Practice Patterns and Outcomes of Retrievable Vena Cava Filters in Trauma Patients: An AAST Multicenter Study

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Background: **The purpose of this study is to describe practice patterns and outcomes of posttraumatic retrievable inferior vena caval filters (R-IVCF).**

Methods: **A retrospective review of R-IVCFs placed during 2004 at 21 participating centers with follow up to July 1, 2005 was performed. Primary outcomes included major complications (migration, pulmonary embolism [PE], and symptomatic caval occlusion) and reasons for failure to retrieve.**

Results: **Of 446 patients (69% male, 92% blunt trauma) receiving R-IVCFs, 76% for prophylactic indications and 79% were placed by interventional radiology. Excluding 33 deaths, 152 were Gunter-Tulip (G-T), 224 Recovery (R), and 37 Optease (Opt). Placement occurred 6 ± 8 days after admission and retrieval at 50 ± 61 days. Follow up after discharge (5.7 ± 4.3 months) was reported in 51%. Only 22% of R-IVCFs were retrieved. Of 115 patients in whom retrieval was attempted, retrieval failed as a result of technical issues in 15 patients (10% of G-T, 14% of R, 27% of Opt) and because of significant residual thrombus within the filter in 10 patients (6% of G-T, 4% of R, 46% Opt). The primary reason R-IVCFs were not removed was because of loss to follow up (31%), which was sixfold higher (6% to 44%, $p = 0.001$) when the service placing the R-IVCF was not directly responsible for follow up. Complications did not correlate with mechanism, injury severity, service placing the R-IVCF, trauma volume, use of anticoagulation, age, or sex. Three cases of migration were recorded (all among R, 1.3%), two breakthrough PE (G-T 0.6% and R 0.4%) and six symptomatic caval occlusions (G-T 0, R 1%, Opt 11%) ($p < 0.05$ Opt versus both G-T and R).**

Conclusion: **Most R-IVCFs are not retrieved. The service placing the R-IVCF should be responsible for follow up. The Optease was associated with the greatest incidence of residual thrombus and symptomatic caval occlusion. The practice patterns of R-IVCF placement and retrieval should be re-examined.**

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Pulmonary embolism (PE) has been described as the third most common cause of death in patients who survive the initial 24-hour period after trauma.[1,2] The combination of stasis, hypercoagulable state as a consequence of systemic inflammation, and/or vascular injury leads to an incidence of deep venous thrombosis (DVT) as high as 27% in patients who do receive some form of prophylaxis and 58% in those who do not, depending upon the technique used to screen patients.[3,4] Certain patients are not candidates for "adequate" prophylaxis and others are not

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candidates for therapeutic anticoagulation if DVT is documented. These patients may be candidates for inferior vena cava filter placement according to current practice guidelines.[5] The risk of DVT and PE in the trauma population is usually limited and the time of risk relatively well defined, hence the use of permanent inferior vena cava filters (P-IVCFs) is unappealing because of associated long-term complications (such a caval occlusion, recurrent DVT, filter migration, perforation, etc).[6,7] Retrievable inferior vena cava filters (R-IVCFs) presumably offer protection from PE during the posttraumatic period of greatest risk, whereas subsequent retrieval is hoped to eliminate the chance of long-term complications. These presumptions stimulated a marked increase in placement of R-IVCFs, based on three assumptions: (1) R-IVCFs are as effective as P-IVCFs in preventing PE, (2) R-IVCFs are in fact retrieved, and (3) the long-term stability of R-IVCFs, if left in situ, are at least equivalent to P-IVCFs.[8–10] The objective of this study is to (1) assess the utilization and procedures of different trauma centers placing filters, (2) estimate the incidence of R-IVCF removal, (3) evaluate the reasons of nonretrieval, and (4) identify differences between P- and R-IVCFs.

PATIENTS AND METHODS

This was a multicenter study coordinated through the American Association for the Surgery of Trauma. Patients who were admitted between January 1, 2005 and December 31, 2005 to the participating centers and underwent placement of a P-IVCF or R-IVCF and follow up, where possible, recorded up to July 1, 2006. Data collected is summarized in the Appendix. Indications were considered prophylactic if there was no indication of DVT or PE before placement, and contraindications to prophylactic or therapeutic anticoagulation were listed. Major complications were defined as recurrent PE, filter migration and symptomatic caval occlusion. Filter migration was defined as a tilt greater than 15 degrees or frank migration proximally, and symptomatic caval occlusion was defined as clinical evidence of venous hypertension coupled with sonographic and/or venographic confirmation. Hospitals were arbitrarily defined as high volume if admitting more than 2,000 trauma patients during the study year and low volume if less.

Results are expressed as means ± SD. Univariate was performed using the χ^2 test for categorical data. The independent pairs *t* test was used for continuous variables. Statistical significance was taken to be $p \leq 0.05$. All statistical analyses were performed with SSPS 15.0 (SPSS Inc., Chicago, IL).

Individual participating centers each obtained permission from their respective institutional review boards.

RESULTS

Overview

During the study period, 599 patients underwent placement of an IVC filter at 21 participating centers. All but one were classified as Level I trauma centers. Of these, 412 (69%) were men, 550 (92%) were prophylactic, and 51 (8.5%) died. All but three (isolated upper extremity fractures) appeared to follow established guidelines for placement of IVCFs.[5,11,12] In 17 instances, patients underwent IVCF placement after development of DVT (11) or PE (6) while on prophylactic anticoagulation, and it was thought that they could not tolerate therapeutic anticoagulation. The mechanism was blunt in 92%, and gunshot wound(s) in the remainder. Patients who had filters placed for prophylactic indications differed from their counterparts who underwent filter placement for therapeutic indications only in that there was a markedly higher incidence of pelvic and long-bone fractures (Table 1). Follow up after discharge was documented in 271 (45%) patients. A total of 226 filters were placed among the 27,382 patients admitted to one of seven high-volume hospitals (0.8%), whereas 373 of 17,662 (2%) patients admitted to one of 14 low-volume institutions underwent filter placement ($p = 0.009$). Three institutions had specific protocols in place that required the service placing the filter to follow the patient and coordinate retrieval after consultation with the admitting service (if different). Ten institutions required the trauma service, either through clinic follow up or nurse coordinators, to track patients and be responsible for arranging filter retrieval. Eight institutions had no protocols for follow up and possible retrieval.

Table 1 Patients Characteristics

	Prophylactic	Therapeutic
n	441	158
Closed head injury	50%	45%
Spine injury	48%	29%
Abdominal injury		
Nonoperative	16%	13%
Operative	16%	16%
Retroperitoneal bleed	12%	9%
Pelvic fracture	44%	32%*
Long-bone fracture	53%	37%*

* $p = 0.001$.

Retrievable Filters

In all, 446 received R-IVCFs (79% of the whole). The population included 69% men, 92% after blunt trauma, and indications were for prophylaxis in 75% of cases. Age was 39.8 ± 17.1 years and Injury Severity Scale (ISS) score was 25.3 ± 12.9.

Excluding 33 (7%) deaths, 152 were Gunter-Tulip (G-T), 224 Recovery (R), and 37 Optease (Opt). The remainder of the discussion in this section includes only those patients (n = 413) who underwent placement of R-IVCF and survived the acute hospitalization. Of these, 310 (75%) were placed for prophylactic indications.

Overall technical features of the procedures are listed in Table 2. The majority were placed in the angiography suite by interventional radiologists. Placement occurred 6 ± 8 days after admission and retrieval was attempted at 50 ± 61 days

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Table 2 Technical Aspects of Retrievable Filter Placement

Aspect	n
Where filter was placed	
Angio suite	337
Operating room	60
Intensive care unit	16
Service placing filter	
Interventional radiology	328
Trauma	34
Vascular/cardiothoracic	51
Access route	
Femoral	374
Internal jugular	39

Table 3 Outcomes of Attempts to Retrieve Filters

	G-T	R	Opt
Attempts made	54	50	11
Technically unable	5 (10%)	7 (14%)	3 (27%)
Residual thrombus	3 (6%)	2 (4%)	5 (46%)

The overall failure to retrieve the Opt (72%) was significantly greater than R and G-T combined (16%, $p = 0.01$).

in 116 (28%) cases. This was not technically possible in 25 (22%) cases either becuaes of technical inability or documentation of residual thrombus in the IVC or trapped in the filters (Table 3). The combined failure rate as a result of technical or persistent thrombi was greater among Optease filters (Table 3). In one case, not listed in the table, a patient who underwent successful retrieval of a Gunther-Tulip filter experienced a minor PE. This patient was noted to have thrombus trapped in the filter but it was small enough to be removed with the filter. The patient was managed with anticoagulation for a short period of time and survived. Thus only 90 (22%) R-IVCFs were actually retrieved, and the technical issues described were the reason in only 6% of instances where a filter was not retrieved.

Intriguingly, retrieval was attempted in 39/103 cases in which R-IVCF was placed for therapeutic indications, and successful in 33 (32%) as opposed to 76 cases in which the indications was prophylaxis, of which 57 (18%) were actually retrieved ($p = 0.003$).

The most common reason R-IVCFs were left in place was a result of loss to follow up, which occurred in 126 (31%) cases overall. In institutions where the service placing the filter had the primary responsibility for follow up, failure to retrieve the filter because of loss to follow up occurred in only 4 of 65 (6%) patients; in institutions which did not have this policy, this occurred in 122 of 273 (45%) of patients ($p = 0.001$).

The second most common reason for nonretrieval was because of total or relative immobility that suggested an increased risk of DVT/PE. This occurred in 124 (30%) patients, and predominantly among those who had sustained vertebral fractures: 50 of 78 (64%) with vertebral fractures versus 74 of 244 (30%) without ($p = 0.001$).

Table 4 Major Complications in Patients Who Underwent Placement of a Retrievable Filter

Complication	G-T (n = 152)	R (n = 224)	Opt (n = 37)
Migration	0	3 (1.3%)	0
Breakthrough PE	1 (0.6%)	1 (0.4%)	0
Symptomatic caval occlusion	0	2 (1%)	4 (11%)*

Of the migration cases, two included tilt >15 degrees, one a proximal migration to the suprarenal level.

* $p < 0.05$ vs. both G-T and R.

The primary reasons for nonretrieval among the remaining 48 cases included risk of DVT (12), residual DVT and inability to anticoagulate (11), patient discharged and despite notification failed to follow up (11), need for multiple other operations (6), patient refusal (3), and miscellaneous (5).

The length of stay of survivors was 28.2 ± 26.3 days and only 211 (51%) patients who underwent placement of a R-IVCF (regardless of whether retrieved or not) and survived had follow up after discharge (5.7 ± 4.3 months). Major complications are listed in Table 4. Complications did not correlate with mechanism, indication for filter placement, ISS score, service placing the filter, site of filter placement, route of access, trauma volume, anticoagulation use, age, or sex. Six patients developed symptomatic caval occlusion (Table 4). This occurred in four patients who were treated with an Optease filter and two with a Bard-Recovery. Of these, one of each occurred in patients undergoing R-IVCF placement for therapeutic indications. The incidence of symptomatic caval occlusion overall was significantly greater among patients receiving the Optease filter (Table 4). Among patients undergoing R-IVCF for prophylactic indications, the incidence of caval occlusion was greater with patients receiving the Optease: 3 of 24 (12.5%) Opt versus 1 of 117 (0.56%) R versus 0 G-T ($p = 0.001$ versus R and G-T).

Screening and Duplex Follow Up

In general, but certainly not uniformly, screening of high-risk patients, particularly those with spinal cord and/or major pelvic/lower extremity orthopedic injuries, is thought to improve detection of DVT and reduce the risk of PE.[13–17] Six institutions had formal protocols to screen for DVT with lower-extremity duplex in patients considered high risk. A total of 17,791 patients were admitted to these institutions. There was no difference in the overall rate of filter placement (approximately 1% for both). However, taking all comers, the overall incidence of PE before filter placement was slightly lower at those institutions who had screening protocols (0.14% with screening versus 0.22% without). In addition, 85% of filters placed at centers with screening protocols were R-IVCFs versus 68% at those without screening protocols ($p = 0.001$).

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Follow-up duplex was more likely to be performed at centers with existing screening protocols than those without: 73 of 175 (42%) with screening protocol versus 63 of 238 (26%) without ($p = 0.001$).

A subset analysis was performed of the 310 patients who had undergone R-IVCF placement for prophylactic indications, which included at least one of the following: lower-extremity fracture (123); closed head injury (113); pelvic fracture (108); need for spine operation (88); upper-extremity fracture (35); and solid organ abdominal injury (33). Ninety-five (31%) had at least one lower-extremity venous duplex study performed after placement (45.6 ± 53.2 days). Of these patients who had a documented follow-up lower-extremity venous duplex, 18 (20%) were found to have a new DVT: infrapopliteal in 8, suprapopliteal in 8, and ileofemoral in 2. These latter two cases were at the insertion site, and at further duplex one had resolved. The incidence of new DVT correlated with ISS score (33.6 ± 14.8 with DVT versus 26.3 ± 11.2 without, $p = 0.03$) and closed head injury (12/40 [30%] with versus 6/55 [11%] without; $p = 0.03$). There was no correlation with the use of anticoagulation after filter placement (2/14 [14%] with versus 16/81 [20%] without; $p = 0.5$). This data needs to be interpreted with caution, as the data does not indicate specifically when anticoagulation was started, rather what type, and if before and/or after filter placement. Of the 103 patients who underwent R-IVCF placement for therapeutic indications, 41 (40%) had at least one follow-up duplex. Twenty-two had no DVT and eight of these underwent filter retrieval.

Of note, 2 (6%) of 33 patients who had undergone R-IVCF for therapeutic indications and subsequently successful retrieval suffered nonfatal PE. Neither patient had undergone repeat lower-extremity duplex exams after filter placement or before retrieval.

Impact of Hospital Volume

High-volume hospitals had a lower incidence overall of filter placement (0.9% ± 0.5% of admissions) compared with low volume centers (2.1% ± 1.0%, $p = 0.009$). No significant differences were noted in age or ISS score between centers. In terms specifically of patients who underwent R-IVCF placement and who survived to discharge, high-volume centers tended to place the filters sooner, less often for prophylactic indications, and were more likely to achieve removal (Table 5).

Permanent Versus Retrievable Filters

In all, 172 P-IVCFs were placed during the same period. Nearly all were placed at 8 of the participating institutions where at least 20% of filters were permanent. These included the following: Greenfield (59); Trapease (46); Venatech (23); Nitinol (14); Bard nonrecovery (7); and Bird's Nest (4). Interventional radiology were more likely to utilize R-IVCFs (82%) versus other specialities (55%, $p = 0.001$). When analyzing the outcomes of these eight centers, compared with R-IVCFs, P-IVCFs were more likely to be placed for therapeutic indications (33% versus 25%, $p = 0.04$) and by surgeons rather than interventional radiologists (45% versus 28%, $p = 0.001$). In these centers the one significant differences between P- and R-IVCF patients was age (P-IVCF 49.4 ± 20 years versus R- IVCF 29.8 ± 18 years, $p = 0.0001$). There were no differences based on whether the indication for filter placement was prophylactic or therapeutic. Eighteen patients who received P-IVCFs died before discharge. No procedural complications or major complications were recorded, although only 41% of survivors had any follow-up, and the duration of follow up (3.5 ± 4 months) was significantly less than that of R-IVCFs.

Table 5 Retrievable Filters: Impact of Hospital Volume

	High Volume	Low Volume	*p* Value
n	148	265	
Days after admission placed	7.9 ± 10.6	5.2 ± 6.6	0.002
Prophylactic indications	100 (67%)	210 (79%)	0.009
PE prior to placement*	28 (19%)	18 (7%)	0.001
Successful retrieval	50 (34%)	40 (15%)	0.001
Technically unable to retrieve	6/56 (11%)	9/49 (18%)	NS
Major complications	4 (3%)	7 (3%)	NS

* A total of 27,382 patients were admitted to high-volume centers, 17,662 to low-volume centers. Thus the reported incidence of PE prior to placement for both was 0.1% (recognizing that this does not take into account patients who had a PE but did not undergo filter placement).

DISCUSSION

Pulmonary embolism remains a constant threat to both the well being of trauma patients as well as to the peace of mind of their caregivers.[1,2,18] The pathophysiology of DVT and PE in trauma patients has been well described elsewhere. In general, DVT is thought to represent a local manifestation of the systemic inflammatory response, coupled with local venous stasis.[2,4] The reported incidence of PE varies. Although it is reported as high as 24% when routine screening of asymptomatic patients is performed, the rate of clinically detectable PE is usually reported as 0.1% to 0.2%.[9,11,19,20] Because of the concern for PE, it is accepted that certain patients at high risk for DVT who cannot undergo adequate prophylaxis are candidates for prophylactic vena cava filter placement.[5] Patients who have a documented DVT (particularly those involving the popliteal or more proximal veins) and/or PE who cannot receive therapeutic anticoagulation are acceptable candidates for therapeutic filter placement. It should be noted that, although it is generally accepted that filters reduce the risk of PE overall and fatal PE specifically, this has not been consistently proven, particularly when used for prophylactic indications.[9,21–25]

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In the prophylactic setting, there has been a reluctance to place permanent filters because of the concern of long-term complications, particularly in younger patients. These complications have included a reported increased risk of DVT, symptomatic caval occlusion, erosion, infection, and breakthrough PE.[21,24,26] The perception that R-IVCFs have reduced complications because of the ability to retrieve them has led to a marked increase in the use of filters, particularly for prophylactic indications.[8,9,27] Filters can in fact be placed at the bedside, using a variety of ultrasound techniques to localize the renal veins, thereby obviating the need to transport a potentially unstable patient to the angiography suite.[28,29] However, attempted retrieval is made in as few as one-quarter of patients, and technical issues (residual thrombus, angulation, in-growth) prevent retrieval in 10% to 25% of cases when attempts are made.[8,9,30,31] The assumption that filters that are designed to be retrievable have the same durability as those designed to be permanent has not been proven.

The actual incidence of complications varies, depending on indications for filter placement, type of filter used and follow up. We noted a complication rate of 2.6%, but with very limited follow up. Greenfield and associates described outcomes using the Greenfield filter in trauma patients with approximately 2-year follow up. They noted that the incidence of symptomatic lower extremity edema and recurrent PE was 25% and 1.5% among patients who received a filter prophylactically, and 43% and 2% for those who had a filter placed for therapeutic indications.[18] Major complications after R-IVCF placement are reported to be approximately 2.5%.[9] Rogers and associates reported on a series of 132 trauma patients who underwent R-IVCF placement for prophylaxis with up to 5-year follow up.[32] They found an incidence of insertion site DVT of 3% (all resolved), filter tilt 5.5%, strut malposition of 38%, IVC thrombosis at 3 years of 3%, and 3 cases (2%) of PE (one fatal). These PEs occurred in patients with either tilt or strut malposition.[32]

The reason for these complications (caval thrombosis, postphlebitic syndrome, new DVT, recurrent PE) is multifactorial. Whether or not simply placing a filter puts a patient at increased risk of new DVT, or whether this is a reflection of the systemic inflammatory milieu associated with trauma, is not clear.[26,33,34] Certainly, the local trauma at the insertion site can act as a nidus for new thrombosis, although this appears to usually resolve over time.[24,32] Duperier and colleagues, in a study of prophylactic filter placement in trauma patients, noted a de novo incidence of DVT of 26%.[35] Decousus and associates, in a multicenter study of a variety of patients including trauma patients, compared patients with DVT who underwent either anticoagulation alone or filter placement without anticoagulation. At 2 years, the incidence of recurrent DVT in patients treated with anticoagulation alone was 11.6%, and in those treated with a filter without anticoagulation 20.8% ($p = 0.02$). They argued that patients who underwent filter placement for therapeutic indications should be placed on prophylactic anticoagulation as soon as feasible to reduce the risk of new DVT.[24] This was in contrast to a later review by Greenfield and Proctor of nearly 1,200 patients with a mean follow up of 9 years who underwent filter placement in the setting of documented DVT. They did not note a significant difference in the incidence of new DVT nor PE or caval occlusion between those given anticoagulants and those not. They suggested that anticoagulants should be employed with the intention to treat the existing thrombus rather than simply because a filter was in place.[33] Breakthrough PE may occur as a result of atypical sources of thrombus or anatomy, including upper-extremity thrombus.[21] In addition, filter migration (including tilt $>14°$) prevents the filter from reliably trapping thrombus. If this is recognized, filter replacement or addition of a second filter should be considered.[32] Finally, major clot burden in the filter itself may serve as a nidus for PE.[21] It should be noted that one reason for filter displacement is inadvertent trapping of a wire during central line placement or exchange.[36] Strut fracture has also been reported over time. Greenfield noted an incidence of 0.05% during several years follow up.[37] Reviewing all filters placed for all indications, Kinney described a late incidence of 1%. Specific data regarding R-IVCFs is lacking. Of note, the Bard-Recovery has been recently "modified" because of concerns about strut fracture and migration.

Frank caval thrombosis has been documented in 0% to 28% of all patients who undergo filter placement.[38] It is probable that caval occlusion is primarily a result of the effect of thrombus trapped in the filter rather than the filter itself. Filters that are hexagonal rather than conical (Trapease, Optease) may be more effective in trapping small thrombi, but have been demonstrated to have a higher propensity to caval thrombosis. This appears to be related to two mechanisms. Thrombus trapped in the apex is exposed to large shear forces, which should aid lysis. However, downstream of the thrombus, an area of stagnation is created as the shear forces are directed laterally against the caval wall.[39] Thrombus trapped in the inferior portion of the basket results in shear stress being directed against the contralateral wall, whereas an area of stagnation extends along the ipsilateral wall.[39]

Technical failures to retrieve filters have been attributed to tilt, detection of significant residual thrombus, and, in the case of the Optease, neointimal hyperplasia of the caval wall, which experimentally appears to occur after 2 weeks.[8,21,34,40,41]

We found a wide variety of practices among the participating centers. Low-volume centers had perhaps a lower threshold for placing filters, and only six centers recorded formal screening protocols. Overall, there was a marked preponderance toward utilizing R-IVCFs, particularly among interventional radiologists. This latter trend could reflect bias among the radiologists or the referring service, which in our experience tended to "demand" R-IVCFs whether indicated or not. The majority of patients had a filter placed for prophylactic indications and therefore were theoretical candi-

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dates for removal. But nearly 80% of R-IVCFs were not retrieved. The top reason was lack of follow up, a common problem in the trauma population. However, it was significant that the rate of "loss to follow up" was increased sixfold when the service placing the filter was not responsible for follow up. The second most common reason was lack of ambulation, most commonly in patients with spine injuries (with or without neurologic deficits). Many of these may have been predictable at the time of placement. These findings suggest that there is a misconception that R-IVCFs, when left in permanently, are benign compared with experience with P-IVCFs. The overall incidence of major complications among patients receiving a R-IVCF was 2.6% among survivors. This is low, but may not reflect the true incidence of complications given the paucity of follow up. It is hard to compare these outcomes with the P-IVCFs that were placed, as these had even less follow up, but certainly there is no evidence to suggest that R-IVCFs, when left in situ, are "better" than P-IVCFs. This does emphasize that the primary reason for using R-IVCFs is that they are intended to be retrieved. If either the system is not designed to optimize follow up, or if it is certain that based on the clinical scenario it will never be retrieved, it may be wiser to utilize P-IVCFs.

One concern that is beginning to be voiced is the risk of PE after filter removal. The incidence was 3% among patients who were followed up; significantly neither of these two patients had a duplex venous study before removal. Thus it is impossible to state whether this represents a de novo event or not. Considering the one-third of patients who underwent prophylactic placement of an R-IVCF and who did have a follow-up duplex study, 20% were documented to have a new DVT. This emphasizes the importance of screening patients before filter removal, which was not done in the majority of cases in our study. Whether or not this would prevent filter retrieval depends upon the comfort level of the team, the need and ability to anticoagulate, and the level of the lower-extremity thrombus. Our data collection tool was not designed to specifically answer whether or not the filter itself predisposes to new DVT formation. However, there was a suggestion that overall injury severity and presence of head injury indicated an increased risk. Furthermore, there did not appear to be a correlation with absence of anticoagulation.

In terms of the specific R-IVCFs, the Optease was associated with the greatest incidence of caval thrombosis, technical inability to retrieve and persistent large thrombus trapped in the device. The possible mechanisms for this have been discussed earlier, but it suggests that if the Optease is the preferred device for a particular institution, great attention should be given to removing or repositioning it earlier rather than later. Based on experimental data, this should be done within two weeks. The Recovery had a higher rate of migration than the Gunther-Tulip, although the numbers are too small to find significance. However recently the Recovery has been withdrawn and re-designed specifically because of concerns regarding its durability as a permanent filter.

In summary, there was a relatively wide pattern of practice in terms of screening for DVT, indications for R-IVCFs, utilization of follow-up lower-extremity duplex, and pattern of retrieval among the participating centers. In fact, nearly 80% of R-IVCFs were not retrieved. The primary reason for failure to retrieve was loss to follow up, followed closely by limited mobility. There was no clearly defined benefit between R- and P-IVCFs, although the follow-up was too short to be definitive. Finally, among the R-IVCFs, the Optease was associated with the greatest incidence of symptomatic caval occlusion and technical inability to retrieve.

This review suffers from two key deficiencies. The first is the documented lack of follow up. It is likely that the complication rates are higher than we have reported. Secondly, the study was not designed to detect the true denominator, including the incidence of DVT/PE in patients who did not under go IVCF placement. Thus we cannot truly argue the relative merits, for example, of routine duplex screening versus prophylactic IVF placement, although there have been strong arguments that favor such screening in the trauma population.[42] Given the general paucity of class I evidence regarding the efficacy and risk/benefit ratio regarding the use of IVCFs in general and prophylactic IVCFs in particular, as difficult as it is we hope that there will be renewed enthusiasm for a multicenter, multiyear prospective study powered to analyze not only outcomes from filters, but the role of screening, follow up, and anticoagulation practices in the trauma population.

We were able to make some observations and recommendations based on the data, however. We could demonstrate that the optimal practice to maximize retrieval is to ensure that the service placing the filter is responsible for follow up. This should be done in conjunction with the primary service (if different). Secondly, we recommend that patients undergo duplex screening of the lower extremities before retrieval. Thirdly, while it may be optimal to start some level of anticoagulation as soon as possible after filter placement, this can be dictated more by the patients overall condition and stability, rather than simply because they have had a filter placed. This appears to be of particular importance in patients with head injuries. When utilizing the Optease, particular attention should be paid to early repositioning or retrieval.

Appendix A
Patient Demographics

- Age
- Gender
- Mechanism
- Injury Severity Score
- Injuries
- Chest AIS
- Operative procedures
- Length of Stay
- Outcome

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System Data

- Level of Trauma Center
- Trauma admissions total
- Screening system in place for DVT?
- Follow-up plan for filters
- Last duplex results

Indications for Filter

- Prophylactic: No evidence of PE or DVT, list contraindications to anticoagulation
- Therapeutic: Documented PE and/or DVT but unable to anticoagulate, unable to therapeutically anticoagulate, event occurred while on therapeutic anticoagulation

Filter Type and Make

Permanent

- Bird's Nest (Cook, Bloomington, IN)
- Nitinol (Bard, Covington, GA)
- TrapEase (Cordis, Europa N.V., L.J. Roden, the Netherlands)
- VenaTech (B. Braun, Boulogne, France)
- Greenfield (BostonScientifific/Meditech, Boston, MA)
- Bard nonrecovery (Bard Peripheral Vascular, Tempe, AZ)

Retrievable

- Gunter-Tulip (Cook, Bloomington, IN)
- Recovery (Bard Peripheral Vascular, Tempe, AZ)
- Optease (Cordis Endovascular, Miami Lakes, FL)

Technical Data

- Days after admission placed
- Days after placement retrieval attempted
- Reasons for nonremoval of retrievable filter
- Procedural complications
- Filter migration
- Location of filter
- Route of placement
- Service placing filter
- Site of procedure

Follow-up Data

- Last duplex results and timing of duplex
- Last clinical follow up (months) after discharge

Evidence of PE, Symptomatic Caval Occlusion, Migration

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DISCUSSION

Dr. Steven R. Shackford (Burlington, Vermont): The authors should be commended for profiling the practice patterns and complications of retrievable vena cava filters in a trauma population. They appropriately note the increase in the use of vena cava filters, the majority of which were placed for prophylaxis of pulmonary embolism.

This is similar to the findings of some work that Fred Rogers and I have done, which will soon be published in the *Journal of Trauma,* analyzing the National Trauma Data Bank, in which 72% of all filters placed between 1991 and 2002 were for extended uses or prophylaxis of pulmonary embolism in patients felt to be at high risk.

I have four questions for the authors. You noted the presence of associated injuries, which some people feel are indications for prophylactic filters, such as multiple long-bone fractures. You also note that many of the centers did not have an established protocol for placing the filters. Did any of the centers adhere to either the Eastern Association for the Surgery of Trauma (EAST) guidelines for the extended uses of vena cava filters, or apply Peggy Knudson's criteria for the placement of prophylactic filters that were published in the *Annals of Surgery* in 2004?

Number 2, in the Methods section, you note that eligibility for patient entry into the study was a "minimum of 6 months to follow up". However, as I read the manuscript, less than 50% of the patients—and I guess you could put 51%—51% of the patients had any follow-up at all, and only one-third had imaging. Since morbidity rates are directly proportional to the vigor with which complications are pursued, would you not agree that your finding of a 2.6% major-complication rate is an underestimate of the true morbidity? In fact, in a recent article appearing in the *Journal of Vascular Surgery*, in which 100% of the patients receiving retrievable vena cava filters had follow-up, the major complication rate was 27%, approximately 10-fold, which you have noted. I might point out that one of the most common complications was filter migration and filter tilt, which makes them ineffective.

Number 3, all of the literature for the use of prophylactic vena cava filters is retrospective, or prospective with historical control certainly less than Class I evidence. Is it not time for a prospective, randomized clinical trial to test the efficacy and safety of vena cava filters? This certainly could be done under the auspices of the American Association for the Surgery of Trauma (AAST) Multicenter Trials Committee, with George Velmahos as chair, and I know George has a particular interest in this subject.

Finally, based on your findings of the very low rate of retrieval of these "retrievable" vena cava filters, is it not time to rename them as "occasionally retrievable" vena cava filters, or in the case of our colleagues in interventional radiology, "rarely retrievable" vena cava filters?

Dr. Riyad Karmy-Jones (Seattle, Washington): Question 1: Most of the patients appeared to follow the guidelines according to EAST and/or Peggy's guidelines. There were three patients that were kind of way out there, and I don't know why they had filter placements. The follow-up protocols that they had were simply for screening, or following up the patients. Many centers didn't have any protocols for that.

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On the complications, I absolutely agree with you. It's clearly understated. I think the paper you referred to included a mixed batch of patients, who were also oncology patients. Clearly, the risks are probably higher, but perhaps they're not as high as in other extreme populations. It adds importance to thoughtful use of these filters.

I agree that a prospective study is warranted. George has been trying to stimulate me and has actually, as you know, stimulated a prospective study that's been stuttering along, and hopefully, this meeting will add importance to that.

Finally, if copyright infringement is not a factor, I could see renaming this paper based on your fourth comments.

Dr. Kenneth A. Kudsk (Madison, Wisconsin): We've placed about 60 filters on the trauma service in our institution. They're all placed by the trauma surgeons, and trauma surgeons remove them all. We've only used one type, the Recovery filter, and have had good luck with it. I have a few questions for you.

What are the criteria that you use for removal? What's the preoperative evaluation? Is it only the duplex? And what do you duplex?

One of the questions I have is the choice of a filter. The Gunther-Tulip is recommended to be either removed within two weeks, or to be moved every two weeks. The only people who put them in at our institution are the radiologists. From a trauma standpoint, that doesn't seem practical because many of these people need them for a longer period than that, particularly the immobilized patient. So what is the rationale for these filters? Can you take these Gunther-Tulip filters out later than 2 weeks?

Dr. Riyad Karmy-Jones: Yes. It's now expanded to at least 6 weeks.

Dr. Kenneth A. Kudsk: It's good data. Well, the longest we've had is 469 days in our series, so that's substantially longer than that. It would be interesting to see what that data is. Can you give us any guidelines as to what the predictors of failure are? With the Recovery filters, you said that whenever there's a 15-degree tilt, that's secondary to migration.

Well, if you really study these, when you initially place them, they can be 15 degrees and an important predictor is whether the head of the filter touches the vena cava. We seem to be able to remove them if that stays touching the vena cava for less than 6 months. After 6 months, we can't remove a single one of them. Do you have any insight into that?

Dr. Riyad Karmy-Jones: First of all, migration is defined as both gross migration as well as significant tilt, greater than 15 degrees, which is associated with, as Steve pointed out, a failure rate. The Recovery has been remodified sort of surreptitiously under U.S. Food and Drug Administration (FDA) guidelines because of the concern of break, fracture, and migration. It was intriguing that the migrations occurred only in the Recovery filters, although it was very low.

At Harborview, we do at least a simple duplex at the time of filter retrieval, as well as a typical vena gram on these patients to determine if there's any thrombus. You can get the filters out if there's extreme tilt. It depends if they're at the renal veins or not. And the Gunther-Tulip can now be removed up to 6 weeks or later. The FDA has allowed it to be expanded to up to six weeks for retrieval.

Dr. Michael J. Sise (San Diego, California): Dr. Karmy-Jones, I appreciated your presentation. Based on our report to the association last year, we have a new recovery program. We call it the "12-Step Recovery Program from Filter Fever." We are very, very concerned about the use of filters and have significantly limited their role in our practice. In whom will you place filters and what are your indications now that you've studied this problem?

Dr. Riyad Karmy-Jones: My indications are patients who have a documented popliteal, deep venous thrombosis or higher, who are at a risk of anticoagulation, which is greater than the risk of putting in a filter; patients who have had a documented pulmonary embolism that cannot be anticoagulated. Our concern is less because at Harborview, we followed all of our patients. We'd call them up. Our concern is less what to do with getting them in than when to get them out. One of our concerns is that if you have a patient who has deep venous thrombosis, and now they get to the state where they can be anticoagulated where the standard of care would not be a filter but anticoagulation, what are the consequences of pulling a filter out?

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