Hypothesis: Prophylactic temporary inferior vena cava (IVC) filters are safe and effective in critically ill patients at high risk for venous thromboembolism.

Design: Prospective cohort study.

Setting: Urban level I trauma center.

Subjects: Multiple-trauma patients and critically ill surgical patients undergoing prophylactic temporary IVC filter placement. All patients were at high risk for venous thromboembolism but had contraindications to low-dose heparin therapy.

Interventions: The interventional radiologist used the femoral or internal jugular approach to place a removable IVC filter in all patients. The filter was removed when the patient could safely be treated with heparin. If the filter could not be removed by 14 days, it was relocated to prevent incorporation precluding retrieval.

Main Outcome Measures: Complications of filter insertion and removal, deep venous thrombosis, and pulmonary embolism.

Results: From May 1, 2001, to October 1, 2002, 44 patients underwent placement of temporary IVC filters. Thirty-seven patients (84%) were severely injured. The mean±SD age was 37±3 years, and 55% were men. The mean±SD Injury Severity Score of the trauma patients was 33±2, and all had blunt injury. There were no complications associated with filter insertion or removal. Nine patients required filter relocation prior to retrieval. Three filters could not be removed: 2 secondary to significant clots trapped below the filter and 1 because of angulation resulting in the inability to grasp the filter. There were no documented instances of venous thromboembolism following IVC filter placement and removal.

Conclusions: Temporary IVC filters are safe and effective in critically ill surgical and trauma patients and allow an aggressive approach to prevention of venous thromboembolism in this challenging group of patients.

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Despite continued improvement in the management of multisystem trauma, venous thromboembolism remains a significant source of morbidity and mortality, leading to prolonged hospitalization and increased cost of care.13 Without prophylactic therapy, the incidence of deep venous thrombosis in high-risk trauma patients is reported to be as high as 35% to 65%.4 Geerts et al4 observed a 58% incidence of lower-extremity deep venous thrombosis, including an 18% incidence of proximal venous thrombosis in patients with an Injury Severity Score greater than 9. The occurrence of pulmonary embolism following trauma is reported to be between 0% and 22%, with mortality estimates ranging from 8% to 35%.4,6 Because clinical diagnosis of venous thromboembolism is difficult and treatment is frequently delayed or inadequate, effective prophylaxis is essential.7,8 The most commonly used prophylactic regimens include mechanical devices, low-dose heparin, and low-molecular-weight heparin. Published studies investigating the effectiveness of these methods, however, report conflicting results.5,9,10 Moreover, many trauma patients have injuries precluding the safe use of anticoagulant prophylaxis or lower-extremity sequential compression devices. The limitations of existing prophylactic regimens have led to enthusiasm for prophylactic insertion of inferior vena cava (IVC) filters in high-risk trauma patients.11-13 Although generally considered safe, IVC filters have been associated with deep venous thrombosis and IVC. 
unproved.21 The purpose of this study was to critically evaluate our experience with the Gunther Tulip (Cook Inc, Bloomington, Ind) retrievable IVC filter for early pulmonary embolism prophylaxis in high-risk, critically ill patients.

PATIENT POPULATION

St Anthony Central Hospital (Denver, Colo) is a busy urban level I trauma center with more than 2000 annual trauma admissions. The trauma service maintains a very aggressive approach to the prevention of venous thromboembolism, usually combining sequential compression devices with low-molecular-weight heparin. Beginning in May 2001, patients at high risk for venous thromboembolism with relative or absolute contraindications to low-dose anticoagulant therapy or barriers to the placement of sequential compression devices underwent prophylactic temporary IVC filter placement. This included patients with major pelvic and/or acetabular fractures with or without associated lower extremity long bone fractures, bilateral lower extremity long bone fractures, spinal cord injury with neurologic deficit, and severe head injury.

FILTER PLACEMENT, MANIPULATION, AND REMOVAL

The Gunther-Tulip IVC filter is manufactured from nonmagnetic metal and consists of 4 legs with small hooks at each end for filter fixation. The 4 legs are arranged as a cone, with 4 additional wires extending from the inferior aspect of the legs to the apex of the cone. At the apex, there is a blunt-tipped hook. The filter is 45 mm in length and 30 mm in maximum diameter.

Filter placement was performed in the interventional radiology suite, using the femoral or internal jugular approach. At the point of insertion, a vena cavaogram was routinely obtained to assess the size and anatomy of the IVC. Unless they were left in place permanently, all filters were manipulated/repositioned or removed within 14 days to prevent filter incorporation precluding removal.

In patients with an initial contraindication to anticoagulation, prophylactic low-molecular-weight heparin therapy was instituted as soon as it was thought safe to do so by the attending physician and relevant consultants. Additionally, adjunctive measures, such as pneumatic compression devices, were used whenever possible.

Filter repositioning and retrieval were again performed in the interventional radiology suite. Typically, the right internal jugular vein was accessed, and a premanipulation or retrieval cavagram was performed to look for trapped emboli within the filter. Significant trapped emboli were considered a contraindication to filter removal.

Patients were followed up clinically for the development of complications until death or discharge. Potential complications of filter placement included filter migration and tilting, vena cava penetration, incomplete deployment, insertion site venous thrombosis, and hematoma. Filter retrieval complications included retrieval failure, embolization of the thrombus, and retrieval site thrombosis and hematoma. Other possible complications included deep venous thrombosis, IVC occlusion, and pulmonary embolism despite filter presence.

Duplex sonography was not performed unless clinically indicated by unilateral leg swelling, calf tenderness, tenderness with passive heel stretch, or suspected pulmonary embolism. Evaluation for pulmonary embolism was performed at the discretion of the attending surgeon and most often consisted of helical computed tomography of the chest. If clinical suspicion warranted, negative chest computed tomography scans were followed by formal pulmonary angiography. Criteria for pulmonary embolism evaluation were varied and included sustained, unexplained hypoxemia, dyspnea, and tachypnea.

STATISTICAL ANALYSIS

All data were stored on an IBM-compatible personal computer using Windows XP and Office XP (Microsoft Inc, Redmond, Wash). Descriptive statistics were performed using SPSS for Windows 11.1 (SPSS Inc, Chicago, Ill). The descriptive nature of this study precluded further statistical analysis. Data are presented as mean±SD.

RESULTS

Between May 1, 2001, and October 1, 2002, 44 retrievable vena cava filters were placed. One patient could not have a filter placed because of a duplicated IVC. Thirty-seven (84%) patients were multiple-trauma patients, and the remaining 7 were critically ill surgical patients. The mean age of the patients was 37±3 years, and 24 (55%) were male. The mean Injury Severity Score of the trauma patients was 33±2. All of these patients had blunt injury. Motor vehicle crashes were the predominant mechanism.

All trauma patients sustained multiple injuries (Table). Traumatic brain injury and complex pelvic fractures were the most common injuries. In 3 patients, traumatic brain injury was the sole indication for prophylactic vena cava filter placement. Two of the 3 patients who had spinal cord injuries had associated long bone fractures.

Filters were placed within 72 hours of admission in 30 (68%) patients. The mean number of days from admission until filter placement was 4±1. Filters were in place an average of 14±1 days (range, 3–30 days) prior to retrieval. Because of continued contraindication to antico-
agulation, 9 patients underwent filter relocation to prolong the duration of filter protection. No patient underwent filter repositioning more than once prior to retrieval. Three filters could not be retrieved: 2 because of significant clots trapped below the filter and 1 because of angulation that prevented grasping of the filter hook. In 4 patients, no attempt to remove the filter was documented.

Remarkably, there were no complications associated with filter insertion or retrieval. In particular, there were no instances of insertion or retrieval site thrombosis, filter migration, vena cava perforation, or occlusion. Moreover, there were no documented pulmonary emboli and no hospital deaths in these patients.

Since their introduction in the 1960s, permanent IVC filters have become widely accepted as the standard mechanical method of preventing pulmonary embolism in patients with contraindications to anticoagulation. The increased risk of venous thromboembolism following severe injury and the relatively poor effectiveness of available prophylactic methods have resulted in increasing enthusiasm for the placement of prophylactic permanent vena cava filters.

Several authors have investigated the safety and efficacy of prophylactic vena cava filters in trauma patients, with inconsistent results. Rosenthal et al observed no pulmonary emboli in 29 high-risk trauma patients treated with prophylactic filter placement. Leach and colleagues reviewed 200 trauma patients who underwent prophylactic filter placement and noted no instances of pulmonary embolism. Rodriguez et al prospectively placed prophylactic vena cava filters in 40 high-risk trauma patients and noted a significant reduction in the frequency of pulmonary embolism as well as in mortality related to pulmonary embolism compared with historical controls. Most recently, Carlin and colleagues documented no pulmonary emboli in patients treated with prophylactic vena cava filters.

Other investigators have experienced less favorable results with prophylactic filter placement. Decousus et al randomized patients with proximal deep venous thrombosis to vena cava filter placement with anticoagulation or anticoagulation alone. The authors demonstrated a reduction in the occurrence of early pulmonary embolism; however, the rate of pulmonary embolism was no different after the discontinuation of anticoagulation. In addition, mortality was no different after 2 years. Moreover, recurrent deep venous thrombosis was significantly greater in patients with vena cava filters. McMurty et al noted an increase in the occurrence of pulmonary embolism when prophylactic filter use was more prevalent.

The preponderance of data, however, suggests that permanent vena cava filters are effective in preventing pulmonary embolism. Whether they are placed prophylactically or therapeutically, however, questions remain regarding their safety. Multiple complications have been reported, including filter migration and fragmentation, vena cava and adjacent organ perforation, and caval occlusion. Decousus et al noted that permanent filters increased the risk of recurrent deep venous thrombosis. Moreover, the authors showed that the protective effect of filters is short-lived. These data not only raise concerns about the long-term safety and efficacy of permanent vena cava filters but also suggest an important role for nonpermanent filters.

Nonpermanent filters can be classified into 2 types: temporary and retrievable. Temporary filters are attached to a catheter or guidewire that protrudes externally. Unfortunately, the design mandates filter removal, increases the risk of infection, and severely limits applicability. Retrieval filters appear to be more versatile because they can be left in place as a permanent filter should the clinical situation require it. The Amplatz filter (Cook Inc) was the first retrievable filter to be described. It was subsequently withdrawn from the market owing to technical problems, in particular, a high rate of vena cava occlusion. The Gunther Tulip filter is a relatively new retrievable filter that has recently been approved in the United States as a permanent filter. A number of reports from Europe and Canada have demonstrated that the Gunther Tulip filter is retrievable up to 14 days after placement, with minimal risk of morbidity. In these reports, only a small number of filters were placed prophylactically, and the patient population in each was predominantly medical rather than surgical or trauma.

Our report documents that the Gunther Tulip filter can safely be used as a temporary vena cava filter in high-risk trauma and surgical patients. In our series of 44 patients, there were no significant complications of filter insertion or removal. Moreover, there were no documented pulmonary emboli in these high-risk patients. We also noted that implantation times of up to 30 days were safe with filter manipulation and repositioning every 14 days.

This preliminary study has several limitations, including a relatively small number of patients, lack of rigorous patient selection criteria, and lack of long-term follow-up data. Regardless, these observations demonstrate the feasibility of prophylactic, retrievable vena cava filters as an aggressive approach to the prevention of venous thromboembolism.

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REFERENCES


DISCUSSION

Gregory J. Jurkovich, MD, Seattle, Wash: To my knowledge, this represents the largest experience with a temporary retrievable IVC filter reported in the United States today. Well, actually, we are in Canada, and the Canadian literature has reported about twice this number in the same sort of format in about 90 patients. But according to Dr Offner, the FDA [Food and Drug Administration] recently approved the use of this device in the United States, and I predict we will see many more variations on this paper, and this one referenced often.

The current report presents data on 44 patients in whom the Gunther Tulip retrievable filter was inserted, of whom 84% were trauma. They report no complications with insertion or retrieval, at least in those that could be retrieved, acknowledging technical failure to removal in 1 patient, or 2%. In a total of 16% of the patients, the filter was never removed. During the period of hospitalization, there were no pulmonary emboli, no filter-related deaths, and no IVC thrombosis was documented, but as Dr Offner acknowledged, the search for this complication was not specifically made. As the authors have appropriately acknowledged, they have shown us that insertion and removal of a temporary IVC is feasible. However, this review is compromised by the lack of any postdischarge information. The authors also fail to present any objective measure of caval or extremity venous thrombosis. Further, they do not describe duplex ultrasound analysis of the jugular vein insertion site, an easy measure that could confirm lack of injury.

Finally, this diverse patient population appears to have been accrued without prior protocol agreement as to indications, and, as such, I wonder if patient consent was obtained when this device was inserted prior to FDA approval.

Many questions, therefore, come to mind, but perhaps the most pressing are the following 2: (1) What patients should receive a temporary removable vena cava filter? (2) Is it worth it? The classic indications for vena cava filter placement are documented pulmonary embolus or proximal DVT [deep venous thrombosis] and either contraindication to full anticoagulation or irreparable major bleeding on full anticoagulation. Of course, vena cava filters have known complications and cost, including migration, perforation, caval occlusion, chronic venous stasis, infection, and occasionally, continued pulmonary embolism.

The attractive, and in fact, in some ways, seductive concept underlying the use of a temporary retrievable filter, is that there are some patients who are at such high risk of pulmonary embolism, even with heparin prophylaxis, as to warrant the expense and possible complications of filter placement without the long-term complications. So perhaps the simple answer to my first question would appear to be that this device or technique is indicated in those patients at high risk for pulmonary embolus who cannot be anticoagulated and in whom this risk is temporary.

But the data necessary to accurately and honestly determine who is this patient and who is at risk and who cannot be anticoagulated and who cannot receive heparin prophylaxis and how long the risk of venous thromboembolic disease remains, is largely absent or at best confusing and often contraindicating. Unfortunately, this paper does not help resolve any of these issues.

Since 1961 when Sevedin Gallagher first reported in the British Journal of Surgery a 65% incidence of DVT and a 16% incidence of PE [pulmonary embolism] in 125 trauma and burn autopsies, there has been an interest in reducing or eliminat-
Weigelt, writing in the care. Nonetheless, we do have some estimates of cost. Brazel and overshadow considerations of cost in most aspects of medical advancements and a seeming conviction of entitlement far I would acknowledge that our society’s fascination with techni- efectively answer the question, is it worth it and does it work?

Again, it begs the question. Is it worth it? Dr Velmahos, in that paper, which Dr Offner also referred, notes that not only were there continued PE’s with the placement of the filter, but there was no difference in overall mortality in those patients simply anticoagulated compared to those anticoagulated and treated with a filter.

There are many other conflicting data on this. He referred George Velmahos’ paper, sponsored by the Agency for Health Care Research and Quality, that reviewed the incidence of DVT filters and prophylaxis, and they acknowledge that vena caval filters can lower the PE rate from 1.5% to 0.2%. Again, it begs the question. Is it worth it? Dr Velmahos, in that paper, also calculated that it would need between 400 and 3000 patients in each arm of a prospectively designed study to ef- actively answer the question, is it worth it and does it work?

To the second question on the cost of the filter replacement, I would acknowledge that our society’s fascination with technical advancements and a seeming conviction of entitlement far overshadow considerations of cost in most aspects of medical care. Nonetheless, we do have some estimates of cost. Brazel and Weigelt, writing in the *Journal of Trauma* in 1997, reported that based on data from their own institution, the combination of bi-weekly duplex scanning, coupled with low-molecular-weight heparin and then insertion of an IVC filter only in those patients who had a proximal DVT and could not be anticoagulated, re- sulted in the cost of $100 000 per patient per PE prevented. That is not per death, that is just for PE prevented.

Dr Greenfield himself has estimated that if a permanent filter was inserted in 1% of the severe trauma patients in the country, societal cost to health care would be $900 million. This seems a bit pricey to me, and I wonder again, is it worth it?

At my own institution at Harborview, we have tried to care- fully track DVT or PE rates in trauma patients over the past 5 years and have instituted a protocol-driven DVT prophylaxis measure, which includes biweekly duplex scanning in certain patients and not adopting prophylactic filter placement. We have between 4500 and 5000 trauma admissions a year, of which about 1200 are severely injured, with ISS greater than 15. We have documented between 18 and 36 pulmonary em- boli per year, with 80% of these patients appropriately receiving prophylaxis. We have had 1 or 2 PE-related deaths per year in this population. This is a 1.5% PE rate in severe trauma pa- tients, and that is similar to that reported by Shacklford (1.7%), Dennis (1%), and Owings (3.5%). Our PE fatality rate is 5% to 10% compared to 17% at Sacramento and the 50% to 70% some- times reported in the literature. So, based on our own data as well as much of the literature, I have a hard time answering the first question, and ask Dr Offner for his thoughts. Who should receive a prophylactic temporary vena caval filter? I think no one. I favor chemical heparin prophylaxis, duplex screen- ing, and placement of a filter for the classic findings of proximal DVT with inability to anticoagulate or occurrence of PE on anticoagulation.

I suspect I have gone over my allotted time and I apolo- gize to the Association for that lapse. So I will close by asking the authors 3 short final questions. What is the incidence of DVT and pulmonary embolism at your institution? What is the fatal rate of pulmonary embolism at your institution? And, how effective are your venous thromboembolic prophylactic tech- niques in preventing these events?

This new technique does hold promise. I thank Dr Offner and the program committee for including it in this year’s meeting, and I expect to see a more widespread use of this attrac- tive device. However, I do hope its availability will stimulate further studies that will help us to better define the appropriate patients and develop a cost-effective strategy for its use.

*Clayton H. Shatney, MD, San Jose, Calif:* You mentioned that you wanted to get those out within 14 days, but if I recall your data correctly, the range was from 3 to 30 days. My question is: in how many patients did you remove it after 14 days, and was there any difficulty? If the answers are fairly high in the first case and none in the second, could one in fact extend the removable window and lengthen the period of po- tential efficacy of the device?

*Dr Offner:* The catheter was repositioned in the 9 pa- tients whose catheter duration was greater than 14 days. This is part of our protocol. The current recommendation for the device is that it be removed or repositioned within 14 days. Some investigators have pushed the envelope and filters have been reported as being left in place for 20 to 30 days without repositioning with successful removal.

I appreciate Dr Jurkovich’s comments in helping to put this paper into its proper perspective and context. He has asked sev- eral questions which are difficult or impossible to answer. We recognize that that objective documentation of complications was lacking, and I am currently working to rectify that shortcom- ing. We now have a registry to facilitate prospectively following these patients with objective criteria for identification of comp- lications. This will likely include routine Duplex screening of high-risk patients. The barrier to that has been cost. We do get consent from patients before placing the filters, and they are in- formed that this is an off-label indication for the filter.

I can’t answer your questions about what is appropriate pa- tient selection. The literature is entirely inconclusive in this re- gard, making it is very difficult to decide which patients are ap- propriate. As a group, we tried to decide on a group of patients that we felt were at high risk, and you saw the criteria that were used, as well as in whom it was not appropriate to use low- molecular-weight heparin or mechanical prophylaxis.

Regarding our institutional incidence of DVT and PE, I wish I could answer that but can’t. That information has not been rigorously tracked at our institution.

This it is a preliminary report and there still remains a lot of work to do to determine what is the appropriate place for these devices in our care of these difficult patients.