

Outcomes of permanent inferior vena cava filters: experiences in Thai patients

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INTRODUCTION We aimed to study the outcomes of permanent inferior vena cava (IVC) filter implantation in Thai patients.

METHODS This was a retrospective study of 28 patients with deep vein thrombosis (DVT) who underwent prophylactic implantation of IVC filters for fatal pulmonary embolism (PE) between January 2005 and June 2008. The patients' operative records, protocol and follow-up data were analysed. 11 (39%) patients had PE at the initial diagnosis. The mean age of the patients was 62.1 (range 33–83) years. Indications for IVC filter implantation included contraindications to and complications of anticoagulant therapy and floating thrombi in the iliofemoral veins.

RESULTS No significant technical complication was noted, except for malposition in one patient (3.5%) and failure of the permanent IVC filter to open fully in another. During the follow-up period (mean 17.5 ± 10.9 months), no patients had any episode of PE and nine (32%) died of unrelated causes. Two patients were lost to follow-up. Among the 17 survivors, six (35.2%) had non-recanalised thrombosis vein, four (23.5%) had clinical evidence of chronic venous insufficiency, two (11.7%) had recurrent DVT in the contralateral limb and one (5.8%) developed IVC thrombosis. There was no evidence of migration of the caval filters. No statistical significance was observed in the effects of post-filter anticoagulation drug on current DVT and in the relation between PE at initial diagnosis and death during follow-up.

CONCLUSION Permanent IVC filter implantation may be effective for preventing symptomatic PE in Thai patients, with no significant sequelae in the lower extremities.

Keywords: outcome, pulmonary embolism, treatment, vena cava filter
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INTRODUCTION

Pulmonary embolism (PE) is a catastrophic complication of deep vein thrombosis (DVT), which leads to high morbidity and mortality in the emergency setting. PE is not an infrequent event in Thailand, and the characteristics of PE patients in Thailand are similar to those reported in European countries.⁽¹⁾ To date, anticoagulant therapy has been widely used to prevent PE. However, some DVT patients could not be treated with anticoagulation therapy due to contraindications to, or failure/complications of this therapy.⁽²⁾ In the absence of appropriate treatment, DVT may result in PE in approximately 60% of cases and a high mortality rate of 30%–40%.⁽³⁾

For several decades, percutaneous inferior vena cava (IVC) filters have been used to prevent PE. However, it was not widely used in the early years due to major complications of the procedure, including caval occlusion, filter migration and recurrent PE.⁽⁴⁾ Nowadays, advances in the composition and design of filters have helped to reduce the number of complications and enhance practical usage.⁽⁵⁾

Although IVC filters have been widely used in European countries, their prophylactic effectiveness is still unclear.⁽⁶⁾ Furthermore, clinical experience in Thailand has demonstrated that ethnic differences between Thai and European patients exist, especially the risk factors of venous thromboembolism.⁽⁷⁾ As a result, it is not appropriate to assume that the results of European studies can apply fully to general practice in Thailand. The aim of

this retrospective study was to analyse the outcomes of permanent IVC filter implantations in Thai patients.

METHODS

A total of 28 DVT patients who were treated with percutaneous permanent IVC filters between January 2005 and June 2008 were identified. The patients' operative records, protocol and follow-up data were collated and analysed. The mean age of the patients was 62.1 (range 33–83) years. Out of the 28 patients, 20 were female and 11 (39%) had PE at the initial diagnosis. The study was approved by the Siriraj ethical committee for research in humans. Informed consent was obtained and documented for all patients.

Clinically apparent DVT was investigated with Doppler ultrasonography (DUS). 16 (57%) patients developed DVT at the left lower extremity and three (11%) at both sides of the lower extremities. Iliofemoral thrombus was present in 22 (79%) patients, IVC thrombus in three (11%), femoropopliteal thrombus in two (7%) and tibioperoneal thrombus in one (3%) patient. Among the 28 patients, total thrombus occlusion was demonstrated in 20 (71%) patients and partial thrombus occlusion in eight (29%). 16 (57%) patients did not undergo anticoagulation therapy during the IVC filter implantation. Among the 11 patients with PE, eight (73%) were diagnosed by computed tomography angiography, four (36%) by radionuclide ventilation/perfusion imaging and two (18%) by pulmonary angiography.

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Fig. 1. Plain abdominal radiograph shows malposition of the permanent inferior vena cava filter located at a suprarenal level. Note that the right limb of the filter has invaded into the right renal vein.

The underlying conditions predisposing to DVT before IVC filter insertion were malignancy ($n = 9$, 32%), immobilisation ($n = 13$, 46%), postoperative status ($n = 4$, 14%), hypercoagulable state ($n = 3$, 11 %) and previous history of DVT ($n = 2$, 7%). Indications for IVC filter placement were contraindication to anticoagulation therapy in 20 (71.4%) patients, complication of anticoagulation in two (7.1%) and floating thrombus in six (21.5%).

The outcomes of permanent IVC filters analysed were as follows: (1) Complications during IVC filter insertion; (2) Safety and effectiveness of IVC filter. Signs and symptoms of current and contralateral DVT, chronic venous insufficiency (CVI) and clinical PE were evaluated by clinical evaluation and DUS, while stability and position of the IVC filters were evaluated by plain frontal radiography of the abdomen. IVC patency was evaluated by DUS and computed tomography venogram (CTV); (3) Mortality rate and cause of death during the follow-up period.

All patients underwent percutaneous insertion of permanent IVC filters (Vena Tech LP, B Braun Interventional Systems Inc, Bethlehem, PA, USA) under local anaesthesia in an operative theatre. All filters were inserted percutaneously through a 9-Fr external diameter sheath under fluoroscopic control via a right subclavian vein and a supraclavicular approach in 27 (96%) patients, and a right femoral vein in one (4%) patient. Venacavogram was performed both before and after implantation to confirm that the upper border of the IVC filter was located at the infrarenal IVC. Intraoperative complications were recorded. Clinical examination and abdominal radiography were performed within 24 hours postoperatively.

The mean follow-up period was 17.5 ± 10.9 (range 2–36, median 19) months. All patients were clinically evaluated on the signs and symptoms of current and contralateral DVT by a vascular surgeon. Current DVT was diagnosed if there was no recanalisation of a previous DVT. Contralateral DVT was diagnosed if there was a new thrombus occupying the contralateral deep veins. A diagnosis of CVI was considered if at least one of the following objective features was present: leg swelling, hyperpigmentation, lipodermatosclerosis, varicose vein and venous ulcers, when compared with the initial assessment. The patients were also questioned regarding symptoms of PE such as dyspnoea with chest pain, haemoptysis and failing or lack of consciousness. Subsequent lung scintigraphy and chest radiography were indicated only when there were symptoms indicating clinically symptomatic PE.

Table 1. Outcomes of patients with permanent inferior vena cava filters.

Outcome	No.
Complications of IVC filter insertion	
Fatal	0
Non-fatal	2
Deaths	9
Deaths caused by PE	0
Current DVT	6
Contralateral DVT	2
Chronic venous insufficiency	4
PE after IVC filter placement	0
IVC thrombosis	
Occlusion	1
Trapped thrombus	0
Migration	0
Destruction of devices	0

IVC: inferior vena cava; PE: pulmonary embolism; DVT: deep vein thrombosis

All follow-up patients underwent plain frontal radiography of the abdomen to evaluate the stability of the IVC filters. We defined migration of the IVC filters by the movement of either a caudal or cephalic direction > 10 mm from the site of the initial film implantation, as a result of the differences in the patient's positioning, respiration and parallax of the roentgen beam.⁽⁸⁾

Evidence of IVC patency and filter thrombosis was confirmed if an intraluminal thrombus in the IVC or filter and an abnormal respiratory phasic flow in the IVC were demonstrated on DUS. All patients with abnormal findings in the IVC were subsequently diagnosed with CTV. The cause of death of all the patients was recorded.

Finally, we analysed the effects of post-filter anticoagulation drugs on current DVT and the relation between PE at initial diagnosis and death during follow-up study. In this series, only 26 patients were successfully investigated, as two patients were lost to follow-up. Data for continuous variables was presented as mean, range or median. The proportions of data were analysed using chi-square statistics, or when appropriate, by Fisher's exact test. A p -value < 0.05 was considered to be statistically significant.

RESULTS

The outcomes of percutaneous IVC filters in our research were derived from the operative records, protocol data and follow-



Fig. 2. CT venogram shows the thrombus lodged in both the inferior vena cava (IVC) and the permanent IVC filter.

up data. No inserted site or fatal complications occurred intra-operatively. Two patients developed intra-operative complications; malposition of the filter in one (3.5%) case (Fig. 1) and failure of the filter to fully open in the other (3.5%). Two patients defaulted follow-up and nine patients died; hence, only 17 patients were evaluated in this study. The safety and effectiveness of IVF filters in the remaining 17 patients are shown in Table I. All patients with CVI developed limb swelling, of which two had current DVT. The mean follow-up time in patients who developed CVI was 23 (range 7–35) months. There was no clinical sign of PE or significant migration of the IVC filter among the patients seen during follow-up. IVC thrombosis was present in one patient (Fig. 2). The mortality rate was 32% ($n = 9$); six died from sepsis, and one each from acute myocardial infarction, epilepsy and malignancy. None of the patients died from PE. Six patients still had current DVT during follow-up, of which four remained on anticoagulation drug ($p = 0.620$) (Table II). Of the nine patients with PE at the initial diagnosis, two died during the follow-up period ($p = 0.418$) (Table III).

Table II. Comparison between post-filter anticoagulation drug and current DVT.

Current DVT*	Post-filter anticoagulation		Total no.
	No	Yes	
No	7	5	12
Yes	2	4	6
Total no.	9	9	18

* $p = 0.620$ (Fisher's exact test)
DVT: deep vein thrombosis

Table III. Comparison between PE at initial diagnosis and death during follow-up study.

PE*	Death		Total no.
	No	Yes	
Absence	10	7	17
Presence	7	2	9
Total no.	17	9	26

* $p = 0.418$ (Fisher's exact test)
PE: pulmonary embolism

DISCUSSION

In Western countries, complications of IVC filter implantation include caval complications such as caval thrombosis^(9,10) and filter migration.⁽¹¹⁾ In our study, however, IVC filter was found to effectively prevent clinically symptomatic PE without the high incidence of device-related adverse effects seen in European patients.

Only one (3.5%) patient in our study developed malposition. Complications during IVC filter insertion, including filter misplacement, common femoral vein perforation and filter tilting or asymmetry, have previously been described.⁽¹²⁾ In normal settings, filter deployment should be located between the renal veins and bifurcation of the IVC. Deployment above the renal veins may increase the possibility of renal vein thrombosis and renal dysfunction, whereas deployment into one of the iliac veins may leave the IVC unprotected from the contralateral iliac system.⁽¹³⁾ Malposition is an uncommon complication, which was found in only 1.6% of cases in one study.⁽¹⁴⁾

Filters may have an abnormal configuration after deployment as a result of incomplete opening of the device. One (3.5%) patient in our study presented with failure of the IVC filter to fully open. Incomplete opening of the IVC filter has been reported in 3%–8% of cases.⁽¹³⁾ West et al reported similar failure of the filter to fully open during deployment of a Vena Tech LP filter. The unopened filter is retrieved with snares in order to avoid filter migration into the right atrium.⁽¹⁵⁾ No migration was seen in our patient with incomplete opening of the IVC filter during the follow-up period; however, awareness of the possibility of migration in this case should be raised during long-term follow-up.

Venous stasis or insufficiency may present with or without concomitant IVC thrombosis. Either new or worsening lower limb swelling is seen in 5%–6% of patients after filter implantation.⁽⁶⁾ In the current study, six (35.2%) patients still had DVT post implantation, of which two (11.7%) developed contralateral DVT and four (23.5%) continued to be on anticoagulation medication

($p = 0.620$) (Table II). Therefore, there was no significant difference observed between current DVT and usage or non-usage of post-filter anticoagulation drug. The findings of the current study is consistent with those of Ray and Prochazka's study on the effect of anticoagulation on rates of venous thromboembolism after IVC filter implantation in 1,369 patients.⁽¹⁶⁾ The authors reported that there was no statistical significance for a decreased venous thromboembolism rate in patients with post-filter anticoagulation.⁽¹⁶⁾ Four (23.5%) patients in our study presented with CVI during the follow-up period, and all developed limb swelling. Thus, our results corroborate the findings of Fox and Kahn's study of 1,552 patients with IVC filter insertion,⁽¹⁷⁾ which showed that IVC filters could be associated with the development of post-thrombotic syndrome.

It is generally accepted that in order to avoid PE, one has to prevent thrombus development with anticoagulation drugs as well as block the passage of disengaged thrombi to the pulmonary circulation with IVC filters.⁽⁸⁾ In most cases, IVC filters are effective, and breakthrough PE occurs in 0%–6.2% of cases.⁽²⁾ Moreover, a reduction in PE has been reported in patients with IVC filter implantations at the eight-year follow-up.⁽¹⁸⁾ No patient with IVC filter was found to have symptomatic PE in the present study. There was no statistical difference between the absence or presence of PE at initial diagnosis and death during the follow-up period ($p = 0.418$) (Table III). Thus, the presence of PE before filter insertion has not been shown to be a predictive factor for death during the follow-up period.

Filter thrombosis may either be the result of successful clot trapping or the presence of the device in the vena cava. Therefore, it is difficult to conclude which of the two could have been responsible for the event. Although filter thrombosis due to successful clot trapping is not a desired effect, it represents a substitution situation between possible thrombosis and inadequate clot trapping with fatal PE.⁽¹⁹⁾ In this study, IVC thrombosis occurred in only one (5.8%) patient, who continued to be on anticoagulation after the filter placement. In a long-term study, Crochet et al reported that out of 142 patients who underwent Vena Tech-LGM filter placement, 28 (19.7%) developed caval occlusion at the nine years follow-up, and demonstrated that caval occlusion was not related to aging, gender, PE, DVT level, underlying hypercoagulable state, filter placement level, anticoagulation usage or death during follow-up.⁽¹⁰⁾

The mortality rate among European patients with IVC filters has been reported to be nearly 21% at the three months follow-up.⁽²⁰⁾ In our series, the mortality rate was 32% ($n = 9$), of which only two had underlying malignancy. Schleich et al's study reported a significantly higher mortality rate among cancer patients (relative risk = 2.13) during a median follow-up period of 11.3 months.⁽²¹⁾ Our study, however, found that underlying disease did not significantly affect the mortality rate.

In conclusion, this study has shown that percutaneous implantation of permanent IVC filters in DVT patients with or without PE is safe and does not result in any serious complications.

In addition, the average 17-month follow-up showed an absence of symptomatic PE and any device-related adverse events among our patients. The findings of this study support the use of permanent IVC filters in Thai patients with well-targeted indications. As the present study was limited by a small sample size and the mid-term follow-up period, it is recommended that the outcomes be investigated in future studies.

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