

DEPLOYMENT OF INFERIOR VENA CAVA FILTERS; EFFICACY AND SAFETY

*M.M.H.NURI**, *SHAHID HAFEEZ***, *WAQAR AHMAD***, *SOHAIL AZIZ***,
*QAISAR KHAN***, *AFSAR RAZA***

SUMMARY

Objective: To study the patient's profile, indications and procedural success of placement of Inferior Vena Cava (IVC) filters at AFIC/NIHD Rawalpindi, Pakistan.

Design: A retrospective observational study.

Place and Duration of Study: The patients were studied in the department of Interventional Cardiology of AFIC/NIHD from May 2004 to Jun 2005.

Material and Methods: 16 patients of either sex who revealed clinical and investigative evidence of recurrent pulmonary embolism (PE) due to deep vein thrombosis (DVT) of lower limbs were selected. All efforts including history, physical examination and laboratory investigations were carried out in order to ascertain the aetiology. A note was made of the associated conditions, past and family history of DVT and PE. IVC filter was deployed through femoral vein in all patients as a life saving treatment modality. The procedure was uncomplicated and all patients had smooth post procedural recovery.

Results: Through femoral vein, IVC filters (Trap Ease Cordis J&J) were successfully deployed below the renal veins. In one patient, another filter was deployed immediately below the tricuspid valve.

Conclusion: IVC filter placement is a simple, safe and effective procedure in stabilizing patients who have recurrent pulmonary embolism.

Key Words: Inferior Vena Cava (IVC) Filter, Pulmonary Embolism (PE). Deep Vein Thrombosis. (DVT).

INTRODUCTION

Deep venous thrombosis (DVT) and pulmonary embolism (PE) represent two points on the continuum of a single disease process. Incidence of nonfatal PE ranges from 400,000 to 630,000 cases per year and fatal PE 50,000 to 200,000 cases per year in USA.¹⁻⁴ Systemic anticoagulation with intravenous heparin followed by oral warfarin remains the mainstay for the treatment of DVT and prevention of PE. However, studies have shown that as many as 20% of patients will have recurrent PE.⁵⁻⁶ Moreover use of anticoagulation therapy is not warranted in certain high risk patients who are prone to bleeding diathesis.

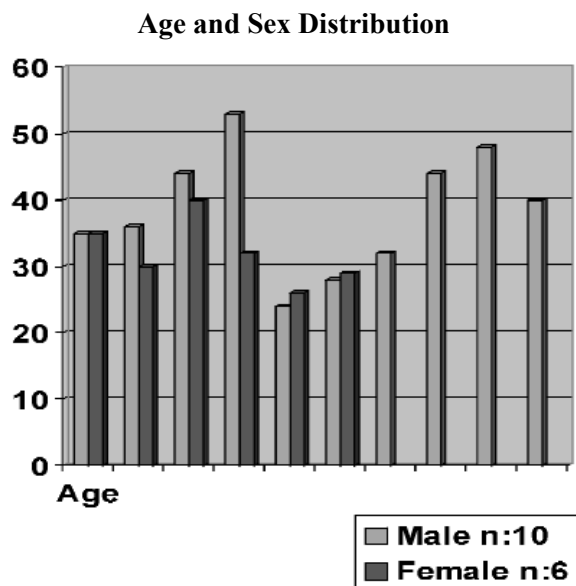
The complication rate associated with anticoagulation has been reported to be as high as 26% with a fatality rate between 5 and 12%.⁷⁻⁸ Approximately 80 to 90% of acute PE cases originate from thrombus migrating from the pelvis or lower extremity veins. In recurrent life threatening PE, IVC filters have been designed to prevent migration of thrombus into the lung. In our population there is no data available about the incidence of DVT and PE. Some of these patients suffer from life threatening PE secondary to DVT that go either unrecognized or untreated. The aim of our study is to highlight the importance of early use of IVC filters in patients with recurrent PE. We have demonstrated that the deployment of IVC filter is a life saving procedure and is an under utilized modality of treatment.

* *Professor of Cardiology, Faculty Member NUST, Army Medical College. (Corresponding Author)*

** *Armed Forces Institute of Cardiology, Rawalpindi.*

MATERIALS AND METHODS

A total 16 patients (10 males and 6 females) between 25 and 55 years, presented to AFIC with recurrent life threatening PE from May 2004 to June 2005. All patients consented for placement of IVC filter. The demographic, clinical and investigational data of patients is presented in the graph and tables.



Clinical Data of Patients

| | |
|--|----|
| * History | |
| * History of exposure to high altitude | 3 |
| * History of Hormone Replacement Therapy | 2 |
| * Past history of DVT | 16 |
| * Past history of anticoagulant therapy | 12 |
| * Associated Conditions | |
| * Pregnancy / postpartum | 5 |
| * Fracture / immobilization | 4 |
| * Anemia | 5 |
| * Ulcerative Colitis | 1 |
| * Obesity | 4 |
| * Hypertension | 3 |
| * Family history of recurrent pulmonary emboli | 2 |
| * Treatment with streptokinase | 5 |
| * Symptoms | |
| * Shortness of breath | 16 |
| * Painful swelling of legs | 12 |
| * Signs | |
| * Tachycardia | 16 |
| * Tachypnoea | 12 |

| | |
|--|----|
| * Raised Blood Pressure | 3 |
| * Signs of Pulmonary Hypertension | |
| * Mild | 0 |
| * Moderate | 5 |
| * Severe | 11 |
| Investigational Data | |
| * ECG Abnormalities | 16 |
| * CXR | |
| * Abnormal | 13 |
| * Normal | 3 |
| * 2D Echo | |
| * Dilated RA/RV and raised PASP | 14 |
| * IVC thrombus extending up to tricuspid valve | 1 |
| * Doppler Ultra Sonography of lower limbs | |
| * (+) for DVT | 15 |
| * Lung Perfusion Scan | |
| * (+) for PE | 14 |
| * D. Dimers | |
| * Raised | 13 |
| * Normal | 3 |

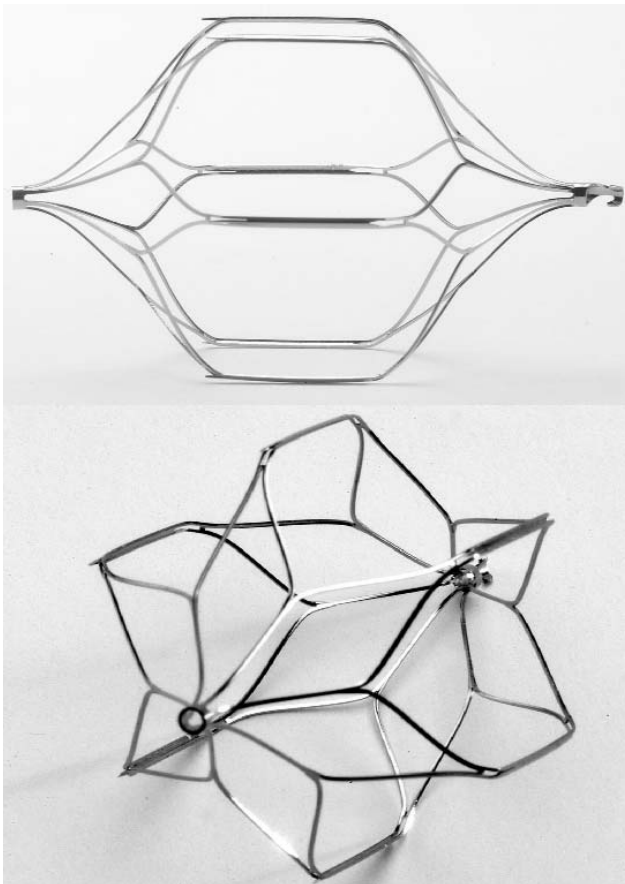
Key : RA: right atrium, RV: right ventricle, PASP: pulmonary artery systolic pressure

TECHNIQUE

The patients selected for IVC filter placement were assessed with history, clinical examination and investigation as noted above. Hematological profile including blood CP, platelet count, INR and PTTK was carried out. Patient were kept nothing by mouth or on clear liquids for at least four hours prior to the procedure. Informed consent was obtained from all patients. The right femoral vein was cannulated with Seldinger's technique under local anesthesia. In one patient, left femoral vein was cannulated as the right femoral vein was thrombosed. A control cavography was performed before filter deployment. The tip of sheath introducer in IVC was positioned below the renal veins. Advancing the obturator slowly advanced the filter in the storage tube into the sheath introducer. After ensuring the correct location of the filter i.e. just inferior to level of renal veins it was

released under constant fluoroscopy. The sheath introducer was placed back over the obturator after keeping it fixed. After the filter was fully released obturator was removed from the sheath. A control cavography was performed after the procedure. As a part of post procedure care all the patients were advised bed rest and periodic monitoring of puncture site for 12 hours. The patients were ambulated within 24 hours. The patients were kept on oral anticoagulant therapy with periodic monitoring of INR for six months. The IVC filter is depicted in the diagram.

IVC FILTER (Trap Ease Cordis J&J)



RESULTS

IVC filter was successfully deployed in all patients without any complication. One of the patient in whom IVC filter was placed during seventh month of pregnancy successfully completed her pregnancy with IVC filter in situ. A young female known to have ulcerative colitis and being treated with corticosteroid developed recurrent PE. 2D Echo revealed IVC

thrombus extending up to tricuspid valve. She had two filters implanted one below and another above renal veins near to the tricuspid valve. In one patient left femoral vein access was used as the right femoral vein was thrombosed. Two patients experienced increased swelling of lower limbs after the procedure. Twelve out of sixteen patients have been followed up for over six months. These patients have shown significant improvement with no clinical evidence of recurrence. Three of these patients have shown mild increase in the swelling of lower limbs with no clinical discomfort.

DISCUSSION

In patients with PE, 2% die within the first day and 10% have recurrent PE; the death rate among the latter group is 45%.⁹ The incidence of recurrent embolization is about 9% (range, 5% to 23%) during the first 2 weeks after initiation of anticoagulant therapy.^{10,11} Inferior vena cava (IVC) filters have been shown to reliably prevent early recurrence of PE. A randomized study¹² compared the use of an IVC filter or no filter in patients receiving anticoagulant therapy who were at risk for PE; recurrent PE was seen in 1.1% of patients with a filter versus 8.6% without a filter after twelve days. Risk of death from recurrent PE is potentially increased by mild to moderate right ventricular dysfunction. Even a minor recurrence puts these patients at risk for hemodynamic instability and death. In such patients who also have residual thrombi in the legs, aggressive heparinization and placement of an IVC filter is recommended. Such an approach is supported by several studies showing that early mortality rates are lowest in patients treated with IVC interruption.^{13,14} A recent decision analysis suggesting that these filters might even be preferable to anticoagulant therapy in selected patients at increased risk of bleeding.

A rare but commonly proposed indication for IVC filter placement is the presence of a free-floating iliofemoral thrombus¹⁵⁻²⁰ and these patients are extremely at high risk for PE.²¹ One of our patients with ulcerative colitis had a free floating IVC thrombus. She underwent successful deployment of filters. Besides anticoagulation, IVC filters are also deployed in pregnancy with recurrent life threatening PE.²² as in one obese lady in third trimester of pregnancy with recurrent PE in our series. Another obese, hypertensive lady on hormone replacement

therapy and two weeks history of fracture of fifth metatarsal bone had massive PE. Following thrombolytic therapy with streptokinase, IVC filter was deployed. A young high altitude dweller with strong family history of recurrent PE, presented with DVT of lower limbs and clinical evidence of pulmonary hypertension. He also underwent successful IVC filter deployment. The deployment of IVC filter in patients with recurrent PE remains as an important treatment modality. 12,15,22

CONCLUSION

We conclude that IVC filters provide protection from life threatening PE with minimal morbidity. IVC filter, a life saving modality of treatment in cases of recurrent PE is under utilized in our set up. Keeping in view the effectiveness, safety and ease of insertion, more and more patients with recurrent life threatening PE should be offered IVC filter deployment.

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