Early Experience with the Retrievable OptEase Vena Cava Filter in High-risk Trauma Patients

C. Meier,1* I.S. Keller,2 R. Pfiffner,2 L. Labler,1 O. Trentz1 and T. Pfammatter2

1Division of Trauma Surgery, and 2Institute of Diagnostic Radiology, University Hospital Zurich, Switzerland

Objectives. Prophylactic vena cava filters (VCF) are efficient in preventing pulmonary embolism. Filter retrieval avoids the potential long-term complications of permanent VCF. Clinical evaluation was focused on filter-related complications and feasibility of retrieval in high-risk trauma patients.

Methods. Analysis of single-institution consecutive case series of patients who received a prophylactic OptEase VCF after multiple trauma between 08/2003 and 12/2004. Data were collected prospectively.

Results. A total of 37 OptEase filters were inserted prophylactically after multiple trauma (median patient age 35 years, range, 17–73 years, median ISS 41, range, 17–59). All patients had contraindications for pharmacological prophylaxis for thromboembolic events. 32 filters (86%) were retrieved after 16 days (range, 7–25 days). 12 of 33 filters (36%) demonstrated trapped clots/thrombosis within the filter structure on pre-retrieval cavography. Two patients received anticoagulation before filter retrieval due to filter thrombosis (6%). Symptomatic PE was observed in 1 patient (3%) 5 days after VCF retrieval. Minor caudal filter migration was observed in 1 patient (3%). Overall mortality was 3%.

Conclusions. Retrieval of the OptEase filter is safe and feasible. Temporary filter placement avoids possible long-term complications of permanent VCF. It is an efficient form of PE prophylaxis when temporary contraindications to anticoagulation are present.

Keywords: Pulmonary embolism; Vena cava filters; Venous thrombosis; Wounds and injuries.

Introduction

Among hospitalised patients, those recovering from major trauma have the highest risk of developing venous thromboembolic events (VTE).1 In some studies the risk of deep venous thrombosis (DVT) exceeded 50% when no prophylaxis was used.2 Pulmonary embolism (PE) was the third leading cause of death in those who survived longer than 24 hours after trauma.3 VTE often develops shortly after trauma emphasising the necessity for early and effective prophylaxis.4 With anticoagulation being the standard for thromboprophylaxis, low-molecular-weight heparin has proven to be superior to low-dose heparin.5–7 Anticoagulation may be contraindicated in the presence of severe head injuries or major abdominal trauma.

Vena caval filters are an efficient form of PE prophylaxis that are widely used in high-risk trauma patients with contraindications to anticoagulant treatment. Most filters currently available are intended for permanent use only but complications such as IVC perforation, occlusion and filter migration are reported in the literature.8,9 Recently, retrievable VCFs have been developed. Contraindications to pharmacological prophylaxis are only temporary for most trauma patients, so retrievable VCFs represent an attractive alternative.10–13

The OptEase filter (Cordis Endovascular, J&J, Roden, The Netherlands) was first approved as a permanent VCF. The purpose of this study was to demonstrate safety, efficiency and indications for retrieval of the optional OptEase filter in the high-risk trauma patient.

Materials and Methods

The OptEase vena cava filter was introduced at our institution in August 2003. All trauma patients receiving this device between August 1, 2003 and December 31, 2004 were registered and entered in a specific database. Only high-risk multiple trauma patients with prophylactic VCF placement were included in this
case series. Patients with therapeutic filter placement or minor trauma were excluded. Multiple trauma was defined according to the guidelines of the German Society for Trauma Surgery as life threatening injury to several physical regions/organ systems with an Injury Severity Score (ISS) ≥16.

All high-risk trauma patients received prophylaxis with pharmacologic methods being the most frequently used. For high-risk patients with contraindications to anticoagulation, prophylactic vena cava filters were used. Indications for prophylactic filter placement after trauma were based upon the guidelines of the Eastern Association for the Surgery of Trauma (EAST). The definition of high-risk patients included injury patterns resulting in immobilisation for a prolonged period such as severe head trauma, incomplete spinal cord injury, complex pelvic fractures with associated long bone fractures or multiple long bone fractures.6 The VTE risk of our study population was assessed using the Risk Assessment Profile for Thromboembolism (RAPT score) within the first 24 hours after trauma.14,15 This score considers a number of risk factors. Patients with a score of 5 or more are three times more likely to develop VTE than patients with a RAPT score of less than 5. All patients in our series had a RAPT score ≥5 ranging from 5 to 22 (median, 15) showing consistency between the EAST guidelines and the RAPT score in identification of high-risk patients.

A total of 3852 patients were admitted to the trauma service during the study, including 268 patients with multiple trauma (median ISS, 33; range, 17–59). Prophylactic Optease vena cava filters were placed in 37 patients representing 14% of all major trauma and 1% of all trauma admissions. No other filter types or therapeutic filters were inserted for trauma patients in this period.

The median age of patients was 35 years (range, 17–73 years) with 14 women (38%) and 23 men (62%). ISS of the study population ranged from 17 to 59 (median ISS 41). Thoracic and abdominal injuries were among the most frequent trauma patterns (Table 1). Median hospital stay was 28 days (range, 11–139 days) including 15 days at the ICU (range, 1–53 days). Mechanical ventilation was performed in 32 patients (87%) for 1 to 27 days (median, 9 days).

The OptEase filter is based on a permanent IVC filter design, the Cordis TrapEase filter which can either be retrieved or remain permanently implanted. It is made from a single nitinol metal tube with a double-basket design with six straight struts connecting the proximal and distal baskets. This self-centring design provides dual-level filtration. Percutaneous placement is possible from both jugular and femoral routes using a 6-F delivery system. The OptEase filter has six fixation barbs at the cranial end of the device to prevent cranial migration. A hook at the caudal end of the filter allows retrieval with an endovascular snares. Percutaneous retrieval is only possible from a transfemoral approach requiring a 10-F guiding catheter is required. One benefit of using the femoral approach over the jugular approach during retrieval is the avoidance of inadvertent passage of the retrieval sheath through the heart, which would lessen the potential for myocardial injury or arrythmia. It is the only retrievable filter that can be recovered from a femoral approach.

All filters were placed and retrieved by an experienced interventional radiologist under fluoroscopic guidance in the angiography suite. Filters were left in place for at least 7 days. Retrieval was routinely performed when there was no longer a contraindication to prophylactic anticoagulation. Maximal indwelling time before filter retrieval was 28 days. If filter retrieval was not possible within this period, filters were left permanently. Before filter retrieval patients were assessed clinically for DVT of the lower extremities. Asymptomatic patients were not routinely evaluated for occult DVT. For patients with suspected DVT duplex ultrasonography was undertaken. Inferior cavoangiography was performed in order to assess patency of the IVC and rule out potential filter migration (Fig. 1). In the presence of trapped clot in the filter, the size of the clot was assessed in relation to the inner diameter of the IVC. For thrombus ≤25% the filter was retrieved in the same session without additional measures. For larger clots retrieval was delayed and anticoagulation therapy was initiated. Thrombolysis was never considered due to the risk of haemorrhagic complications. Retrieval was not considered in patients with long-standing contraindications to prophylactic anticoagulation or in the presence of persisting filter thrombosis >25%.

Results

Median interval between trauma and VCF placement was 1 day (range, 0–11 days). Patients who were seen

<table>
<thead>
<tr>
<th>Injury</th>
<th>AIS &gt;2</th>
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</thead>
<tbody>
<tr>
<td>Head</td>
<td>17 (46%)</td>
</tr>
<tr>
<td>Face</td>
<td>4 (11%)</td>
</tr>
<tr>
<td>Chest</td>
<td>30 (81%)</td>
</tr>
<tr>
<td>Abdomen</td>
<td>24 (65%)</td>
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<tr>
<td>Pelvis</td>
<td>19 (51%)</td>
</tr>
<tr>
<td>Spine</td>
<td>11 (30%)</td>
</tr>
<tr>
<td>Extremity</td>
<td>20 (54%)</td>
</tr>
<tr>
<td>Integument</td>
<td>1 (3%)</td>
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AIS, Abbreviated Injury Score.
Initially at another hospital and then referred to our trauma centre had a longer delay ($n = 10$). For 27 patients who were directly transferred to our unit after trauma, the longest interval was 7 days. 36 OptEase filters were placed percutaneously through the femoral approach (97%). The right jugular vein was accessed in 1 patient (3%) due to the pattern of injury. Retrieval was performed using the transfemoral approach.

A Duplex scan was performed in 12 patients (32%) with clinical suspicion of DVT of the lower extremities before filter retrieval, but no DVT was discovered. 32 VCFs were retrieved (86%) after 16 days (range, 7–25 days). Technical success rate of retrieval was 100%.

33 patients underwent inferior cavography before retrieval. 12 filters presented with strands of organised thrombus on the filter struts (36%). In 8 cases with a thrombotic mass $\leq 25\%$ (24%) the filter was immediately removed in the same session without additional treatment. Preretrieval cavography demonstrated partial filter thrombosis (50–75\%) in 4 cases (12\%) which was combined with minor caudal VCF migration in 1 patient (3%, Fig. 2A–D). Retrieval was delayed and anticoagulation therapy was initiated for 2 patients 12 days after trauma as they had no ongoing contraindication to anticoagulation. On follow-up cavography 22- and 25 days after trauma, no residual filter thrombosis was seen. Uneventful
retrieval of both devices was performed in the same session. Another patient had his filter retrieved and successfully replaced by a second device in order to prevent impending IVC occlusion in the same session 13 days after initial placement. The second filter was necessary due to ongoing contraindication to anticoagulation after a severe head injury. Uneventful retrieval of the second VCF was performed 12 days later. Filter retrieval was cancelled due to partial filter thrombosis seen on preretrieval cavography and ongoing contraindication to therapeutic anticoagulation in 1 patient. 3 filters (8%) were left permanently due
to severe brain injuries and abdominal trauma with long lasting contraindications to pharmacologic prophylaxis and 1 patient died due to a severe brain injury 15 days after trauma before retrieval was considered. In total, 5 patients (14%) did not have their VCF’s retrieved.

Symptomatic PE was seen in 1 patient (3%) 5 days after filter retrieval. This severely injured patient (ISS 50) showed no signs of DVT and no pathology was seen on preretrieval cavography 17 days after VCF placement. Following retrieval prophylactic low-dose heparin was initiated. PE was confirmed 5 days later by contrast-enhanced helical CT scan and a second VCF was immediately placed as therapeutic anticoagulation was not possible due to imminent danger of secondary brain haemorrhage. This second filter was retrieved 10 days later when therapeutic anticoagulation could have been started.

We observed no IVC occlusion or injury. No haematoma, AV-fistula or venous thrombosis occurred at the access site either for insertion or retrieval. Mortality was 3%. A 48-year old woman died 15 days after trauma due to a severe brain injury. Death was unrelated to VCF or venous thromboembolic events. Autopsy showed a correct filter position and no signs of VTE or filter thrombosis.

Thirty-three patients were seen in outpatient clinic 6- and 12 weeks following trauma. Three patients were not available for follow-up. Of the 30 patients with previous filter retrieval, no one presented with a history or clinical signs of VTE. No further investigations were performed for detection of occult DVT in asymptomatic patients.

The 3 patients with permanent VCFs were additionally assessed by an interventional radiologist regarding their VTE and filter related complications. Median follow-up was 5 months (range 3–11 months) after filter placement. Follow-up included a plain radiograph of the abdomen and duplex ultrasonography for detection of DVT and filter-related complications. No filter showed signs of migration. Late filter thrombosis was seen in 1 out of 3 patients. This patient developed symptomatic DVT despite adequate prophylaxis with deltaparin 4 months after trauma. Follow-up 1 month later revealed asymptomatic IVC occlusion with persistent DVT despite therapeutic anticoagulation.

No complication from anticoagulation occurred in our study group. Of the 32 patients who had their filters retrieved, 6 patients received therapeutic oral anticoagulation for 6 to 16 weeks after trauma according to their injury pattern. In 20 patients with ongoing contraindication to anticoagulant therapy, deltaparin in prophylactic dosage was continued for the same period of time. Six patients did not receive any VTE prophylaxis at all after filter retrieval.

### Discussion

Streiff et al., in a literature review of the outcome of IVC filter use found a late PE rate of 2.6–3.8%, incidence of DVT ranged from 5.9% to 32% and postphlebitic syndrome was observed in 14% to 41%. IVC thrombosis occurred in 3.6 to 11.2%. Decousus et al. demonstrated a reduction in the incidence of PE in patients with filters compared with patients treated with anticoagulant therapy by day 12. However, no difference was found between the two groups concerning PE after two years. The incidence of recurrent DVT was significantly higher in patients with VCFs at the 2-year follow-up. They suggested that late thrombosis at the filter site may be related to this excess of recurrent DVT. The recently published eight-year follow-up results showed a reduced risk of PE and a significant increase of symptomatic recurrent DVT for the filter group. No difference was found in the occurrence of post-thrombotic syndrome. However, symptomatic VTE and mortality showed no significant difference. This data support the use of retrievable VCFs to avoid potential long-term complications.

DVT and PE can occur shortly after trauma. Schultz found an 24% incidence of asymptomatic PE using contrast-enhanced helical CT scanning for diagnosis between 3 and 7 days after trauma. Following our concept, filter placement was performed as soon as possible and all patients were evaluated for filter retrieval. We achieved a retrieval rate of 87%. We observed 1 symptomatic PE 5 days after filter retrieval suggesting that retrieval might have been performed too early. This patient had no signs of DVT, preretrieval cavography showed no pathology and adequate pharmacologic prophylaxis was given. Duplex scanning may be beneficial to detect occult DVT before VCF retrieval. Some authors have advocated serial colour-flow Doppler imaging to detect occult DVT. UltraSound screening asymptomatic patients may be of lower sensitivity compared to venography and it may be difficult to perform in patients with injuries to the lower extremities.

Cavography before potential filter retrieval revealed partial filter thrombosis in 12 out of 33 patients (36%). The filters may have trapped small emboli or thrombogenicity of the filter itself may have contributed to this finding. Clinical studies investigating the TrapEase (Cordis Endovascular,
have been reported in the literature. Asch has documented the efficiency of the recovery filter (Bard, West Sussex, England), like the OptEase device made from nitinol, in 32 patients with a maximum implantation time of 134 days. Selected trauma patients benefit from retrievable VCFs as retrieval avoids the potential long-term complications of permanent filters.

According to the manufacturer’s recommendation the OptEase filter should be retrieved within 14 days if placed as a temporary device. This time period seems rather short as vena caval filtration is often necessary for a longer period. In a goat model, the struts of OptEase filters were overgrown with neointima 46 days after implantation. The authors concluded that filter incorporation into the vessel wall decreases the risk of retrieval complications. Filter repositioning to prolong dwell times or VCF replacement involves at least one additional procedure which increases cost and perhaps filter-related morbidity. A retrospective analysis in the manufacturer’s 510(k) approval request described 29 patients with a mean implantation time of 16.4 days and a maximum of 48 days. In our series filters were retrieved up to 25 days. Our technical success rate was 100% and all filters were removed percutaneously without any adverse effects suggesting that extended implantation time is feasible for the OptEase filter. The maximum period of time during which this filter can safely be retrieved has not been determined. Safe retrieval of OptEase filters up to 48 days after implantation has been reported in the literature. In the largest clinical series so far, Rosenthal et al. reported their experience with 49 prophylactic OptEase filter placements in multiple trauma patients under intravascular ultrasound guidance. They observed 2 groin haematomas (2%) and 1 insertion site DVT (1%). 31 filters (33%) were retrieved after 5 to 25 days. Three filters (9%) were not removed due to significant trapped thrombus (>25%) within the filter. All patients underwent Duplex scan before retrieval, but no DVT was identified.

Other retrievable VCFs such as the Günther Tulip filter (William Cook, Bjaeberskov, Denmark) come with similar recommendations regarding implantation time, but much longer intervals up to 317 days have been reported in the literature. Asch has documented the efficiency of the recovery filter (Bard, West Sussex, England), like the OptEase device made from nitinol, in 32 patients with a maximum implantation time of 134 days. Selected trauma patients benefit from retrievable VCFs as retrieval avoids the potential long-term complications of permanent filters.

References


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