kaplan-Meier survival curves for patients receiving anticoagulants after IVC filter insertion and those in whom long term anticoagulation was not used were compared using the log rank test. The Fisher exact test was used to compare survival between the groups and the odds ratio calculated.

Abbreviations: VTE, venous thromboembolism; IVC, inferior vena cava; DVT, deep vein thrombosis

Table 1 Demographic details of the study patients

Number of patients	109
Male/female (number)	46/63
Age (mean and range) (years)	67.4 (19–96)
Length of follow up (median and range) (months)	12 (0.25–54)
Concomitant illnesses*	
Malignancy	39
Hypertension	38
Ischaemic heart disease	28
Diabetes mellitus	23
Cerebrovascular accident	21
Peptic ulcer disease	15
Atrial fibrillation	11
Congestive heart disease	11
Chronic obstructive airways disease	9

*Thirty five patients had three or more concomitant illnesses. Seventy one patients had one to two concomitant illnesses, and three patients had no concomitant illnesses.

RESULTS

During the four year study period, IVC filters were inserted in 109 patients: 70 at the Meir Hospital, and 39 at Beilinson Hospital. In 2000, 13 filters were inserted, in 2001, 27 filters, in 2002, 39 filters, and 30 filters were inserted in 2003. In 107 patients a Greenfield permanent IVC filter was used, while in two patients a Gunther Tulip retrievable filter was inserted. Two interventional radiologists at each hospital inserted all of the filters using a uniform insertion protocol that complied with the manufacturers' recommendations. In all cases filter insertion was performed under fluoroscopy.

Of the 109 patients, 46 (42%) were male and 63 (58%) were female. The average age was 67.4 years (range 19–96). The median duration of follow up was 12 months (range 0.25–54).

Indications for IVC filter insertion

The most common indication for IVC filter insertion was an absolute contraindication to anticoagulation in patients with acute VTE ($n = 61$, 56%), followed by prophylactic insertion ($n = 29$, 27%), recurrent thromboembolism while receiving adequate anticoagulation ($n = 17$, 15%) and non-compliance with anticoagulation ($n = 2$, 2%). Contraindications to anticoagulation were active gastrointestinal bleeding ($n = 27$), intracranial bleeding ($n = 17$), and haematuria ($n = 7$). Other contraindications to anticoagulation were retroperitoneal haemorrhage, haemoptysis, muscle haematoma ($n = 3$ for each), and epistaxis ($n = 1$).

Complications of IVC filter insertion

Complications related to the insertion of the IVC filter were minimal: groin haematoma that was successfully managed using a pressure dressing in four patients (3.5%) and localised infection at the puncture site that resolved without specific treatment in one patient (0.9%).

Figure 1 Number of patients who died during the study. AC+ denotes patients receiving anticoagulant therapy. AC– denotes patients not receiving long term anticoagulant therapy.

Clinical course and survival of patients after IVC filter insertion

Fifty six patients (51.4%) died during the study period. No deaths occurred in the immediate post-procedure period (first 24 hours). Twenty patients (35.7%) died within the first month after IVC filter insertion, an additional 31 patients (55.4%) died in the remaining 11 months of the first year and five patients (8.9%) died in the second and third years of follow up.

The cause of death was systemic infection in 19 patients (33.9%), malignancy in 18 (32.1%), myocardial infarction in six (10.7%), pulmonary embolism in five (8.9%), ischaemic stroke in three (5.4%), acute renal failure in two (3.6%), hypovolemic shock in two (3.6%), and unknown in one patient (1.8%).

Figure 2 Kaplan-Meier survival curves for patients treated with long term anticoagulants and those not receiving long term anticoagulants.

Table 2 Causes of mortality among patients undergoing IVC filter insertion as a function of the interval between filter insertion and death

Cause of death (n)	Day 1	Day 2–day 30	1–12 Months	> 12 Months
Infection	0	8	8	3
Malignancy	0	2	13	3
Myocardial infarction	0	1	2	3
Pulmonary embolus	0	3	2	0
Stroke	0	1	2	0

Table 2 shows the causes of death at different time points during follow up.

Anticoagulation after IVC filter insertion

Anticoagulation was begun as soon as possible after IVC filter insertion in 55 patients (50.5%) and was continued throughout the study period. In the remaining 54 patients (49.5%), anticoagulants were not given after IVC insertion, largely because of persistence of a contraindication to anticoagulation. The decision whether or not to give anticoagulants after filter insertion was at the discretion of the treating physician. Of the 56 patients who died, 22 received anticoagulants and 34 did not. Of the 20 patients who died in the first month, 10 (50%) received anticoagulants and 10 (50%) did not. Of the 31 patients who died in the remainder of the first year, 10 (33%) received anticoagulants while 21 (67%) did not. Of the five patients who died in the second and third years of follow up two (40%) were taking anticoagulants and three (60%) were not (fig 1). Anticoagulant use was related to the cause of death only in the case of infection leading to death (5 of 19 patients dying of infection were treated with anticoagulants while 14 of 19 patients were not ($p = 0.01$)). Half of the 18 patients who died of malignancy received anticoagulants while half did not, and of the five patients who died of pulmonary embolus, three were treated with anticoagulants (INR was in the therapeutic range) while two patients were not.

Overall and thrombosis free survival was greater in the anticoagulant treated group (median survival not reached) than in the untreated group (median survival = 12 months) ($p = 0.03$ by log rank comparison) (fig 2). Patients not receiving long term anticoagulation after IVC filter insertion were nearly 2.5-fold more likely to die or experience VTE ($p = 0.03$ by Fisher's exact test, odds ratio = 2.4, 95% confidence interval 1.1 to 5.2). Table 3 shows that irrespective of the indication, patients undergoing IVC filter insertion had a higher mortality rate if long term anticoagulation was not given. Because of the small numbers of patients in the subgroups, statistical analysis was not possible. Furthermore, when analysing the patients in whom prophylactic filter insertion was performed, it is apparent that long term anticoagulation did not improve outcome in this cohort of patients: eight patients (35%) died while receiving long term anticoagulation and two (33%) died with no long term anticoagulation.

DISCUSSION

In this retrospective study of the use of IVC filters in routine hospital practice, we have shown that most of the patients who underwent filter insertion for indications recognised by the American College of Chest Physicians (ACCP) as class 1C: 61 patients (56%) had an IVC filter inserted because of a contraindication to anticoagulation, and 16 (15%) for failure thereof. Twenty nine patients (27%) had a filter inserted for pulmonary embolism prophylaxis before neurosurgery or after major trauma, a procedure that is not considered to be evidence based by the ACCP. Filter insertion related complications were rare in our study: groin haematoma that was successfully managed using a pressure dressing in four patients (3.5%) and localised infection at the puncture site that resolved without specific treatment in one patient. The mortality in our study was high with most patients dying in the first month after filter insertion, reflecting the prevalence of advanced malignancy in a large number of patients in the study. Half of the patients received long term anticoagulation after filter insertion. This treatment had a salutary effect on long term survival in patients who survived for more than one month after IVC filter insertion. There were no serious haemorrhagic events associated with long term anticoagulation in the study.

The role of anticoagulation after IVC filter insertion remains uncertain. A retrospective study of 1191 patients undergoing IVC filter insertion because of deep vein thrombosis (DVT) reported that after a mean of nine years of follow up of 465 of the patients for whom complete follow up data were available, there was a 12% rate of recurrent DVT in patients who were given long term anticoagulation and a 15% recurrence rate in those who were not.⁸ This suggests that anticoagulation was not protective against recurrent thrombosis in these patients. However, the overall rate of DVT recurrence in this study was comparatively low, a factor that may account for the lack of protective effect of anticoagulation. By contrast, Blebea *et al*⁹ have reported a 40% incidence of new proximal DVT at 12 days after IVC filter insertion, suggesting the need for continued anticoagulation in these patients whenever possible. Only one randomised controlled trial addressing this issue has been published.⁴ In this study of 400 patients with proximal DVT who received anticoagulant therapy alone or with the insertion of a filter, the incidence of pulmonary embolism early (by day 12) was reduced in the group of patients with

Table 3 Patient survival after IVC filter insertion as a function of the indication for filter insertion

Indication for IVC filter insertion	Anticoagulant therapy		Outcome (%)	
Contraindication to anticoagulation (n = 61)	Yes	15	Alive	7 (47)
	No	46	Dead	8 (53)
Prophylactic (n = 29)	Yes	23	Alive	18 (39)
	No	6	Dead	28 (61)
Failure of anticoagulation (n = 17)	Yes	15	Alive	15 (65)
	No	2	Dead	8 (35)
Poor compliance (n = 1)	Yes	1	Alive	4 (67)
	No	0	Dead	2 (33)
Other (n = 1)	Yes	1	Alive	9 (60)
	No	0	Dead	6 (40)
	Yes	1	Alive	0 (0)
	No	0	Dead	2 (100)
	Yes	1	Alive	1 (100)
	No	0	Dead	0 (0)
	Yes	1	Alive	0 (0)
	No	0	Dead	0 (0)
	Yes	1	Alive	1 (100)
	No	0	Dead	0 (0)
	Yes	1	Alive	0 (0)
	No	0	Dead	0 (0)

an IVC filter. However, this risk reduction was not maintained after two years of follow up, and overall mortality was the same in both groups. Furthermore, the IVC filter group experienced twice the number of recurrent DVT than did the anticoagulant only group. These findings have led to expert opinion recommendation suggesting that anticoagulant therapy be given to patients with an IVC filter as soon as possible after its insertion.⁵ However, it should be noted that the above study did not include patients with a contraindication to anticoagulation or its failure, but sought to examine whether an IVC filter would add a measure of safety to routine anticoagulation in patients with proximal DVT. The results of our study showing a significant survival advantage in patients receiving anticoagulants after IVC filter insertion further support this recommendation.

In our study, patients undergoing prophylactic IVC filter insertion had no excess mortality whether they received long term anticoagulation (8 of 23 patients, 35%) or did not (2 of 6 patients, 33%). Although these numbers are small and do not support definite conclusions, they suggest that in patients with no active thrombotic diathesis, long term anticoagulation may not be necessary. The post-IVC filter thrombotic complications seen in patients with a contraindication to anticoagulation or the failure thereof, may reflect these patients' underlying thrombotic tendency rather than the thrombogenic nature of the filter itself. In assessing the long term outcome of patients with IVC filters, patients in whom prophylactic filter insertion is performed may need to be considered separately as their prognosis seems unaffected by the continued use of anticoagulants.

An ideal solution to the problem of excess VTE after IVC filter insertion is the use of retrievable filters. A number of such devices have been licensed for use worldwide, and experience in their use is accumulating. Most temporary filters are designed to remain in situ for 10–14 days before their removal, thus avoiding the problem of late thromboembolic complications.

Although our study involves patients treated at only two medical centres, we feel that it provides a fair representation of common practice regarding the indications, complications, and outcomes of IVC filter insertion in hospital practice. This is because of the large number of clinical departments involved in the management of these patients. Furthermore, the retrospective nature of the study allows for the observation of actual clinical practice outside of the constraints of a controlled study. Finally, by collecting data from the patients' primary physicians we were able to achieve a longer duration of follow up of patients with IVC filters than has been previously reported. These features of the study make its results applicable to the broader population of patients

undergoing IVC filter insertion. An important point, however, is that the procedure related complications (negligible in our study), are related to the competence of the operator responsible for insertion of the filter. In this study all of the filters were inserted by one of four interventional radiologists, and thus a general conclusion regarding insertion complications is not possible from this study.

In conclusion, we have shown that IVC filter insertion was a safe procedure and was performed for appropriate indications. The high short term mortality rate seen in this study reflected the important comorbidities present in a large number of patients, particularly advanced malignancy. In patients surviving for longer than 30 days, prolonged administration of oral anticoagulants was associated with improved survival with no significant increase in haemorrhagic complications.

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