Early Placement of Optional Vena Cava Filter in High-Risk Patients with Traumatic Brain Injury

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Abstract

Objectives: Patients sustaining severe trauma are at high risk for the development of venous thromboembolic events (VTE). Pharmacologic VTE prophylaxis may be contraindicated early after trauma due to potential bleeding complications. The purpose of this study was to evaluate safety and feasibility of early prophylactic vena cava filter (VCF) placement and subsequent retrieval in multiple injured patients with traumatic brain injury (TBI).

Methods: Analysis of single-institution case series of consecutive patients who received a prophylactic VCF after severe TBI (Abbreviated Injury Scale, AiS ≥ 3) between August 2003 and October 2006.

Results: A total of 34 optional VCF were prophylactically placed with a median delay of 1 day after trauma (range, 0–7 days). All patients had sustained multiple injuries (median Injury Severity Score 41, range, 18–59) with severe TBI (median AiS 4, range 3–5). Median age was 41 years (range, 17–67 years). Two patients had succumbed before potential filter retrieval. Of the remaining patients, 27 (84%) had their filters uneventfully retrieved between 11 and 32 days (median, 18 days) after placement with no retrieval-related morbidity. Five VCF (16%) were left permanently. In one patient (3%) early inferior vena cava occlusion and deep venous thrombosis occurred 14 days after VCF placement. Symptomatic pulmonary embolism was observed in one patient (3%) 5 days after VCF retrieval. Overall trauma-related mortality was 9%.

Conclusions: Early VCF placement may be of benefit for multiple injured patients with TBI when pharmacologic VTE prophylaxis is contraindicated. VCF retrieval is safe and feasible. Filter placement- and retrieval-related morbidity is low.

Key Words
Optional vena cava filter · traumatic brain injury · VTE prophylaxis · Vena cava filter retrieval · Multiple Trauma

Eur J Trauma Emerg Surg 2007;33:407–13

DOI 10.1007/s00068-007-6211-9

Introduction

Trauma patients are at high risk for developing venous thromboembolic events (VTE) due to local and systemic alterations in rheology, blood viscosity, endothelial functions, and released thrombosis-promoting cellular and humoral factors which are influenced by the initial injury and subsequent alterations including pharmacologic alterations [1]. Incidence of deep venous thrombosis (DVT) and pulmonary embolism (PE) in the trauma population vary widely in the current literature. In some series, PE is the third major cause of death after trauma in those patients who survive longer than 24 h after injury [2]. PE after trauma is associated with a mortality rate as high as 18–50% [3–5]. In a meta-analysis of the trauma literature on VTE the pooled estimate was 11.8% for deep venous thrombosis (DVT) and 1.5% for PE with higher incidences expected for specific risk factors, such as severe head injury, pelvic frac-

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Received: December 12, 2006; revision accepted: February 4, 2007;
Published Online: July 17, 2007

ture, older age or increasing Injury Severity Score (ISS) [4, 6, 7].

As PE can develop even shortly after trauma [8–10], early initiation of effective VTE prophylaxis is of great importance. Despite the increased risk of developing VTE, the only method of prophylaxis currently recommended uniformly for patients with traumatic brain injury (TBI) are pneumatic compression devices because of concerns of bleeding complications with the use of heparin early after trauma [6, 11]. Recently, some reports have indicated that early administration of low-molecular-weight heparin (LMWH) and low-dose unfractionated heparin (LDUH) after TBI is not associated with increased bleeding complication [12–14]. However, as these studies differ in design and outcome measures, their data and conclusions still require further validation.

Vena cava filters (VCF) show excellent success rates in preventing PE (98%) from lower extremity DVT [15]. However, permanent VCF are associated with long-term complications like inferior vena cava (IVC) occlusion in as much as 11.2% and significant increase of symptomatic recurrent DVT [16, 17]. Long-term vena cava filtration is rarely necessary in trauma patients because high risk of VTE and contraindication to pharmacologic prophylaxis is mostly limited to a relatively short period during the early phase after trauma. Optinal VCF are devices, which can remain in place, acting as a classic permanent VCF, or be removed percutaneously as a retrievable filter.

With the safety of LDUH and LMWH remaining to be established in patients with TBI, early placement of VCF is an alternative method of PE prophylaxis in TBI patients with potential intracranial bleeding complications. The purpose of this study was to demonstrate feasibility and efficacy of our concept with early VCF placement and subsequent retrieval when pharmacologic VTE prophylaxis is considered safe.

Materials and Methods

The OptEase vena cava filter (Cordis Endovascular, J&J, Roden, The Netherlands) was introduced at our institution in August 2003. All trauma patients receiving this device between 1 August 2003 and 31 October 2006 were registered and entered a specific database. Only patients with TBI (Abbreviated Injury Scale, AIS ≥ 3) and high-risk for development of VTE with prophylactic VCF placement were included in this case series. Patients with therapeutic filter placement were excluded.

High-risk patients for VTE were defined by injury patterns rendering the patients immobilized for a prolonged period of time such as severe head trauma, incomplete spinal cord injury, complex pelvic fractures with associated long bone fractures or multiple long bone fractures according to the guidelines of the Eastern Association for the Surgery of Trauma (EAST) [6]. Furthermore, the VTE risk of our patients was assessed using the Risk Assessment Profile for Thromboembolism (RAPT score) within the first 24 h after trauma [18, 19]. This score weighs different individual risk factors. Patients with a score of five or more are three times more likely to develop VTE than patients with a RAPT score of < 5.

All high-risk trauma patients received some form of VTE prophylaxis with LMWH being the treatment modality of choice as soon as possible after trauma. High-risk patients with contraindication to pharmacologic prophylaxis > 5 days due to TBI with increased bleeding risk were evaluated for optional VCF placement within the first 24 h after trauma. Contraindication to anticoagulation was determined by assessment of the initial CT scan by an experienced neurotrauma surgeon on an individual basis for each patient. VCF placement was performed by a senior interventional radiologist in the angiography suite under fluoroscopic guidance as soon as the patient's condition allowed the procedure. All filters were placed infrarenally. 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 patients with optional VCF were evaluated for filter retrieval when there was no contraindication to pharmacologic prophylaxis anymore. Before potential filter retrieval patients were clinically assessed for DVT of the lower extremities. Asymptomatic patients were not routinely evaluated for occult DVT. For patients with suspected DVT a Duplex scan was carried out.

Patients planned for retrieval were started on pharmacologic prophylaxis for at least 24 h prior to retrieval. Maximal indwelling time before filter retrieval was initially 14 days at the beginning of the study period and increased with growing experience to 48 days by the end of the study period. If filter retrieval was not possible within this period, filters were left permanently.

Inferior cavography was performed in order to assess the patency of the IVC and to determine the exact filter position. In presence of trapped clot in the filter, the size of the clot was assessed in relation to

Table 1. Clinical characteristics of the 34 study patients. ISS: Injury Severity Score; RAPT: Risk Assessment Profile for Thromboembolism.

Variable	Median	Range
Age (years)	41	17–67
ISS	41	18–59
RAPT score	17	5–26
Intensive care unit length of stay (n = 34, days)	19	1–42
Length of mechanical ventilation (n = 31, days)	11	1–38
Hospital length of stay (days)	27	3–136

Table 2. Injury pattern. AIS: Abbreviated Injury Scale.

Variable	AIS ≥ 3
Head	34 (100%)
Face	7 (21%)
Chest	25 (74%)
Abdomen	13 (38%)
Pelvis	18 (53%)
Spine	12 (35%)
Extremity	20 (59%)
Skin	0 (0%)

Table 3. Specific intracranial injuries diagnosed on initial CT scan.

Diagnosis	Number of patients	%
Hemorrhagic brain contusions	18	53
Shearing injuries	13	38
Epidural hematoma	8	24
Subarachnoid hemorrhage	7	21
Subdural hematoma	6	18

Table 4. Reasons for permanent vena cava filter placement.

Variable	Number of patients
Traumatic brain injury[a]	2
Technical problem with retrieval	1
Vena cava filter thrombosis	1
Patient refusal	1

[a] Ongoing contraindication to pharmacologic prophylaxis

the inner diameter of the IVC. For thrombus ≤ 25% the filter was retrieved in the same session without additional measures [20]. For larger clots retrieval was delayed and therapeutic anticoagulation (PTT-controlled heparin administration) was initiated in the absence of ongoing contraindications. Retrieval was not considered in patients with long-standing contraindications to pharmacologic prophylaxis or in the presence of persisting filter thrombosis > 25%. In these cases the filter was left permanently.

Results

A total of 220 patients with severe TBI (AIS ≥ 3) were admitted to the trauma service between August 2003 and October 2006. Of these, 98 patients (45%) presented with severe isolated head injury while 122 patients (55%) sustained additional multiple injuries with an ISS ≥ 16. Of these 122 patients 34 patients (28%) were eligible for the present evaluation.

The clinical characteristics of the study population are listed in Table 1. All patients fulfilled the criteria for multiple trauma according to the German Society for Trauma Surgery as life threatening injury to several physical regions/organ systems with an ISS ≥ 16 (Table 2). Initial Glasgow Coma Scale (GCS) was < 8 in 53% of our patients. The predominant TBI in our study population were hemorrhagic brain contusions and shearing injuries (Table 3).

All VCF were prophylactically placed with a median delay of 1 day after trauma (range, 0–7 days). All filters were placed and retrieved percutaneously through the femoral vein. No bleeding complication or thrombosis at the insertion/retrieval site was observed. Two patients died 2 and 15 days after trauma before potential filter retrieval was evaluated. Of the remaining patients, 27 VCF (84%) were retrieved after 18 days (range, 11–32 days) while five (16%) remained in place for various reasons (vida infra) (Table 4). Filter retrieval had to be aborted in one patient due to technical difficulties. Technical success rate of retrieval was 96%. Twenty-eight patients (88%) underwent planned inferior cavography before potential retrieval. A total of nine filters (32%) showed strands of organized thrombus on the filter struts with the majority (7 VCF) encompassing less than 25% of the IVC diameter. These filters were retrieved in the same session without complications.

Retrieval was delayed in one patient (4%) demonstrating partial filter thrombosis of 75% 12 days after placement. Therapeutic anticoagulation was initiated in the absence of contraindication. Uneventful retrieval with no signs of residual clots was performed 9 days later. A 19-year-old patient with severe TBI (AIS 5, epidural hematoma, hemorrhagic brain contusions) presented with a partial 50% occlusion of the VCF on follow-up cavography. This filter was replaced by a second VCF in order to avoid impending IVC occlusion 13 days after trauma as therapeutic anticoagulation was still considered contraindicated. The second filter was retrieved 12 days later.

Acute IVC occlusion with symptomatic bilateral DVT was observed in one patient 19 days after primary amputation of the right thigh due to an open comminuted fracture of the distal femur with neurovascular injury. Therapeutic anticoagulation was started and catheter-directed thrombolysis was performed. Despite these measures the IVC could not be recanalized successfully. The filter was left permanently and therapeutic anticoagulation was switched to coumarin on a long-term basis.

Symptomatic DVT in combination with trapped emboli in the VCF was diagnosed in one patient 10 days after trauma. The filter insertion site was not involved. Therapeutic anticoagulation was initiated and filter retrieval delayed. Due to persistent DVT catheter-directed thrombolysis of the iliac veins was performed 17 days after trauma. The filter was retrieved 30 days after placement. Symptomatic DVT was observed in one patient 5 days after VCF retrieval subsequently treated by therapeutic anticoagulation for 3 months.

Symptomatic PE was observed in one patient (3%) 5 days after VCF retrieval despite standard VTE prophylaxis with LMWH. Contrast-enhanced helical CT scan revealed multiple segmental emboli. However, DVT as a possible source for the PE was not found. In the presence of ongoing temporary contraindication to therapeutic anticoagulation, a new VCF was placed for a period of 12 days followed by long-term therapeutic anticoagulation after filter retrieval.

The four patients (12%) requiring anticoagulation therapy or catheter-directed thrombolysis underwent serial follow-up CT scans of the head without evidence of bleeding complications. Thrombolysis resulted in one bleeding complication at a forearm following internal fracture fixation. The haematoma could be evacuated surgically without further compromise.

In two cases (6%) the bleeding risk after TBI was considered too high for pharmacologic prophylaxis within 2 weeks after trauma. Overall, mortality was 9% (2/34) with TBI having been the only cause of death.

Discussion

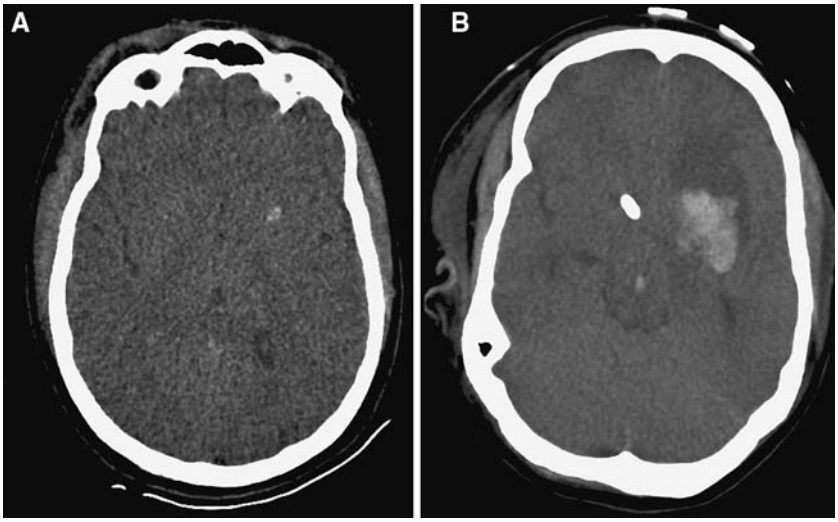
TBI patients are at high risk for PE. The incidence is even higher in the presence of other significant trauma [3, 4, 18]. Published data on VTE prophylaxis in the trauma patient deal with a variety of different populations and subgroups making a reliable comparison difficult. As the trauma population is poorly studied, conclusions and recommendations based on research of other populations like medical or elective surgical patients cannot necessarily be extrapolated to trauma patients [21]. The current status of VTE prophylaxis following trauma has recently been described as a story of confusion and uncertainty [21]. The controversially discussed debate on early VTE prophylaxis still lacks convincing data on necessity, specific agent, point of initiation, length of administration and potential complications. To add to the present confusion recent interest even focuses on agents as e.g., recombinant activated factor VII (raFVII) used to support local thrombus formation while we are thinking about having to avoid thrombus formation.

Sequential compression devices and pharmacologic prophylaxis have become the dominant method for VTE prophylaxis. LMWH has shown to be superior to LDUH in trauma [22]. However, studies of the effectiveness and safety of pharmacologic prophylaxis in trauma patients show inconsistent results [21]. The efficacy of pneumatic compression devices, footpumps and antithrombotic stockings in the trauma setting has been questioned and remains unproven [6, 23]. Furthermore, application of these devices is often impossible due to injuries to the lower extremities.

Nevertheless, guidelines on VTE prophylaxis have been issued by different groups [6, 11]. Prophylactic use of VCF has not been recommended by the latest guidelines of the American College of Chest Physicians Conference (ACCP) [11]. In contrast, the EAST pleaded for prophylactic VCF in very high-risk patients who cannot receive pharmacologic prophylaxis because of increased bleeding risk [11].

The bleeding risk in the initial phase after severe trauma is difficult to determine due to a number of individual factors as, e.g., trauma pattern, coexisting hypothermia, trauma-associated coagulation disorders, metabolic acidosis and others which increase in frequency and magnitude with the severity of trauma. Decision-making may be based on individual experience rather than on an objective risk evaluation process. Most studies dealing with LDUH- or LMWH-associated bleeding excluded patients with TBI from their evaluation [22, 23].

A pooled average of bleeding complication rates in three studies evaluating heparin prophylaxis in patients undergoing elective neurosurgery was 2.7% [14]. Some recent reports indicate that early administration of LMWH and LDUH after TBI is not associated with increased bleeding complication [12–14]. However, none of these studies were randomized and they all followed different study protocols. Norwood and colleagues reported a bleeding complication of 4% in 150



Figures 1a and 1b. Representative CT scan of the head after traumatic brain injury. This patient did not receive any pharmacologic VTE prophylaxis during the early phase following trauma. a) The initial scan obtained 1 h after trauma showed only minor hemorrhagic brain contusion within the anterior part of the internal capsule on the left side. Following this CT scan an external ventricular drainage was inserted in this multiple injured patient. b) Follow-up CT scan obtained 24 h after trauma demonstrated massive progression of the hemorrhagic brain contusion with perifocal edema.

patients with traumatic intracranial hemorrhagic injuries and LMWH administration beginning 24 h after admission [14]. Patients with coagulopathy were excluded and 39% of the patients sustained isolated TBI. Patients with minor TBI (AIS 2) were also included in the study. Intracranial hemorrhage became worse in 29% on follow-up CT 24 h after admission before LMWH was started. Only 4% demonstrated progression after beginning LMWH. This is in gross contrast to own observations from our TBI registry (Fig. 1). We found a progression or new onset of intracranial hemorrhage in 49% on follow-up CT scan even with early pharmacologic prophylaxis withheld (unpublished data). Kim and coworkers started their patients on LDUH within 72 h of admission [12]. In some patients intracranial hemorrhage was only assessed by clinical examination without follow-up CT scan [12]. Bleeding complications were not found increased compared to later onset of LDUH administration. Despite early prophylaxis, PE was observed in two patients. The authors concluded that LDUH does not significantly reduce incidence of VTE.

Even a low heparin-induced bleeding complication may be deleterious for the subsequent regeneration process and may even have fatal consequences for the individual patient outweighing the risk of sustaining fatal PE in the initial days after trauma. The true incidences of both heparin-induced intracranial bleeding complication and clinically relevant PE remain unknown.

Prophylactic insertion of optional VCF in high-risk patients has shown to provide effective protection from potentially fatal PE with low insertion – and retrieval related morbidity [24–28]. With the safety of LDUH and LMWH not being established yet, early placement of VCF may be an alternative method of PE prophylaxis in TBI patients with severe additional injuries at risk for potential intracranial bleeding complications.

Hoff and colleagues placed 35 prophylactic Gunther-Tulip VCF (William Cook, Bjaekerskov, Denmark) in trauma patients (ISS 30) with a delay of 3 days after trauma [25]. Thirty-four percent of their patients sustained TBI without further details given. The reported retrieval rate was 51%. In the largest series so far, different VCF devices were placed in a total of 127 trauma patients (ISS 27) with 90.5% of all VCF inserted within 48 h after trauma [28]. Head trauma was present in 46%. Retrieval rate reached 52% with a mean indwelling time of 71 days. In a previous study, we reported our experience with prophylactic insertion of optional VCF in multiple injured patients with a median ISS of 38 [26]. From a total of 95 VCF placed before August 2004 68% were retrieved after 13 days with a maximal indwelling time of 25 days. With growing experience, our concept has been implemented more rigorously leading to the results presented herein. To our knowledge, this is the first study which addresses exclusively prophylactic VCF insertion in patients with TBI. Compared to other studies with prophylactic VCF in trauma, we had the highest retrieval rate (84%) which has been published so far.

PE often develops shortly after trauma. Schultz and coworkers found a 24% incidence of asymptomatic PE using contrast-enhanced helical CT scanning between 3 and 7 days after trauma [9]. A recent retrospective analysis of a mixed trauma population of 25,658 patients revealed an overall PE incidence of

0.6% with 54.1% of all PE occurring within 7 days after trauma [10]. Owings et al. demonstrated that 6% of all PE in the trauma setting occurred on day 1 following injury [8].

VCF placement was performed within 1 day after trauma in the majority of our patients (71%). We did not perform VCF placement under real-time intravascular ultrasound (IVUS) guidance at the intensive care unit bedside as described in the literature [29]. By applying this technique delay in filter placement may be further decreased.

No symptomatic PE was detected between trauma and VCF retrieval. Potential preretrieval cavography revealed partial filter thrombosis in 9 out of 28 patients (32%). Whether this was caused by highly effective vena cava filtration trapping even small emboli or by a possibly increased thrombogenicity of the filter itself with in situ thrombus formation on the filter structure remains unclear [27, 30]. Optimal duration of vena caval filtration in the trauma population is an issue of debate. We observed symptomatic PE in one patient 18 days after trauma and 5 days after VCF retrieval despite standard prophylaxis with LMWH. Follow-up inferior cavography before filter retrieval was normal and the patient presented no signs of DVT. Our study is definitively underpowered for a complication in this range to draw any conclusions in this respect. However, this observation raises the issue of optimal timing for safe filter retrieval [10]. Furthermore, the maximum indwelling time after which the OptEase filter can safely be retrieved has not been determined yet. Safe retrieval up to 48 days after implantation was reported in the literature [28]. Another consideration is the initiation of pharmacologic VTE prophylaxis in relation to planned filter retrieval. Again, no conclusive data are available in the literature.

In summary, current VTE prophylaxis in trauma and particular in severely injured patients with significant head trauma raises more questions than providing answers to date. Further extensive research is necessary to validate potential benefits and complications of different VTE prophylaxis modalities in trauma patients. With the efficacy of preventing fatal PE established, early placement of optional VCF should be considered in high-risk patients in the presence of potential bleeding complications when pharmacologic VTE prophylaxis is contraindicated. Filter retrieval is feasible and safe. The optimal duration of temporary vena cava filtration remains yet to be determined.

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