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Vena cava thrombosis after vena cava filter placement: Incidence and risk factors

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Abstract

Background The objective of this study was to assess the clinical safety and efficacy of vena cava filter (VCF) placement, with particular emphasis on the incidence and risk factors of inferior vena cava thrombosis (VCT) after VCF placement. **Methods** Clinical data of patients with venous thromboembolism (VTE), with or without placement of VCF, were analyzed in a retrospective single-center audit of medical records from January 2005 to June 2009. The collected data included demographics, procedural details, filter type, indications, and complications. **Results** A total of 168 cases of VTE (82 with VCF; 86 without VCF) were examined. Over a median follow-up of 24.2 months, VCT occurred in 18 of 82 patients with VCFs (11 males, 7 females, mean age 55.4 years). In 86 patients without VCFs, VCT occurred in only 6 individuals (4 males, 2 females) during the study period. VCT was observed more frequently in patients fitted with VCFs than in those without VCFs (22% *vs.* 7.0%). **Conclusions** The incidence of VCT in patients with VTE after VCF implantation was 22% approximately. Anticoagulation therapy should be continued for all patients with VCF placement, unless there is a specific contraindication. Almost all instances of VCT in patients with VCF implants in our study occurred after stopping anticoagulation treatment. The use of VCFs is increasing, and more trials are needed to confirm their benefit and accurately assess their safety.

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Keywords: vena cava filters; venous thromboembolism; complication

1 Introduction

Venous thromboembolism (VTE) including deep vein thrombosis (DVT) and pulmonary embolism (PE) is a significant cause of hospitalization and long-term morbidity and mortality worldwide.[1] Vena cava filter (VCF) placement appears to be effective in the prevention of PE.[2] However, the incidence of vena cava occlusion or thrombosis and post-thrombotic syndrome increases significantly in relation to VCF use.[3] The reported incidence of vena cava occlusion or thrombosis following filter placement varies. The overall incidence of vena cava thrombosis (VCT) among the individuals fitted with current-generation filters varies from 20% to 30%.[4] VCT is a serious complication that can arise weeks to years following VCF placement, but the incidence and risk factors for VCT after VCF placement among the Chinese population are unclear. The objective of this study was to investigate the safety and efficacy of VCF placement in the Chinese population, with particular emphasis on the incidence and risk factors of VCT after VCF placement.

2 Methods

2.1 Study population

Patients treated for VTE at the Department of Cardiology and Periphery Vascular Medicine of the First Affiliated Hospital of Medical College of Xi'an Jiaotong University, from January 2005 to June 2009 were classified into those receiving VCF placement (VCF group) and those not receiving VCF placement (no-VCF group) as part of their therapy. DVT was confirmed by ultrasonography or ascending venography, and PE was confirmed by ventilation/perfusion lung scan or pulmonary angiography. All patients were evaluated using vena cava radiography, including angiography, multislice helical CT angiography or ultrasonography of vena cava to confirm the absence of complications from inferior vena cava thrombosis or occlusion before

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VCF placement or at the beginning of this study.

Patients diagnosed with VTE for whom there were no records of interval assessment or follow-up were excluded from analysis.

2.2 Vena cava filter placement

Inferior venacavography was performed in all patients prior to filter placement. Following filter insertion, venacavography was repeated to confirm the filter location and patency of the inferior vena cava. The indications for VCF placement were: VTE with contraindication for anticoagulant therapy (n = 26); VCFs were placed by experienced, board-certified, interventional radiologists. Filters were inserted through either the femoral or the jugular venous approach. The following types of filters were implanted: TrapEase (Cordis Corp., Miami, FL, USA), permanent Vena Tech (VT) filters (B. Braun Medical S.A., Boulogne, France), and retrievable Gunther Tulip filters (GT) (William Cook Europe, Bjaeverskov, Denmark).

2.3 Data collection and management

The follow-up of identified patients was based on clinical reports in the medical record. Patients in the study were followed from three to 45 months (average 24.2 months) using clinical medical records, as well as subsequent outpatient and inpatient notes. The information reviewed for each patient included hospital charts, outpatient clinical notes, operative reports, interventional radiology reports, and noninvasive vascular laboratory records. We also collected information on patient demographics, indication for the filters, procedural complications, long-term complications, and concurrent use of anticoagulant therapy.

2.4 Statistical methods

Demographic and procedural data were summarized by using counts and percentages or mean ± SD. Associations were evaluated for statistical significance using Student's t-test for continuous data and the Fisher exact test for categorical data, as a result of low expected cell counts. These data were analyzed with SAS statistical software (version 10.1; SAS Institute). The significance level was set at $P < 0.05$.

3 Results

The patient characteristics for individuals in the VCF and no-VCF groups are outlined in Table 1. The main baseline demographic and clinical characteristics of patients were similar.

Table 1. Patient characteristics.

Characteristic	VCF group	no-VCF group
Cohort, *n*	82	86
Male	51	44
Female	31	42
Median age in years (mean ± SD)	48.5 ± 24.2	45.6 ± 26.1
Underlying medical condition		
Post-trauma	31	32
Malignancy	16	15
Antiphospholipid syndrome (APLS)	2	1
Chronic lung/heart disease	3	4
Central nervous system diseases	10	13
Liver disease	3	2

VCF: vena cava filter placement.

We observed no cases of clinically-apparent filter migration or significant perioperative hemorrhage. VTE with failure of anticoagulant therapy (n = 11); prophylaxis related to a surgical procedure (n = 14); and prophylaxis associated with multiple-system trauma (n = 31).

Patients were followed for an average of 24.2 months (range: 3 to 45 months). Ten patients (12.20%) in the VCF group and eight patients (9.30%) in the no-VCF group died over the course of the study. The main causes of death were cancer (11 patients), unexplained death presumed to be of cardiovascular origin (three patients), cardiac disease (three patients), and bleeding (one patient). Pulmonary embolism was directly involved in the death of three patients. Two patients had renal failure on follow-up. Known cancer and cardiac or respiratory insufficiency were the only significant predictors of death.

The incidence of procedural-related complication in our cohort was very low, consistent with published reports. Recurrent DVT occurred in 32 patients (39%) in the VCF group and 20 (23%) in the no-VCF group. Recurrent PE occurred in 6 patients (7.3%) in the VCF group and 8 (9.3%) in the no-VCF group. Post-thrombotic syndrome occurred in 37 patients (45%) in the VCF group and 22 patients (26%) in the no-VCF group. Among these patients, 8 (9.8%) and 9 (10%), respectively, received no antagonist during the study period. The cumulative rates of clinical outcomes of patients in the VCF and no-VCF groups are outlined in Table 2.

VCT occurred in 18 of 82 patients (22%) in the VCF group during the study period. The mean age of these 11 male and seven female patients was 55 ± 16 years. VCT occurred in 6 of 86 patients in the no-VCF group (7.0%) during the study period. The mean age of the four male and two female patients was 53 ± 14 years. VCT was observed more frequently in the patients with VCFs compared those

without VCFs (22% *vs.* 7%; $P > 0$ .05). The characteristics of patients in the VCF and no-VCF groups who experienced VCT are outlined in Table 3.

Table 2. Cumulative rate of clinical outcomes.

Varity	VCF group	no-VCF group
Recurrent DVT*	32	20
Recurrent PE	6	8
Postthrombotic Syndrome*	37	22
Death	10	8
Major bleeding	2	3

DVT: deep vein thrombosis; PE: pulmonary embolism. *$P < 0.05$ for removable indicator *vs*. demographic variable.

Table 3. Patient characteristics of vena cava thrombosis.

Characteristic	VCF group	no-VCF group
Male	11	4
Female	7	2
Median age in years	55.5 ± 16.2	53.4 ± 14.2
Underlying medical condition		
Post-trauma	2	1
Malignancy*	8	3
APLS/SLE	0	0
Chronic lung/heart disease	1	0
Central nervous system disease	2	0
Liver disease	1	0
Anticoagulation		
Therapeutic anticoagulation in < 1 months	2	2
Therapeutic anticoagulation in 1–3 months	6	1
Therapeutic anticoagulation in 3–6 months	2	1
Therapeutic anticoagulation in > 6 months	1	0
No anticoagulation	7	2

*$P < 0.05$ for removable indicator *vs*. demographic variable.

The average time between VCF placement and the occurrence of VCT was 6.4 months (range 2 to 26 months). Almost all instances of VCT following the placement of a VCF in our study occurred after stopping anticoagulation treatment. The mean time between the occurrence of VCT and the cessation of anticoagulant therapy was 3.2 months (range 2 to 12 months) in the VCF group. Seven of the 18 patients (39%) who experienced VCT after of the placement of a VCF received no anticoagulation treatment during the study period. The incidence of asymptomatic individuals and those with symptomatic VCT following filter placement were 61% and 39%, respectively.

During the study period, VCT occurred in 6 patients in the no-VCF group. Two patients were symptomatic, and 4 patients were asymptomatic. For these individuals VCT occurred within a follow-up range of one to 24 months, and the median time to thrombosis of was 8.3 months.

In both the VCF group and the non-VCF group, the incidence of asymptomatic VCT was more common than symptomatic VCT. The only two VCT-related fatalities presented with phlegmasia cerulea dolens and abdominal compartment syndrome. The two cases were treated with catheter-directed thrombolysis and rheolytic thrombectomy with successful re-establishment of caval flow, although none had complete recanalization of the inferior vena cava sufficient for filter removal.

Multivariate analysis revealed that known cancer at inclusion was associated with a significantly increased incidence of VCT, and recurrence of VTE during the study period.

4 Discussion

VTE is a common medical condition associated with high mortality and morbidity rates, and substantial immediate and long-term costs to society. Anticoagulation remains the first line therapy for VTE, and is credited with preventing PE in 95% of patients with DVT.[5] Major bleeding is the main complication of anticoagulation therapy, and hence, VCF placement is a possible alternative means for preventing PE in patients with DVT for whom anticoagulant therapy is contraindicated. However, VCF offers only transient prevention of PE, and VCF placement may not be the best treatment strategy for many patients. VCF placement can potentially cause major morbidity, and may offer no additional benefit over conventional anticoagulant therapy. VCFs are increasingly being used in the clinical setting, however, only limited outcome data are available regarding the complication rates for VCF placement.[6] The main long-term complication of VCF placement is an increased incidence of DVT. The incidence of VCT also increases with the use of VCF.

VCF placement is an addition to the therapeutic armamentarium for the prevention of pulmonary embolism. There are a variety of complications that have been described with the currently available VCF devices [7]. Complications associated with VCF can be short-term or long-term. Complications reported after VCF insertion and/or retrieval included vena cava thrombosis, PE, bleeding, infection, and device migration or embolization.[8]

Our results showed that the incidence of VCT increased with the use of VCF. The incidence of VCT in patients after placement of VCF was approximately 22% in this study. VCF placement is also associated with an increased risk of

recurrent VTE and VCT. Patients with cancer-related VTE, in particular, were found to have an increased risk of VCT and recurrent VTE.

We found a paucity of studies specifically addressing the need for anticoagulation therapy following VCF placement. It may be difficult to ascertain whether thrombosis is related to filter placement or the initial DVT. A thrombus found in the VCF of a patient may point to inadequate or ineffective anticoagulation therapy. In 1998, Decousus *et al*.[9] published the results of a large trial comparing anticoagulation therapy with and without concomitant VCF placement. Although the study did not specifically address the need for long-term anticoagulation following VCF placement, it showed that the risks associated with VCF without concomitant anticoagulation far exceed the benefits. The question that deserves to be addressed is whether or not the use of a VCF is safe for patients who cannot receive concomitant anticoagulation therapy. In this study, almost all instances of VCT in patients with filters occurred after stopping anticoagulation treatment. Therefore, we conclude that anticoagulation therapy should be continued after VCF placement, except in those patients for whom anticoagulation therapy is specifically contraindicated.

The incidence of symptomatic VCT was small, and the occurrence of VCT was most often asymptomatic in our study. VCT is associated with significant morbidity including lower extremity swelling and edema, renal failure (suprarenal thrombosis), and systemic or pulmonary embolization. As such, filters should be used cautiously and only as required.

Permanent filters remain in situ for the remainder of the patient's life, and any complications from the filters are of significant concern.[10] Retrievable filters, developed to avoid or decrease the complications associated with the use of long-term filters, appear to be a significant advance in the prevention of PE.[11–12] The original implantation time of 10 to 14 d has been extended to a mean implantation time of more than 100 d with some filter types. Follow-up (preferably prospective) is necessary for all patients with retrievable filters, whether or not they are retrieved. More prospective, randomized trials evaluating optional retrievable filters are needed to answer these important questions [13].

This study was a retrospective investigation of the complications observed after VCF placement. The studies that were available had small sample sizes, were nonrandomized, and did not use systematic follow-up for outcomes and, as such, are subject to numerous biases and limitations in follow-up. However, this seems unlikely if the complication of VCT is assumed to be a rare event. Our results describe a higher-than-expected incidence of complications after VCF placement. These findings have led our group to be very cautious in the application of VCF.

5 Conclusions

The incidence of VCT in patients after of placement of VCF was approximately 22% in our study. VCF use was associated with an increased risk of recurrent DVT and vena cava occlusion or thrombosis. Anticoagulation therapy should continued for patients after VCF placement, unless it is specifically contraindicated. The majority of instances of VCT in patients with VCF placement in our study occurred after of stopping anticoagulation treatment. The use of an optional or retrieval VCF would eliminate the long-term complications associated with permanent VCF placement. VCF use is increasing, and more trials are needed to confirm their benefit and accurately assess their safety.

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