Prophylactic Insertion of Optional Vena Cava Filters in High-Risk Trauma Patients

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Abstract

Background: Vena cava interruption is a form of pulmonary embolism prophylaxis that is being used in high-risk patients who do not tolerate pharmacologic prophylaxis. Retrievable prophylactic vena cava filters (VCFs) are of particular interest for severely injured patients where the necessity for VCF is often only temporary.

Methods: In a single-institution case series of consecutive patients who received prophylactic VCFs after polytrauma, between 04/1998 and 07/2004, the demographic data, injury pattern and complications were analysed.

Results: Ninety-five prophylactic VCFs were placed in polytrauma patients (median ISS of 38). Median age was 38 years (range 16–80 years). Median delay between trauma and filter placement was 1 day (range 0–31 days). No complication was seen related to filter insertion or retrieval. Sixty-five VCFs (68.4%) were retrieved after 4–25 days (median 13 days). One filter migration (1.1%) was observed. Retrieval failed in two patients (3.0%). A total of 30 VCFs (31.6%) were left permanently. One non-fatal PE (1.1%) occurred 21 days after filter retrieval despite prophylaxis with LMWH. DVT developed in two patients (2.1%) including one vena caval occlusion (1.1%). Overall mortality was 7.4%.

Conclusions: Early prophylactic placement of VCF in a high-risk trauma patient should be considered when anticoagulation is contraindicated. Filter insertion and retrieval is safe with a low complication rate.

Key Words
Prophylactic vena cava filters · Optional · Retrievable · High-risk trauma patients

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Received: July 26, 2005; revision accepted: December 20, 2005.

Eur J Trauma 2006;32:37–43
DOI 10.1007/s00068-006-0086-z

Introduction

Deep venous thrombosis (DVT) and pulmonary embolism (PE) play a major role in trauma. The incidence for venous thromboembolic events (VTE) varies widely in the literature from 5 to 58% [1–3]. In some series, PE represents the third major cause of death after trauma in those patients who survive longer than 24 h after injury [4]. Mortality associated with PE was 18.7% in an analysis of 1,602 episodes of VTE from the National Trauma Data Bank [5]. Since most PE are clinically silent, the incidence of occult PE is surely underappreciated. Schultz et al. [6] documented a 24% incidence of asymptomatic PE in a study of 90 moderately to severely injured trauma patients undergoing surveillance contrast-enhanced helical CT scanning. Thirty percent of patients receiving pharmacologic prophylaxis had a PE in this study.

Unfractionated heparin followed by oral anticoagulation for 3 months prevents PE in 95% of patients with proximal DVT [7, 8]. However, low-dose heparin (LDH) has very little proven efficiency in the prevention of VTE after trauma [9, 10]. Several studies have indicated that low-molecular-weight heparin (LMWH) is superior to LDH for prophylaxis with the same or less bleeding risk [10–12]. The use of pneumatic compression devices and arteriovenous foot pumps in trauma has shown no benefit over no prophylaxis [11–14]. Most DVT develop in the first 2 weeks after injury [15]. In a retrospective case series Owings et al. [16] demonstrated that 6% of all PE in the trauma setting occurred on day 1 following injury. This finding demonstrates the importance of efficient early VTE prophylaxis. Severely

injured patients are often at higher bleeding risks in the first days after trauma. As a secondary cerebral or abdominal hemorrhage may have fatal consequences, selection of VTE prophylaxis can be a challenging balance between VTE risk and bleeding risk.

Vena cava interruption became common after vena cava filters (VCFs) became available in the late 1960s [17]. Inferior VCFs are effective in preventing PE [17–19], but they do not prevent DVT or postthrombotic syndrome. In high-risk trauma patients without DVT, prophylactic insertion of a VCF has shown to decrease the rate of PE in multiple studies [20–22]. Interruption of the inferior vena cava (IVC) for the prevention of PE has become popular in trauma patients. Rogers et al. [20] considered 4.3% of all trauma patients admitted to one-centre appropriate candidates for prophylactic insertion of VCFs.

The first VCFs were designed for permanent placement. Retrievable filters have been developed to avoid potential long-term device-related complications, such as IVC perforation or occlusion, thrombosis and filter migration [23, 24]. Optional filters are devices which can remain in place, acting as a permanent VCF, or be removed percutaneously as a retrievable filter [25]. This advantage is of particular interest in trauma patients. For many of these patients anticoagulation is only contraindicated for a short period after trauma and the necessity for vena cava interruption in trauma patients is often time-limited. For these cases an effective filter, which can be safely retrieved, is an attractive alternative to permanent filters.

Patients and Methods

The trauma registry and interventional radiology database were reviewed for all VCFs placed in trauma patients from April 1998 to July 2004. Clinical and radiological records were reviewed for age and gender of the patient, injury pattern, indication for VCF, type of filter, interval between trauma and VCF insertion, time of retrieval, complications and long-term follow-up for permanent vena cava filtration. Only patients with polytrauma and prophylactic insertion of a VCF entered the study. Polytrauma was defined, according to the guidelines of the German Society for Trauma Surgery, as a life-threatening injury to several physical regions/organ systems with an Injury Severity Score (ISS) $\geq$ 16.

All patients without contraindication to pharmacological prophylaxis initially received intravenous LDH administered continuously over 24 h. This regimen was changed to either LMWH or to wafarin derivates according to the injury pattern later on. Prophylactic VCF placement was evaluated according to the guidelines of the Eastern Association for the Surgery of Trauma (EAST) [11]. In addition, the patient's risk for VTE was assessed using the RAPT score developed by Greenfield and co-workers [3] (Table 1). High-risk trauma patients (RAPT score $\geq$ 5) were evaluated for prophylactic VCF when pharmacologic prophylaxis for VTE was contraindicated. All patients received high-thigh antiembolic stockings. Patients unable to wear these stockings, because of fractures or open wounds of the lower extremities, had them applied unilaterally whenever possible. Insertion of the VCF was performed as early as possible regarding the patient's condition. For patients with cardiovascular instability, high intracranial pressure and other physical conditions forbidding transport to the angiography suite and the stress of an interventional procedure filter insertion was delayed.

All filters were inserted and retrieved by a senior interventional radiologist under fluoroscopic guidance in the angiography suite. The VCFs were exclusively placed infrarenally. Two different optional filter models

Table 1. VTE risk factor assessment in adult trauma patients (RAPT score).

	Weight
Underlying conditions	
Obesity	2
Malignancy	2
Abnormal coagulation factors at admission	2
History of thromboembolism	3
Iatrogenic factors	
Femoral venous line > 24 h	2
Transfusion > 4 units during the first 24 h	2
Surgical procedures > 2 h	2
Repair/ligation of venous injury	3
Injury-related factors	
AIS > 2 for the chest	2
AIS > 2 for the abdomen	2
Spinal fractures	2
AIS > 2 for the head	3
Glasgow Coma Score < 8 for > 4 h	3
Complex lower extremity fracture	4
Pelvic fracture	4
Spinal cord injury (complete or incomplete)	4
Age (years)	
$\geq$ 40 but < 60	2
$\geq$ 60 but < 75	3
$\geq$ 75	4

were used in the time studied. In total, 65 Günther Tulip devices (William Cook, Bjaekerskov, Denmark) and 30 OptEase filters (Cordis Endovascular, J&J, Roden, The Netherlands) were placed. The former was inserted from April 1998 to August 2003 and the latter from August 2003 to July 2004.

The Günther Tulip filter consists of four stainless-steel legs forming a cone. The clot-trapping areas are formed by thinner wires which are shaped like tulip leaves. They extend from the apex to the distal ends of each leg. Small barbed hooks at the caudal ends of the legs provide fixation in the IVC. A hook at the proximal end of the device facilitates retrieval.

In contrast, the OptEase device has a double-basket design with six straight nitinol struts connecting the proximal and distal baskets. Six fixation barbs at the cranial end of the filter prevent migration. A hook located at the caudal base of the device allows retrieval.

Both filter types can be delivered through either a jugular or femoral venous approach. Access for retrieval depends on the particular filter designs. The Günther Tulip device must be retrieved through the jugular vein whereas retrieval of the OptEase filter is from the femoral vein access.

Since contraindication for anticoagulation is often only temporary in trauma patients, filter retrieval was routinely evaluated. All patients considered candidates for retrieval underwent inferior cavography prior to the planned procedure. The presence of only minor thromboemboli at the filter struts, defined as less than 25% of the diameter of the IVC, was no contraindication for retrieval. For larger thromboemboli the filter was left in situ and a therapeutic anticoagulation with intravenous heparin was initiated with follow-up cavography between 7 and 14 days later. Filter retrieval was performed in the same session when a reduction of the thromboembolic mass to the aforementioned dimension was evident on cavography. For persistent filter thrombosis the filter was left in place and the patient was started on a long-term anticoagulation.

Patients with permanent VCF were asked to attend follow-up examination which was performed by a fellow interventional radiologist. Follow-up included a clinical examination, color-flow duplex scan and a plain radiograph of the abdomen.

Results

A total of 107 trauma patients underwent vena cava interruption at our department. Ninety-five patients (88.8%) with polytrauma and prophylactic insertion of a VCF entered the study. Five polytrauma patients (4.7%) with therapeutic VCF insertion were excluded from further evaluation. Seven patients (6.5%) with single injuries or non-life-threatening multiple injuries were excluded from the study as well.

Median age was 38 years (range 16–80 years). Sixty-seven patients were male (70.5%), 28 female (29.5%). The ISS ranged from 17 to 66 (median 38). Injuries to chest, abdomen and head were among the most frequent injury patterns (Table 2). Median hospital stay was 26 days (range 6–159 days) including 11 days (range 1–50 days) at the ICU. Patients were ventilated for a median time of 7 days (range 1–36 days).

Indication for prophylactic VCF placement was based on the EAST guidelines [11]. Ninety-three patients (97.9%) fulfilled the high-risk criteria of the RAPT score. Two patients (2.1%) with rib fractures in combination with a ruptured spleen and liver, respectively, received a VCF despite a RAPT score < 5. Both patients were treated nonoperatively. Decision making for temporary vena cava interruption in these patients was based on individual judgement by the treating physicians and was not in accordance with our concept. Both patients were included in the study, and filter retrieval in these patients was assessed and performed similar to the patients with a RAPT score > 5.

The interval between trauma and filter placement averaged 2.4 days (median 1 day, range 0–31 days). For the last year of our observation period this interval decreased to 1.8 days (median 1 day, range 0–7 days). Fifty-four patients (56.8%) had their VCFs placed within 1 day after admittance. All filters were placed infrarenally. Both filter types were predominantly delivered through a femoral venous approach (n=91, 95.8%); the jugular vein was accessed in 4.6% (n=4). Thirty-six Günther Tulip filters (94.7%) were retrieved from the

Table 2. Injury pattern.

Injury	AIS >2
Head	55 (57.9%)
Face	3 (3.2%)
Chest	64 (67.4%)
Abdomen	61 (64.2%)
Pelvis	49 (51.6%)
Spine	26 (27.4%)
Extremity	46 (48.4%)
Integument	1 (1.1%)

jugular vein access; in two cases (5.3%) a combined femoro-jugular access was necessary. Only the femoral vein was accessed for retrieval of the OptEase device (n=27).

Overall, 65 VCFs were placed temporarily (68.4%) and 30 filters (31.6%) were permanent. VCF retrieval was successful in 65 out of 67 cases (97.0%). Two retrieval procedures (Günther Tulip filter) had to be abandoned due to technical difficulties (3.0%). Both filters presented with a tilt of $> 10^{\circ}$ within the vessel structure, making it technically impossible to grab the filter hook. The median duration between placement and retrieval was 13 days (range 4–25 days). One patient decided to be transferred to another hospital for further treatment, 5 days after trauma. As VCF retrieval was not available in the other hospital, it was decided to remove the filter exceptionally early 4 days after insertion. All other patients had their filters placed for at least 7 days.

A total of 21 filters (22.1%) showed strands of organised thrombus on the filter struts on follow-up cavography before potential retrieval. Thirteen VCFs with a thrombotic mass ≤ 25% were retrieved as planned without delay or additional antithrombotic therapy. No complication related to retrieval of these filters was observed. Preretrieval cavography demonstrated partial filter thrombosis (50–75%) in two cases which was combined with caudal filter migration towards the right common iliac vein in one patient (1.1%). Retrieval was delayed and anticoagulation therapy was initiated for both 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. VCF retrieval was cancelled in six cases due to critical sizes of filter thrombosis (> 25%) and ongoing contraindication to anticoagulation. One of these patients 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. Uneventful retrieval of the second VCF was performed 12 days later.

No hematoma or thrombosis occurred at the access site neither for insertion nor retrieval. One nonfatal PE (1%) was diagnosed 21 days after filter retrieval despite adequate prophylaxis with LMWH. This 30-year-old woman was involved in a road traffic accident, sustaining an unstable lumbar spine fracture and a blunt trauma to chest and abdomen (ISS 32, RAPT score 10). Damage control laparotomy with perihepatic packing and insertion of bilateral chest tubes were performed. Two second-look laparotomies followed within 4 days. A VCF was placed less than 48 h after trauma. The spine fracture was stabilised by an internal fixator 4 days later. VCF removal took place 13 days after trauma. Symptomatic PE occurred 21 days later. Helical CT angiography showed multiple segmental pulmonary emboli and therapeutic anticoagulation was initiated. DVT was observed in two patients. One IVC occlusion with DVT was detected on inferior cavography 12 days after filter placement. The filter was not retrieved and long-term anticoagulant therapy was initiated. Thirty-seven days after filter placement duplex scanning revealed persistent DVT, but a recanalised IVC. At follow-up (73 months after VCF insertion) duplex scanning showed no residual thrombosis either in the IVC or the deep venous system of the pelvis and lower extremities. Mortality was 7.4%; no death was related to VTE or the VCF. Median interval between trauma and death was 13 days (range 7–99 days). Five patients died after the decision was made to leave the filters permanently; in two cases death occurred before filter retrieval was considered.

The ratio of retrieved filters compared to permanent placements was more favourable for the OptEase device (90.0 vs. 58.5%) which replaced the Günther Tulip filter in August 2003. This difference in the retrieval rate between the two devices may be partly due to increasing lenience towards the presence of clot in the filter as a contraindication for retrieval as the operator's experience grew. Furthermore, changing the practice concerning contraindication to anticoagulation for different injury patterns over the last years has led to increasing numbers of filter retrieval. Head injury, for example, is not a strict contraindication to pharmacologic prophylaxis anymore. Indication and timing for anticoagulation is determined for each head trauma patient individually by neurosurgical consultation. The same practice is pursued for blunt abdominal trauma and other injuries. This approach in combination with extended interval for filter retrieval has gained increasing acceptance in our unit. Filter retrieval is now the standard practice for trauma patients, leaving permanent filters for special situations only (Table 3).

Of the 23 survivors with permanent VCF follow-up, imaging was possible in 14 patients (60%; 12 Günther Tulip, 2 OptEase). Mean time of follow-up was 33.7 months (range 0.9–76.7 months). All patients under-

Table 3. Reasons for permanent filter placement.

	No. (%)
Partial VCF thrombosis	5 (16.7)
DVT (including 1 ICV occlusion)	2 (6.7)
History of recurrent VTE	1 (3.3)
Failed retrieval	2 (6.7)
Patient not suitable for transport	1 (3.3)
Severe head injury	11 (36.7)
Patient refusal	3 (10.0)
Death	4 (13.3)
Unknown	1 (3.3)
Total	30 (100)

went colour-flow duplex scanning. A plain radiograph of the abdomen was obtained for nine patients. In one patient filter position was assessed on thoracoabdominal computed tomography which was performed for other reasons. Abdominal X-ray was refused by four patients. Twelve patients with Günther Tulip VCFs (57.1%) were available for follow-up (mean 38 months, range 1–77 months). No filter migration was found. Filter tilt was seen in two patients (16,7 %). All VCFs were patent and no signs of chronic venous insufficiency were recorded. OptEase devices were permanent in only three patients. One patient died from his severe head trauma; the other two patients presented for follow-up (mean 8 months, range 3–12 months). Both patients showed a patent IVC, no signs of filter migration or tilt and no DVT.

Discussion

Prophylactic filter placement for high-risk trauma patients without documented VTE is still controversial. Current recommendation is based on Level III data according to the EAST Practice Management Guidelines Work Group [11]. There is no question about filter efficiency. In most series a decrease in the incidence of PE is reported when prophylactic VCFs were inserted. Greenfield and Proctor [26] reported a success rate of 98% in preventing PE from lower extremity DVT. In contrast only one retrospective study was published demonstrating a significantly higher rate of PE in a time period when more filters were placed compared to a time period with more restrictive filter indications [27]. The authors did not give any explanation for this finding.

Defining who should receive a filter remains a major issue. Level I data supported only spinal cord injuries and spinal fractures, both being high-risk factors for venous thromboembolism. Age was an increased risk factor, but the analysis failed to determine the exact age at which the risk increased substantially. All other traditional risk factors such as long bone fractures, pelvic fractures or head injuries were not found to be powerful risk factors on meta-analysis [11].

However the authors outlined the need for additional adequately sized prospective studies for re-evaluating the role of different possible risk factors. In the same article the EAST Practice Management Guidelines Work Group had suggested that prophylactic VCF should be considered in patients with contraindication to anticoagulation and high-risk criteria, such as prolonged immobilisation including severe head trauma and spinal cord injury, complex pelvic fractures and multiple long bone fractures.

Beside the EAST guidelines we routinely applied the RAPT score to identify patients with a high risk for thromboembolism [3]. Vena cava interruption was considered for all patients with a score ≥ 5 and contraindication for pharmacologic prophylaxis. According to the literature, patients with a RAPT score of ≥ 5 are three times more likely to develop VTE than patients with a lower score [3, 28].

An optional VCF is an attractive alternative to permanent or temporary filter systems for polytrauma patients. It can be left permanently if long-term vena caval interruption is indicated. Patients who subsequently undergo anticoagulant therapy after initial contraindication benefit by having the filter safely removed. Our experience with optional filter systems is comparable with the literature [29–32]. We had a retrieval technical success of 97.0% with no retrieval-related morbidity. Compared to the literature we had a high retrieval rate of 68.4% and only 31.6% of permanent placements. In the last year of observation this rate increased to 90.0% displaying the consequent implementation of our concept.

Recommended interval for retrieval of most optional filters is within 14 days. Our longest interval was 25 days with uneventful retrieval. Intervals for Günther Tulip filters up to 126 days are reported in the literature [33]. This suggests that retrievable filters can potentially provide caval interruption for a longer time period without the risk of long-term complications whenever retrieved.

Decousus et al. [18] showed that VCFs only prevent PE in the short term after placement. They also found that medical patients receiving a VCF had significantly

higher rates of DVT recurrence than those treated with anticoagulation alone. They suggested that long-term anticoagulant therapy should be considered after placement of a permanent filter to counterbalance this possible effect. However, a higher DVT rate was not seen in trauma patients with prophylactic filter placement compared with non-filter patients [34].

On a long-term follow-up (4–42 months), Patton et al. [35] found that 26% of the patients had physical findings and duplex evidence of postphlebitic syndrome. Wojcik et al. [36] reported an early DVT rate of 44% after prophylactic VCF placement in trauma patients who could not initially receive anticoagulation. Diagnosed by routine duplex scanning only 39% of the patients were symptomatic. Greenfield et al. [37] reported a DVT rate of 15.6% after prophylactic filter placement during hospitalisation. At follow-up (mean 2.4 years) another 10.8% presented with new DVT, a long-term PE rate of 1.5% and no late filter-related complications. They emphasised the importance of continued DVT prophylaxis after filter placement. There is no question about the necessity of adequate DVT prophylaxis at the earliest possible time in high-risk trauma patients. Whether insertion of prophylactic VCF makes patients more prone to subsequent DVT is not known. Very high-risk patients as classified by Geerts et al. [1] had a DVT rate of 40–50% without VCF. In what way the use of retrievable filters may result in a lower incidence of late DVT remains unclear at present.

In our series filter thrombosis was seen in 22.1%. In most cases the mass was measured to be $<25\%$ of the diameter of the IVC. This raises the question of the origin of these thrombus formations. Adherent thrombotic material, usually containing fibrinous material, on the filter struts is commonly seen [31]. This material probably does not represent embolisation, but rather in situ thrombus formation [29]. The other possible origin is from trapped small thromboemboli which otherwise would have caused asymptomatic PE. This can clearly not be considered a complication as VCFs are designed to trap thromboemboli.

DVT and PE can develop shortly after trauma. Schultz et al. [6] studied 90 patients with an ISS ≥ 9 without symptoms suggestive of VTE undergoing contrast-enhanced helical CT scanning between 3 and 7 days after trauma. A 24% incidence of asymptomatic PE with mainly a minor clot burden was found. This report and others emphasize the timing of VTE prophylaxis. In a retrospective case series Owings et al. [16] demonstrated that 6% of all PE in the trauma setting occurred on day 1 following injury. Fifty-six percent of our patients had their VCFs placed within 1 day and 77.9% within 3 days after admittance, providing early protection from fatal PE.

Wicky et al. [38] published the only study, so far, reporting long-term outcome of nine non-retrieved Günther Tulip filters with a mean follow-up of 30 months (range 12–55 months). All presented with patent IVC. Proximal filter migration of 20–25 mm was observed in two patients (22%). Another two filters showed a tilting of 10°. Duplex scan showed no venous thrombosis. In our study 12 patients with Günther Tulip filters were available for follow-up (mean 38 months). We did not see any filter migration and a comparable long-term tilt rate of 16.7%. Like Wicky et al. [38] we did not find any correlation between tilt and occurrence of VTE.

In conclusion, early prophylactic placement of VCFs in a high-risk trauma patient should be considered when anticoagulation is contraindicated. Optional VCFs can act as permanent filters but also allow retrieval. Patients who subsequently undergo anticoagulant therapy after initial contraindication benefit by having the filter safely removed, avoiding potential long-term complications.

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