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THE LATE OUTCOMES OF VENA CAVA FILTERS IN THE PREVENTION OF PULMONARY EMBOLISM

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ABSTRACT

Background: *Pulmonary embolism (PE) is the most serious complication of deep venous thrombosis (DVT) resulting in high morbidity and mortality rate. The purpose of this study is to evaluate the long-term results of vena cava filters (VCFs) placement for prevention of PE in high- risk patients.*

Methods: *Between June 1999 and March 2002, at the Trauma and Surgical Emergency Service of Istanbul Medical Faculty, 15 high-risk patients who underwent placement of filters were evaluated.*

Results: *There were eleven males (73%) and four females (27%) with mean age of 50 years (range 14 to 76). Eleven of VCFs were placed for prophylactic and four for therapeutic purposes. The indications of VCFs placement are as follows: Spinal cord injury with life-long paraplegia in eight and quadriplegia in two patients, venous thromboembolism while on anticoagulation in two patients, contraindications to anticoagulation in three patients. The mean duration of follow-up was 17 months (range 3-32 months). No patients developed DVT and recurrent DVT. No patients clinically had signs or symptoms of PE. There was one insertion site thrombosis that related to VCF complications, which resolved with medical therapy. Four patients died during the study period. Medical records revealed no evidence of PE.*

Conclusion: *Although VCF placement seems to prevent PE in high- risk patients, prospective randomized trials with larger patient groups and longer-term follow up period are necessary to evaluate efficacy and safety of VCF in prevention of PE before making definitive conclusion.*

Key words: *vena cava filter, pulmonary embolism, deep venous thrombosis, long-term results.*

INTRODUCTION

Venous thromboembolism is a common and important clinical entity. The majority of patients with deep venous thrombosis (DVT) also have symptomatic or asymptomatic pulmonary embolism (PE).[1] PE is the most serious complication of DVT resulting in high morbidity and mortality rate. The third most common cause of death in trauma patients who survive longer than 24 hours is PE.[2] Furthermore, PE causes 240,000 deaths per year in the United States.[3]

Spinal injuries, spinal cord injuries, advanced age, surgery, cancer and ileofemoral venous injury are the major risk factors for development of DVT and subsequent PE.[4-7] The incidence of venous thromboembolism in trauma patients with injuries has been reported between 54 and 69 percent.[8] PE may occur in as many as 50% of patients with DVT.[9]

There is no single modality to treat and prevent DVT and PE. Although anticoagulant therapy is the treatment of choice in venous thromboembolism,[10] vena cava filters (VCFs) have recently gained an important alternative role following failure in anticoagulation, when anticoagulants are contraindicated or complications of anticoagulation occur.[11] VCFs with a Greenfield filter has been proven to be effective in reducing PE and has an extremely low morbidity rate.[12]

Although the long-term safety and durability of VCFs has been demonstrated in carefully performed studies by Greenfield and Proctor for up to 20 years,[13] the effect of VCF in the prevention of PE is controversial for the high-risk patients. While some authors showed that VCFs can not reduce the rate of PE in high risk patients,[14] the results of several studies have demonstrated that vena cava filters diminish the incidence of pulmonary embolism in high risk patients.[4-6]

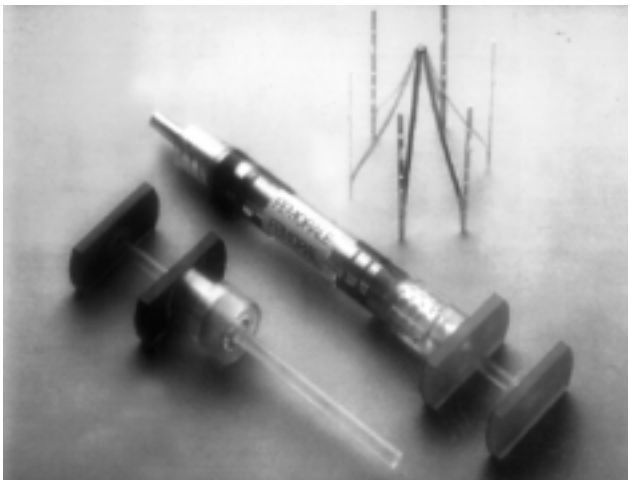
A previous study at our center has reported the short-term benefits of filters placement.[15] Therefore, the purpose of this study is to evaluate the long-term results of VCF-placement for prevention of PE in high- risk patients.

MATERIAL AND METHODS

Between June 1999 and March 2002, at the

Trauma and Surgical Emergency Service of Istanbul Medical Faculty, 15 patients who underwent placement of VCFs were evaluated. All patients were at high-risk for development of PE. The median time from admission to placement of the VCF was four days.

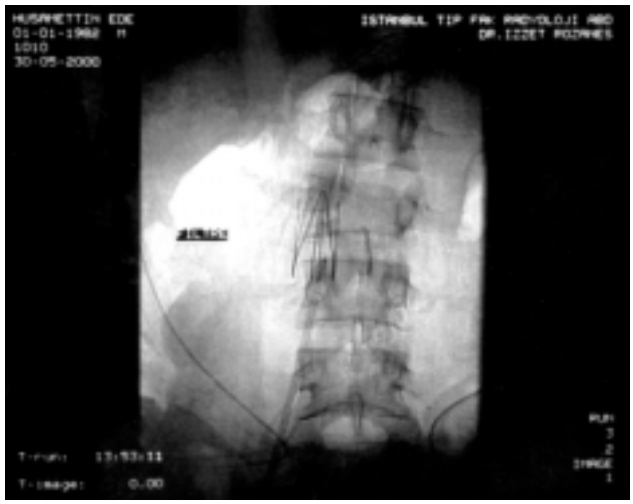
VCFs were placed in Department of Radiology, Istanbul Medical Faculty by interventional radiologists, in an angiography room with the use of imaging guidance. Permanent VCF was Vena Tech LGM (B.Braun, Celsa-Cedex, France) (Picture 1), temporary VCF was Poliser (Cordis Europe N.V.-Johnson and Johnson Company) (Picture 2). Filters were placed just below the renal veins (Picture 3).



Picture 1. Permanent vena cava filter

Following filter placement, patients continued to receive DVT prophylaxis with low-molecular-weight heparin during hospitalization, if there was no contraindication of anticoagulation. At

Picture 2. Temporary vena cava filter



Picture 3. Apperance of a placed vena cava filter

discharge, all patients were asked to report any symptoms of DVT and PE.

Follow-up visit were scheduled at six months, one year and two years. During follow-up; Patients underwent i) Physical examination, ii) Abdominal X-ray was employed to determine filter location, integrity, and evidence of migration, iii) The levels of D-dimer were measured, iv) Duplex ultrasound of the inferior vena cava and lower extremity was performed to assess patency of vena cava and the presence of DVT.

Indications of VCFs placement, recurrent DVT, insertion site thrombosis of filters, occurrence of PE and DVT, complications of filters, age, gender and mortality were assessed.

RESULTS

There were eleven males (73%) and four females (27%) with mean age of 50 years (range 14 to 76). Twelve VCFs were inserted through the femoral venous system and three were inserted through the internal jugular vein (two temporary and one permanent). Thirteen of the VCF were permanent and two of them were temporary filters (one patient with subarachnoidal hemorrhage due to head trauma had DVT at the 8th day of hospitalization and one with subdural hematoma and subarachnoidal hemorrhage due to head trauma and multiple lower extremity fractures). Eleven of VCFs were placed in prophylactic and four in therapeutic purposes (Table I).

The indications of VCF placement are as follows: Spinal cord injury with life-long paraplegia in eight and quadriplegia in two patients, venous thromboembolism while on anticoagulation were in two patients (one with bladder cancer, one with

Table 1. Purpose of placement of VCFs

No of patients	Diagnosis	Type	Duration
10	Spinal cord injury	Prophylactic	Permanent
1	Severe head injury	Prophylactic	Temporary
1	Severe head injury +DVT	Therapeutic	Temporary
1	Cervix cancer+DVT	Therapeutic	Permanent
1	Bladder cancer+DVT	Therapeutic	Permanent
1	Symptomatic aortic aneurism+DVT	Therapeutic	Permanent

aorta aneurysm), contraindications to anticoagulation were in three patients due to the high risk bleeding (one with subarachnoid hemorrhage and DVT, one with subdural hematoma and subarachnoid hemorrhage, and one with late stage cervical carsinoma having DVT) (Table II).

Table 2. Indications of VCF placement

Indications	Number of patients
Prophylactic placement at high risk patients	10
Venous thromboembolism while on anticoagulation	2
Contraindication to anticoagulation with DVT	2
Contraindications to anticoagulation (prophylactic)	1
Total patients	**15**

Four patients died during the study period. Medical records revealed no evidence of a pulmonary embolism. Two multi-trauma patients died due to sepsis and multiorgan failure during hospitalization. Cancer was the cause of death in other two patients (one 3 months later, the other 9 months later).

The mean duration of follow-up was 17 months (range 3-32 months). None of patients developed DVT and recurrent DVT. None of patients had clinically signs or symptoms of PE. The levels of D-dimer were normal except for one patient. In this patient, investigations revealed no source of tromboembolism event. There were no VCF-related complications in the course of study period except for one insertion site femoral thrombosis on day 20, which resolved with medical therapy.

DISCUSSION

It is estimated that DVT and PE are associated with 300,000 to 600,000 hospitalizations a year in the United States.[16] In patients with proven PE, examination of the iliofemoral veins revealed thrombosis in 73%.[17] Conversely, PE may occur in as many as 50% of patients with ilioferomal venous thrombosis.[9] The presence of free-floating elements in an iliofemoral thrombosis has been associated with a 60% incidence of pulmonary embolus even in the presence of therapeutic anticoagulation.[18] Even with adequate DVT prophylaxis, DVT and PE occur in up to 10% of high-risk in trauma patients and 14% of trauma patients can not have anticoagulation because of their injuries.[6] So, a variety of therapeutic approaches have been instituted to address this potentially lethal complication, one of which is VCF placement. The mortality rate after recurrent PE is reported to reach 30% without adequate therapy, it decreases to 8% with anticoagulant therapy and to 0,8% with additional IVC filter placement.[19,20] Furthermore, patients who receive filter placement, most of them without anticoagulant therapy, have less than a 5 percent incidence of pulmonary embolism,[21,22,23] which is similar to the incidence in patients receiving anticoagulant therapy alone.

Since more than 90% of PE cases are reported to be caused by DVT from the pelvis and lower extremities,[22] VCF is now being accepted as an effective treatment for the prophylaxis of PE in patients with DVT.[21] Despite the use of VCFs for more than four decades as a means of protecting patients with DVT against PE, the indications and clinical approach to potential caval filter candidates is variable. The indications of VCF insertion are generally regarded to be as follows;[25,26,27] 1) recurrent thromboembolization despite adequate anticoagulant therapy; 2) contraindications for anticoagulant therapy; 3) PE requiring embolectomy; 4) prophylaxis in high-risk patients; 5) documented free-floating ileofemoral thrombus and 6) bleeding complications when anticoagulation is employed.

Although 30,000 to 40,000 caval filters are placed each year in the United States[28] and now placed prophylactically, particularly in trauma patients up to 50 percent[11,29,30] it's definite role in prevention of PE is not clear. In a study the authors reported long-term safety and efficacy of prophylactic VCFs in prevention of PE in high-risk groups of trauma patients with the mean follow-up time of 67.7 months.[6] Despite having only 33 of 90 patients being available for evaluation (35%), they noted no PE. Contrary to this study, McMurtry et al. reported that increased used of prophylactic VCF in trauma patients can not decreased the rate of PE.[19] Most of VCFs in the present study placed for prophylactic purposes and no PE encountered in the course of the study period.

In a randomized study, to compare VCF placement plus anticoagulant and anticoagulant alone in patients with DVT, VCF reduces the incidence of PE at day 12 (the incidence of PE between the filter and no filter groups was statistically difference (1.1% and 4.8%, respectively) but it does not diminish the rate of early or late overall mortality. Also in the same study, patients with filters placement had more recurrent DVT than non-filters patients at two years observation (20.8% and 11.6% respectively).[31] It has also been reported that the incidence of recurrent DVT was only 3% of a population of patients with Greenfield filters in patients who have been followed for more than 20 years.[13] Four patients with DVT in our study underwent placement of VCF, none of them had recurrent DVT. We found an elevated D-Dimer levels in one patient but could not reveal any source.

Some authors recommend that a temporary VCF can be inserted before thrombolytic therapy is initiated, especially if the thrombus is floating or extends into the inferior vena cava to prevent migration of partially lysed thrombi.[32,33] In the present study two patients had temporary filter placement.

Several complications of Greenfield VCF have been described; such as 0-0,5% mortality rate, a 3-4% risk for PE,[34] migration into heart or the renal / iliac veins,[35,36] fracturing of the filter struts,[37] filter struts perforated the wall of the vena cava into the aorta,[38] liver,[39] small intestine[40,41] spinal column,[38] kidneys,[42] insertion site thrombosis. Following Greenfield filter placement, DVT and inferior vena cava thrombosis develop in 6% and 3.6%, respectively, which result in 19% postphlebitic syndrome.[43] We observed one insertion site thrombosis as a complication of filters placement in the present study.

All patients with Greenfield filter should be followed by regular intervals to detect complication early. A periodic plain abdominal radiography is recommended to detect changes in filter shape, position, span, and angle.[44] Ultrasound, venography, or CT may be useful in cases in which doubt exists.

Although VCFs placement seems to prevent PE in high- risk patients, prospective randomized trials with larger patient groups and longer-term follow up period are necessary to evaluate efficacy and safety of VCF in prevention of PE before making firm conclusion. We recommend placement of an inferior vena caval filter, when there is clearly contraindication of anticoagulant therapy or when DVT occurs despite adequate anticoagulation and in an individual with high risk for DVT and PE.

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