Evaluation of Percutaneous Insertion of Caval Filters (Indications and Complications)

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Abstract: Aim: The aim of this study was to evaluate the percutaneous insertion of vena caval filters in different indications and also to assess the complications of vena caval filters. **Patients and methods:** During the period between Aug. 2009 and Dec. 2011, twenty vena caval filters were inserted in twenty patients at high risk of pulmonary embolism or with contraindications to anticoagulation, percutaneous transfemoral approach was used in all patients under local anaesthesia, pre and post deployment duplex scan was performed. **Results:** Twenty vena caval filters were inserted in 20 patients at high risk of pulmonary embolism or with contraindications to anticoagulation. All caval filters were inserted, only one case faced technical failure (5%) so the technical success was 95%, two patients died within two months after filter insertion due to unrelated causes, the other patients were followed up for a median time of 14 months (range from 4 to 24 months), filter migration above renal veins was detected in one patient (5%) and groin haematoma in another patient (5%). **Conclusion:** Vena caval filters represent an important weapon in every clinician for the treatment of venous thromboembolism (VTE), these devices are implanted in patients at high risk for life-threatening pulmonary embolism (PE) or for whom the anticoagulation therapy is ineffective or contraindicated. The filters either permanent (permanent filters) or with intent to remove them (retrievable filters).
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1. Introduction

Venous thromboembolism (VTE) is a significant cause of morbidity and mortality world wide, anticoagulation is the preferred treatment for VTE, however, in selected patient populations the risk of bleeding from anticoagulation outweighs its benefit, for these patients, alternative methods of pulmonary embolism prevention are needed as percutaneous insertion of IVC filters **(White, 2003)**.

Deep venous thrombosis (DVT) with or without associated pulmonary embolism is a common preventable cause of morbidity and mortality. Contraindications to anticoagulation include intolerance of therapy, non- compliance with treatment and therapeutic failure, also in patients with pulmonary embolism, vena caval filter (VCF) may be of benefit. VCF have been developed to replace surgical ligation or placement of the inferior vena caval clips to prevent fatal pulmonary embolism **(Stawicki *et al.*, 2005)**.

Vena caval filters are devices implanted in patients at risk for life-threatening pulmonary embolism who cannot tolerate anticoagulation therapy or for whom the anticoagulation therapy is ineffective or contraindicated. The filters are implanted either permanent (permanent filters) or with intent to remove them (Retrievable filters) when the risk of PE has passed or when anticoagulation therapy can be initiated, VCF preventing or reducing the likelihood of PE (VCF do not prevent or treat the formation of blood clot) **(Kaufman, 2011)**.

The vena caval filter is an established therapeutic option for the prevention of pulmonary embolism in individuals with deep venous thromboembolism in whom conventional anticoagulation is contraindicated or deemed ineffective. The major complications associated with inferior vena caval filters include intravascular and extra vascular migration, filter and venous thrombosis, recurrent pulmonary emboli and inferior vena cava obstruction **(Geetali *et al.*, 2009)**.

The indications for vena cava filter (VCF) placement, the selection of filter type and the management after filter insertion are still controversial because of paucity of prospective data **(Girard *et al.*, 2002)**.

The indications for VCF include 1- proximal DVT with absolute contraindication for anticoagulation 2- New or extending DVT or PE despite therapeutic anticoagulation 3- complications of anticoagulation 4- "free flooting" thrombus in the IVC, iliac or femoral veins 5- spinal cord injury 6- poor compliance with anticoagulation 7- multiple long bone/ pelvic fractures 8- closed head injury 9- severe cardio- pulmonary diseases (including COPD) with concomitant DVT 10- cor pulmonale with DVT/ PE 11- prophylaxis in high-risk patient populations 12- prophylaxis in joint replacement surgery "controversial" 13- DVT/ PE in pregnancy "controversial" **(James *et al.*, 2008)**.

Contraindications to IVC filter placement are uncommon but should be promptly recognized when they are present, absolute contraindications include uncorrectable severe coagulopathy and complete thrombosis of the IVC, relative contraindications to vena caval filter placement include young patient age and sepsis as well as segmental thrombosis of the IVC

between the access site and the deployment site **(Lanzer, 2007)**.

The complications associated with vena caval filter insertion, in addition to the occurrence of adverse reactions to intravenous contrast they include 1- Arrhythmias secondary to guide wire contact with endocardiam 2- Air embolism during the procedure, especially when using jugular insertion route 3- pneumothorax and haemothorax 4- Extravascular penetration of the guide wire 5- Arterio- venous fistula at the insertion site 6- Insertion site infection and/ or pyophlebitis 7- Bleeding and/ or haematoma at the insertion site 8- Retained misplaced or broken off catheters and venous insertion sheaths. The other complications include 1- Filter tilting, angulation and incomplete opening 2- Filter misplacement 3- Filter fracture 4- Filter migration and embolization 5- Filter penetration / erosion into pericaval stractures **(Vergara *et al.*, 2007)**.

Indications and contraindications of vena caval filter (VCF) **(Kaufman *et al.*, 2006)**

A- Indications:

I- Absolute indications (proven VTE)

1. Recurrent venous thrombo embolism "VTE" (Acute or chronic) despite adequate anticoagulation. 2. Contraindications to anticoagulation. 3. Complications of anticoagulation. 4. Inability to achieve/ maintain therapeutic anticoagulation.

II- Relative indications (proven VTE):

1. Ilio- caval DVT. 2. Large free- floating proximal DVT. 3.Difficulty establishing therapeutic anticoagulation. 4. Massive pulmonary embolism treated with thrombolysis/ thrombectomy. 5.Chronic PE treated with thromboendartrectomy. 6. Thrombolysis for iliocaval DVT. 7.VTE with limited cardiopulmonary reserve. 8.Recurrent PE with filter in place. 9.Poor compliance with anticoagulant medications. 10.High risk complication of anticoagulation (e.g., ataxia, frequent falls).

III- Prophylactic indications (NO VTE, Primary prophylaxis not feasible*)

1. Trauma patient with high risk of VTE. 2. Surgical procedure in a patient at high risk of VTE. 3. Medical condition with high risk of VTE.

B- Contraindications to filter placement

1. No access route to the vena cava. 2. No location available in vena cave for placement of filter

* Primary prophylaxis not feasible as a result of high bleeding risk, inability to monitor the patient for VTE.

Aim of the work

The aim of this study is to assess the indications and complications of percutaneous insertion of vena caval filter.

2. Patients and Methods

During the period between Aug. 2009 and Dec. 2011, twenty vena caval filters were inserted in twenty patients at high risk of pulmonary embolism or with contraindication to anticoagulation, informed written consent was obtained from all patients, all filters were inserted percutaneously under local anaesthesia in angio-suit by vascular surgeon, pre and post-deployment duplex scan was performed and monitoring of clinical data suggesting PE was also carefully recorded, this is in addition to routine post insertion abdominal and chest X-Ray to check filter position and the development of PErespectively.

Percutaneous transfemoral approach was used in all patients, in most cases the access through right femoral vein was performed, in all cases fluoroscopy and non-ionic contrast medium were used to assure proper placement of the filter in the inferior vena cava (IVC).

The filter set consist of 0.035 guidewire, 12 fr. sheath / dilator set, an introducer catheter, and the filter. A 0.035 guide wire and catheter are inserted and cavagram is preformed to determine the level of lowest renal vein. The 12 French sheath / dilator is introduced over the guide wire to the level a above renal veins. The filter introducer catheter is then inserted via the sheath till it reach the desired level, by holding the filter introducer catheter in position and withdrown the 12fr. Sheath over it and slowly pull all the way back, this will release the filter. A completion cavagram to check the final position of the filter.

3. Results

During the period between Aug. 2009 and Dec. 2011, 20 vena caval filters were inserted in 20 patients at high risk of pulmonary embolism (as extensive DVT despite therapeutic anticoagulation or free floating thrombus in the ivc, iliac or femoral vein, spinal cord injury, multiple fracture with DVT, active bleeding from peptic ulcer, intracranial haemmorrhage, ileofemoral DVT after head injury with cerebral haemorrhage confirmed by C.T) or absolute contraindications to anticoagulants, the age of the patients was range from 28-62 years (mean age 45 years), there were 8 males and 12 females.

The prevalence of risk factors were diabetes in 6 patients, smoking in 7 patients, hypertension in 7 patients, ischaemic heart disease in 5 patients, obesity in 6 patients, prolonged immobility in 7 patients and bleeding diathesis in 2 patients and 4 patients suffered from preexisting DVT.

All patients underwent preoperative duplex scan, plain x-Ray chest, and postoperative duplex scan and plain x-Ray chest and abdomen; twenty caval filters were inserted with 95% technical success.

Two patients died within two months after filter insertion from unrelated causes due to the development of pneumonia and/or adult respiratory distress syndrome or because of head injury on admission, the

other patients were followed up for a median time of 14 months (ranges from 4 to 24 months),.

Filter migration above renal veins was detected in one patient(5%)6months post-insertion during routine abdominal X-Ray, but the IVC was still patent, it is confirmed by duplex scan, the patient who had coagulopathy developed groin haematoma (5%) that spontaneously resolved, there was neither significant bleeding after removal of the sheath nor groin infections developed in any of those patients.

During the period of follow- up, filter- related complications especially IVC thrombosis and wall penetration were not detected.

There were no clinical and/ or radiological evidence of PE in all patients after filter insertion during the period of follow up.

Table (1): patient's demographic data and risk factors

Variables	Number of patients "20"	%
Gender		
Males	8 patients	40%
Females	12 patients	60%
Diabetes	6 patients	30%
Smoking	7 patients	35%
Hypertension	7 patients	35%
Ischaemic heart disease Obesity	**5** patients	25%
Prolonged immobility	**6** patients	30%
Bleeding diathesis	**7** patients	35%
Preexisting DVT	**2** patients	10%
	4 patients	20%

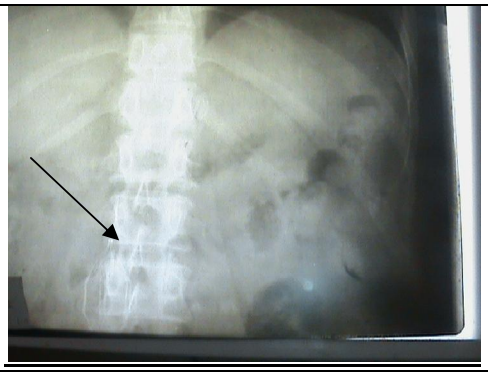

Fig (1): Caval filter

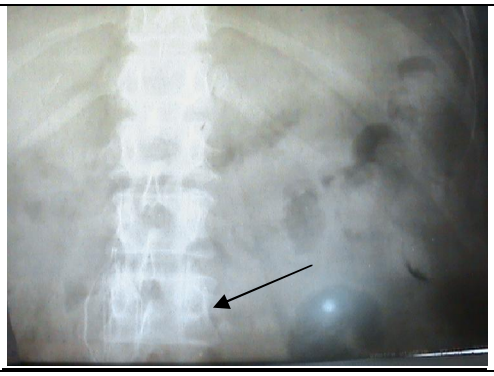

Fig (2): Caval filter

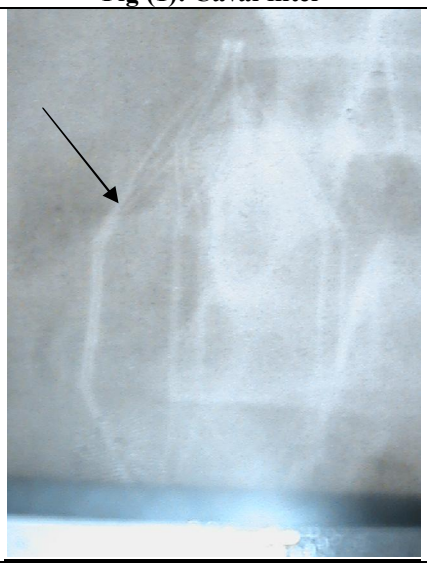

Fig (3): Caval filter

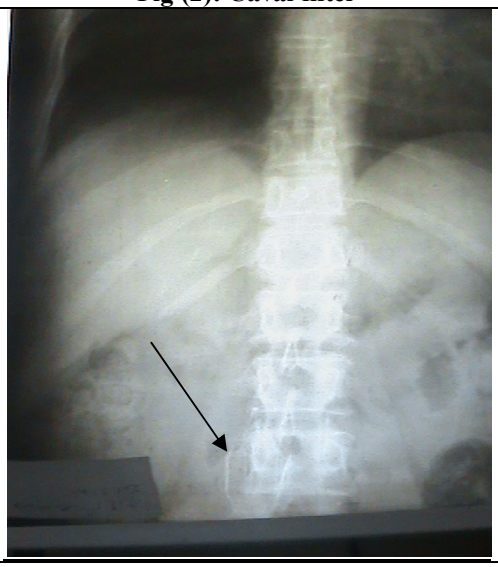

Fig (4): Caval filter

4.Discussion

Deep Venous Thrombosis (DVT) with or without associated pulmonary embolism (PE) is a common preventable cause of morbidity and mortality **(Lam *et al.,* 2004)**.

Despite the success of aggressive prophylaxis and screening programs, the rates of DVT and / or PE continue to be relatively high **(Stawicki *et al.,* 2005)**.

Anticoagulation remains the standard therapy for DVT/PE and has been demonstrated to improve clinical outcomes, heparin therapy has been shown to decrease the risk of fatal PE by 75% and to reduce the risk of recurrent PE by over 90%, contraindications to anticoagulation include intolerance of therapy, non compliance with treatment and therapeutic failure, for this group of patients, a vena caval filter (VCF) may be of benefit **(Decousus *et al.,* 1998)**.

Pulmonary embolism is a well-recognized fatal complication of VTE, it represent one of the leading cause of morbidity and mortality in the developed countries despite different prophylactic measures **(Bick, 1999)**.

Venous thrombo -embolic disease (VTE) include lower limb deep venous thrombosis (DVT) and pulmonary embolism which are dreaded sequelae of certain medical and surgical conditions, in general population the yearly incidence of VTE is approximately 1 per 1000 persons, fatal pulmonary thrombo embolism has reported to be from 0.01%-5% depending on the underlying risk factors **(Priya and Sharma, 2009)**.

The clinical suspicion of VTE should be increased in patients with history of VTE, recent surgery, spinal cord injury, trauma and malignancy. Also a variety of medical illness increase the risk of venous thrombosis including congestive heart failure, myocardial infarction, stroke with paresis, cigarette smoking and obesity, they also recommended that hypercoagulable status, such as antithrombin III deficiency, protein C deficiency, protein S deficiency should be considered in those patients who develop VTE in the absence of known risk factors. Additionally, the presence of vena caval filters doesn't exclude the possibility of PE ***(*Kim and Spandorfer, 2001)**.

Mc Dowall, 1973 reported 0.49% incidence of fatal emboli in patients with VTE. **Warden *et al.*, 1973** have reported autopsy findings of PE reaching 30%. Therefore, it is clear that VTE and associated PE represent major problems that require application of a new treatment modality especially in a high-risk group of patients.

The goals of treatment in VTE are to arrest the growth of the thrombus and to prevent further complications such as PE; anticoagulants are the mainstays in treating VTE. However, the difficult issue when medical treatment fails and / or there is a contraindication to it **(Rue *et al.,* 1992)**.

Temporary IVC filters are safe and effective in critically ill surgical and trauma patients and allow an aggressive approach for prevention of venous thromboembolism in this challenging group of patients **(Offner *et al.,* 2003)**.

Septic patients are at risk of thrombo-embolism, however, the food and drug administration guidance for intravascular filter states that "filters shouldn't be implanted in patients with risk of septic embolism" but **Greenfield and Proctor (2003)** reported that the Greenfield filter is a safe method of prophylaxis for septic patients.

Multisystem traumatic injury is a significant risk factor for the development of a deep venous thrombosis, without thromboprophylaxis, overall DVT rates exceed 50%.Although DVT alone is not life-threatening, a resulting pulmonary embolism carries potentially significant morbidity and mortality. PE is estimated to be the third leading cause of death in injured patients who survive beyond the first day of life, so the insertion of caval filter is recommended in traumatic patients **(Datta *et al.,* 2010)**.

The prophylactic indication for vena caval filter placement in patients with trauma is associated with a low incidence of adverse outcome and providing protection from fatal pulmonary embolism **(Greenfield *et al.,* 2000)**.

Pulmonary embolism is one of the most frequent cause of death following complex spine surgery, in which the rate of symptomatic PE can be as high as 12% with 1 to 2% mortality, the prophylactic use of IVC filter decrease the rate of symptomatic PE from 12% to 0% **(Rosner *et al.,* 2004)**.

The indications for filter application that include recurrent emboli despite anticoagulations, complications of anticoagulants and failure of previous filters. The prophylactic filter insertion is recommended in cases of neurologic injury, spine and hip surgery, paraplegia, pelvic fractures and prolonged immobilization **(Patton *et al.,* 1996)**.

Prophylactic filter insertion is confined to patients at higher risk of VTE and PE. Such patients are usually had one or more of the following risk factors: obesity, prolonged immobilization, elderly patients and patients with polytrauma **(Greenfield *et al.,* 1997)**.

Mortality attributed directly to placement or presence of a vena cava filter is extremely rare, but although the all-cause mortality for vena cava filter is low, there have been case reports of sudden cardiac arrest due to migration of the filter into a cardiac chamber. Deaths were the result of fatal arrythmias, massive pulmonary embolism and / or cardiac tamponade. In each case the filters original infra-renal position was confirmed by radiography and migration occurred days later **(Haddadian *et al.,* 2008)**.

In this study two patients died within two months after filter insertion from unrelated causes to filter insertion due to the development of pneumonia or adult respiratory distress syndrome and because of head injury on admission.

The reported rate of VCF migration ranges from 1% to 18% **(Otero *et al.*, 2007)**.

The walls of the vena cava are known to move with respiration and changes in intra abdominal pressure result in flexion on the limbs of the filter **(Brown *et al.*, 1999)**.

Different subtypes of filter migration include a-local migration "into the adjacent portion of the IVC" b-regional migration "into the ostia of the renal or hepatic vein" or c-distant migration (embolization) "into the pulmonary artery or right atrium". Local or regional migration is rarely an indication for intervention because these patients are almost always a symptomatic, but distant migration may require VCF retrieval **(Bochenek *et al.*, 2003)**.

In this study, filter migration above the renal veins was detected in one patient (5%), 6 months post insertion during the routine abdominal X-Ray, but the IVC was still patent and it is confirmed by duplex scan. **Decousus *et al.* (1998)** published the first randomized study of vena caval filters in the prevention of PE. They randomized 400 patients using a 2×2 factorial design to a vena caval filter or no filter and enoxaparine or unfractionated heparine, four different types of vena caval filters (titanium greenfield, bird's nest, vena tech and cardial filters) were used, all were placed within 48 hours. Ventilation-prefusion scans were performed at baseline and after 8 to 12 days of anticoagulation, vena caval filters were associated with a significant decrease in the incidence of PE compared with anticoagulation alone at 8 to 12 days of follow-up. After two years, however this difference was no longer statistically significant although the trend still favoured vena caval filter. Symptomatic PE occurred at a similar frequency in both groups after 3 months. Fatal emboli were more common among patients treated with anticoagulation alone, in contrast, vena caval filters were associated with significantly more recurrent DVT than with anticoagulation alone, no difference in bleeding or overall mortality was documented. In light of these data, one can conclude that vena caval filters in combination with standard anticoagulation do appear to offer significantly more protection from PE than standard anticoagulation alone.

One of the clinical controversies whether anticoagulation is necessary after vena caval placement? Many investigators recommend routine anticoagulation after vena caval filter placement **(Ballew *et al.*, 1995)**.

However, little data are available to support the utility of this practice. Several cases series have attempted to address this issue **(Ortega *et al.*, 1998)**.

Another important controversy, are vena caval filters superior to anticoagulation for treatment of VTE?

No randomized studies have been performed to address this question. The randomized study of **Decousus *et al.* (1988)** suggest that filters may provide additional short-term protection against PE in anticoagulated patients, but doesn't address the comparative efficacy of these therapies.

An unrandomized retrospective case series found no significant differences in recurrence rate of lower extremity symptoms between the patients treated with anticoagulation and filters **(Jones and Fink, 1994)**.

Savin *et al.* (2002) reported the technical success was 99% Technical success requires proper placement of the filter in the vena cava in such manner as to protect against pulmonary embolism, the optimal location is in the infrarenal inferior vena cava with the apex of the filter just below the level of the lowest renal vein, at this level a thrombus trapped in the filter will be exposed to renal vein blood flow, which may promote dissolution by the intrinsic lytic system. A filter placed at/or above the renal veins can lead to renal vein thrombosis and deterioration of renal function, suprarenal vena caval filter may be more difficult to place and more prone to migration than one placed below the lowest renal vein **(Matchett *et al.*, 1998)**.

In this study the technical success was 95%.

Conclusion

Pulmonary embolism is one of the most severe complications of venous thromboembolic disease, PE occurs when a blood clot formed in a vein breaks free, becomes an embolus travels to the lungs and blocks pulmonary blood vessels, the placement of an IVC filter is considered standard preventive treatment for PE.

Vena caval filters are devices implanted in patients at high risk for life threatening pulmonary embolism who cannot tolerate anticoagulation therapy or for whom the anticoagulation therapy is ineffective, the filters which are implanted either permanent or retrievable.

The use of vena caval filters has increased significantly since the introduction of percutaneous placement techniques and the development of reduced-profile devices.

The prophylactic indications for vena caval filter placement is confined to patients at higher risk of PE such as in polytraumatic patients, spine injury, prolonged immobilization, elderly patients and in obesity, it is associated with a low incidence of adverse outcomes and protecting from fetal pulmonary embolism.

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