

Prophylactic placement of an inferior vena cava filter in high-risk patients undergoing spinal reconstruction

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Object. The purpose of this study was to evaluate the safety and efficacy of prophylactic inferior vena cava (IVC) filter placement in high-risk patients who undergo major spine reconstruction.

Methods. In the pilot study, 22 patients undergoing major spine reconstruction received prophylactic IVC filters. These patients were prospectively followed to evaluate complications related to the filter, the rate of deep venous thrombosis (DVT) formation, and the rate of pulmonary embolism (PE). These data were compared with those obtained in a retrospective review for PE in a matched cohort treated at the same institution. At a second institution the treatment guidelines were implemented in 17 patients undergoing complex spine surgery with the same follow-up criteria.

In the pilot study, no patient experienced PE (0%), whereas two had DVT (9%). Bilateral DVT developed postoperatively in one patient (associated morbidity rate 4.5%), who required thrombolytic therapy. One patient died of unrelated surgical complications. The PE rate in the matched cohort at the same institution was 12%. At the second institution, no patient had PE, and no complications were noted.

Conclusions. In this patient population, prophylactic IVC filter placement appears to decrease the PE rate substantially, from 12 to 0%. The placement of IVC filters appears to be a safe and efficacious intervention for prevention of PE in high-risk patients.

KEY WORDS • vena cava filter • prophylactic blood filter • pulmonary embolus • deep venous thrombosis

Pulmonary embolism is a significant cause of morbidity and mortality after spine surgery. Multiple prophylactic measures have been suggested and include venous compression boots, subcutaneously administered heparin, and early ambulation to prevent DVT. In complex spine surgery, the current practice for postoperative DVT prophylaxis depends primarily on the surgeon and institution. Mechanical prophylaxis alone is often not sufficient, whereas anticoagulation therapy carries a significant risk of bleeding complications.^{10,50} The treatment of PE often involves mandated systemic anticoagulation therapy. Specifically in spine surgery, anticoagulation with heparin may be associated with complications in up to 67% of patients.¹⁰ As an alternative to this treatment, IVC filters have been demonstrated to prevent PE in selected patients who are prone to thromboembolic disorders. Furthermore, the indications have expanded as easier insertion techniques have resulted in lower complication rates.^{31,44,64} In this paper we describe a select group of patients at two in-

stitutions who underwent major spine reconstruction and were considered at high risk for development of a thromboembolic event. The preoperative IVC filter concept was prospectively evaluated at the initial institution, with encouraging results. The treatment guidelines were subsequently implemented at a second institution for further evaluation.

CLINICAL MATERIAL AND METHODS

Study Design

A group of high-risk patients undergoing complex spine surgery was studied prospectively to evaluate the role of prophylactic filters in the IVC. A matched cohort was reviewed retrospectively for the presence of PE. The treatment guidelines were implemented at a second institution for data verification.

The initial study of preoperative IVC filter placement was performed at the senior author's institution. From May 1999 to February 2002, the senior author (S.L.O.) conducted a prospective analysis of 22 patients who underwent prophylactic IVC filter insertion. The risk of a thromboembolic event was calculated for every patient undergoing complex spine surgery and high-risk criteria

Abbreviations used in this paper: AP = anteroposterior; BMI = body mass index; CT = computerized tomography; DVT = deep venous thrombosis; IVC = inferior vena cava; PE = pulmonary embolism.

were identified. Patients were included in the analysis if they met two of the following high-risk criteria: contraindication to anticoagulation therapy; past or concurrent thromboembolism, hypercoagulability, or malignancy; staged operations for multiple segments (> five levels); bedridden for long periods prior to surgery (> 2 weeks); combined anterior and posterior approaches; significant manipulation of abdominal vessels; active smoking; obesity; birth control pills/estrogen replacement therapy; and anesthesia duration estimated at longer than 8 hours (Table 1).

The IVC filters were placed preoperatively in all patients at times ranging from several months before up to the day of surgery, broken down as follows: day of surgery (13 patients); 1 to 4 days preoperatively (six patients); and 2 to 4 months preoperatively (three patients). All patients also received thigh-high compression stockings and intermittent pneumatic compression for DVT prophylaxis postoperatively. Both devices were applied immediately after administration of anesthetic agents and were used until the patient was ambulatory or discharged from the hospital. None of the patients were routinely treated with prophylactic or therapeutic doses of anticoagulating agents throughout their hospital stay.

Patients were prospectively followed for complications related to the IVC filter, rate of DVT formation, and rate of PE. In the inpatient setting, scanning for DVTs included weekly Doppler ultrasonography in all patients until discharge. Patients were also followed clinically on a daily basis for signs and symptoms of DVT and/or PE. Doppler ultrasonography and/or ventilation/perfusion lung scans were used when patients showed signs or symptoms of DVT and/or PE, respectively. Additionally, pulmonary CT angiograms were used for the PE workup. After discharge, patients were followed clinically in the outpatient setting for these same complications. Thereafter, all patients were compared with a matched cohort treated at the same institution to assess the PE and DVT rates by using a retrospective chart review.

Based on the results of the pilot study, investigators (T.R.K., M.K.R., and R.M.) at a second institution implemented the treatment recommendations in a selected group of patients. Between January, 2003, and May, 2004, 17 patients were identified who were at high risk for development of a thromboembolic event, and these pa-

tients underwent preoperative IVC filter placement. All IVC filters were placed immediately before the planned surgery (between 2 days preoperatively and the day of surgery). Based on findings in the pilot study, these patients were only followed clinically for signs and symptoms of DVT and/or PE postoperatively. They were also followed for complications related to filter placement, rate of DVT formation, and rate of PE.

Patient Population and Risk Factors

In the pilot study, the mean patient age was 51.5 years (range 36–80 years), and there were seven men and 15 women (M/F ratio 0.46). Diagnoses included scoliosis (eight patients), severe spinal stenosis (six), fixed sagittal imbalance (five), and spondylolisthesis, multiple-level spine fracture, and osteomyelitis (one each). Seventeen patients (77.3%) underwent a staged operation, and in five (22.7%) only a single surgery was performed. A combined anterior–posterior approach was used in 16 patients (73%), posterior only was used in five (22.5%), and anterior only was used in one patient (4.5%). Four patients underwent three operations, 13 had two procedures, and in five a single operation was performed. In 21 cases (95.4%) an operation involving both the anterior and posterior spinal column was performed, with six patients treated by the combined approach. All patients were non-ambulatory between the staged operations.

Interestingly, in three patients (13.6%) a DVT was documented before surgery, and five (22.7%) had a history of thromboembolic disease (DVT and/or PE). Previous spine surgery was documented in 11 patients (50%). Four patients (18.2%) had preoperative paresis, and 13 (59.1%) experienced limitations in function (confinement to bed or poor ambulation because of motor deficit and/or severe pain). The other five exhibited normal preoperative function. The mean number of vertebrae involved in surgery was 11.4 ± 6 levels (mean \pm standard deviation; range 2–23).

Intraoperative Course

Eleven patients (50%) were considered to have sustained significant manipulation of the abdominal vessels. Perioperative anticoagulation therapy was used in 19 patients (86%); however, none received standard prophylactic doses that would allow them to be considered pharmacologically protected throughout the high-risk perioperative period. Two patients did not receive anticoagulation agents because of excessive blood loss during surgery, and one patient in whom heparin-induced antibodies developed received Lepirudin (recombinant DNA). The mean operating time was 10.9 hours per surgery and 22.4 hours per patient. The estimated blood loss was 2330 ml per surgery and 4553 ml per patient. Twelve patients had a history of smoking, and six continued to smoke in the immediate preoperative period. Obesity was also assessed according to the BMI, as defined by the National Institutes of Health. The BMI averaged 27.5 ± 3.8 kg/m² (mean \pm standard deviation; range 21.9–35.5). Six patients (27.3%) were considered obese (BMI > 30 kg/m²), 10 (45.4%) were overweight (BMI 25–29.9 kg/m²), and six (27.3%) were within normal limits for weight (BMI 18.5–24.9 kg/m²). Eight patients (36.4%)

TABLE 1

*High-risk criteria in patients undergoing spinal reconstruction and prophylactic anticoagulation therapy**

Contraindication to Anticoagulation Therapy
history of or concurrent thromboembolism, hypercoagulability, or malignancy
staged ops for multiple segments (>5 levels)
bedridden for long periods prior to op (>2 wks)
combined ant & pst approaches
significant manipulation of abdominal vessels
smoking
obesity: BMI >30 kg/m ²
birth control pills or estrogen replacement therapy
anesthesia estimated at >8 hrs

* Pst = posterior.

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had a primary malignancy, six had a concurrent malignancy, and two had a history of malignancy. Four had a history of a hematological disorder, and four women were receiving estrogen replacement therapy (Table 1). In total, there were more than two risk factors per patient.

At the second institution, the mean patient age was 66 years (range 56–80 years), and there were five men and 12 women. Four patients (24%) underwent staged operations, whereas 13 (76%) had only one surgery. A combined anterior–posterior approach was used in five patients and a posterior approach only was used in 12. Seventeen operations involved both the anterior and posterior spinal columns. All other guidelines established in the pilot study were followed. Consistent with the pilot study, each patient met at least two of the same high-risk criteria and had undergone surgery of the same type, duration, and complexity as in the earlier study.

ILLUSTRATIVE CASE

This 60-year-old woman presented with significant positive sagittal balance and a failed lumbar fusion performed at another hospital. Neuroimages were obtained on presentation (Fig. 1A). A review of her preoperative evaluation revealed that she met several criteria for prophylactic IVC filter placement (staged surgery, surgery duration > 8 hours, obesity, estrogen replacement therapy, and abdominal vessel manipulation). The patient received an IVC filter preoperatively and underwent staged anterior–posterior T2–iliac fusion with deformity correction (Fig. 1B and C). She recovered without suffering a PE or DVT. Additional neuroimaging provided a closer look at spinal implants in relation to the IVC filter (Fig. 1D–G).

RESULTS

Retrospective Group. In the spine surgery population treated between 1996 and 2002 at the senior author's in-

stitution, a matched cohort of 122 patients was considered at high risk for a thromboembolic event. These patients all met the same high-risk criteria and had undergone surgery of the same type, duration, and complexity. All records were reviewed to estimate the incidence of symptomatic PE in complex spine surgery. A diagnosis of PE was considered if patients had high-probability findings on ventilation/perfusion scanning, positive results on pulmonary angiograms or spiral CT scans of the chest, or if a PE was found on postmortem examination. In this investigation we identified 16 patients who had a symptomatic PE (13.1%), which included two who died of a massive PE (1.6%).

Pilot Prospective Group. In the pilot study there were no pulmonary emboli during an 18-month follow-up period. Given the fact that most pulmonary emboli are not symptomatic, however, the zero rate in reality refers to clinically significant lesions. As for complications, bilateral DVTs developed in one patient with spinal meningiomatosis, who required thrombolytic therapy. This patient had paresis both pre- and postoperatively, and thus this incident cannot be directly attributed to insertion of the filter. In fact, it is more likely the result of a large embolus that had migrated and caused occlusion, and which otherwise might have caused a fatal PE. Of the four patients who presented with a DVT prior to surgery, none suffered PE postoperatively. Fifty-nine days after surgery, and a few days after taking an airline trip, one additional patient suffered a DVT. She was also treated successfully with anticoagulant drugs.

Second Institution. In the 17 patients treated at the second institution, the incidence of symptomatic PE was 0% over a follow-up period of up to 16 months. This again assumes a rate of 0% for clinically significant PE because the true incidence of these lesions may not be assessable based on clinical significance. No death occurred as a result of the filtering itself. No complications were associated with filter insertion, and no patient had a clinically

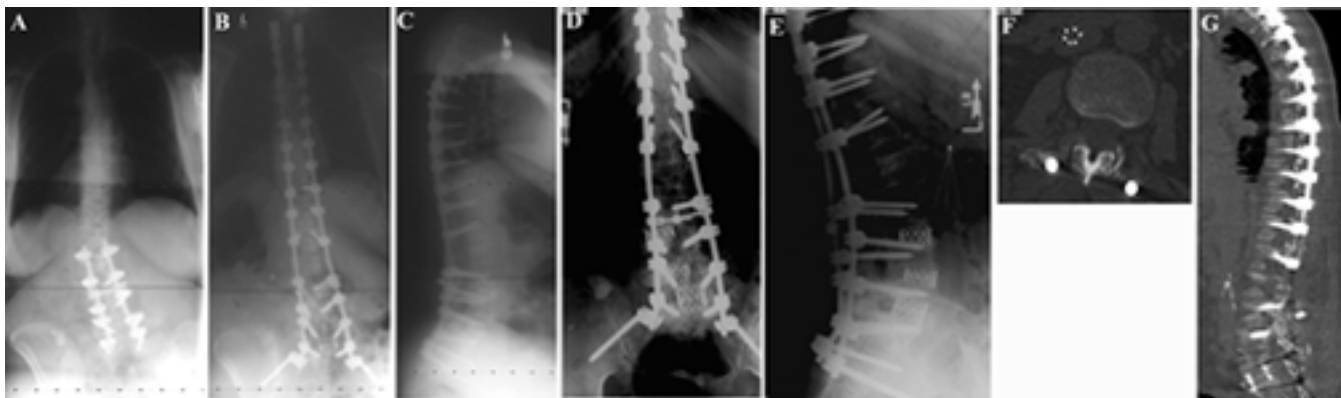


Fig. 1. Neuroimages obtained in a 60-year-old woman who presented with significant positive sagittal balance and a failed lumbar fusion performed at another hospital. A: Admission x-ray film demonstrating AP scoliosis. On review of her preoperative evaluation, the patient met several criteria for prophylactic IVC filter placement (staged surgery, surgery duration > 8 hours, obesity, estrogen replacement therapy, and significant abdominal vessel manipulation). B and C: The patient received an IVC filter preoperatively and underwent staged anterior–posterior T2–iliac fusion with deformity correction, demonstrated on AP scoli (B) and lateral scoli (C) x-ray films obtained to determine scoliosis. She recovered without development of a PE or DVT. D–G: Additional neuroimaging presenting a closer look at spinal implants in relation to the IVC filter. D, AP lumbar spine x-ray film; E, lateral lumbar spine x-ray film; F, axial CT scan; and G, sagittal CT scan.

significant DVT during the follow-up period after insertion. Two patients reported bilateral lower-extremity edema several months after surgery; this symptom resolved on follow-up review. For more information, see *Illustrative Case* and Fig. 1.

DISCUSSION

Pulmonary embolism is the primary cause of death in 50,000 to 100,000 patients annually in the US.^{13,53} It also is a contributing cause of death in tens of thousands of other patients. A disorder specifically in the surgical patient population, PE appears clinically in 1.8% of patients and has been estimated to occur undetected in 14 to 45%.^{1,18,40,51,55} In prospective studies conducted in neurosurgical patients, a 29 to 43% incidence of thromboembolic events was reported.^{34,61} Specifically in spine surgery, the DVT and PE rates range up to 21 and 8%, respectively.^{5,6,12,16,17,39,45,46,49,57,62,69} This range difference is often attributed to patient population differences, selection bias, surgical procedure, and surgical complexity.⁶³ Older patients undergoing longer operations tend to have a higher risk for development of a thromboembolic event.^{51,60,61} In addition, DVT rates (0.3–21%) also vary in the literature depending on the extent of surgery and the use of antithrombotic agents.^{42,56,60,66}

West and Anderson⁶⁶ reported on 41 patients who underwent posterior spinal surgery and who were screened 1 day before discharge; these investigators found six patients (14%) with DVT. They also estimated a 9.8% incidence of DVT, yet none of the patients had a clinically significant PE. Valladares and Hankinson⁶¹ reported a series of 100 patients who underwent elective cranial and spinal surgery and noted a DVT incidence of 29%. More specifically, in the same series the investigators reported a 20.7% incidence of DVT among 29 patients who underwent laminectomy. Dearborn, et al.,¹⁴ reported a 0.5% incidence of PE with posterior decompression, which subsequently increased to 6% with combined anterior–posterior spinal surgery. Traumatic spinal cord injuries are also associated with a 6.3% incidence of PE.⁶⁸ Bostrom, et al.,⁷ reported an 8% incidence of DVT in patients without paraplegia compared with a 14% incidence in patients with paretic or paraplegic lower extremities. The incidence of fatal PE in more than 1200 patients with acute paraplegia was noted to be 2%.³⁴

Although the issues of DVT and PE management continue to evolve, the presence of a DVT by itself is not life threatening. Nevertheless, when they are associated with PE, DVTs can lead to death. Thus, DVT and PE remain a medical management dilemma, with wide discrepancies in reported morbidity and mortality rates.^{26–28} In older hospitalized patients, the presence of PE predicts a 21% death rate during the course of the hospitalization, and a 39% death rate over the next 12 months.^{2,37} Patients presenting with DVT also have a recurrence rate of 30% and a 1-year mortality rate from PE that exceeds 20%.^{37,52} In patients undergoing spine surgery, Freed, et al.,²² reported three PE-related deaths in 243 patients, whereas Kostuik³⁹ reported a 1% mortality rate from PE in adult patients with scoliosis.

The standard treatment for DVT/PE remains anticoagulation therapy.

In nonsurgical patients, anticoagulation therapy carries a potential risk of exacerbating a bleeding complication, whereas administration of anticoagulation drugs in surgical patients carries an even greater risk of bleeding complications.^{4,11,23,51} Patterson, et al.,⁵⁰ reported a 30% incidence of bleeding and a 25% incidence of wound complications in a series of 112 patients who were given therapeutic doses of heparin following joint arthroplasty. In patients undergoing spine surgery, decortication of the bone elements predisposes patients to potential bleeding complications and hematoma formation. In the review published by Cain, et al.,¹⁰ of patients in whom PE developed after thoracolumbar or lumbar fusion and who subsequently received heparin therapy, there was a 67% morbidity rate.

Although anticoagulation therapy clearly has associated risks, the current medical prophylaxis protocol for the prevention of PE remains controversial. Mechanical and pharmacological means of prevention do not necessarily provide long-term protection in certain high-risk patients. Specifically, in an intensive care unit setting, there was a 34% incidence of reported DVT in patients who received heparin or pneumatic compression, compared with 32% in patients who received no such prophylaxis.³² For this study, however, it is unclear how many patients received heparin and how many received pneumatic compression. In support of prophylaxis with IVC filters, Becker, et al.,³ reported on 2019 patients who underwent IVC filter placement and noted a PE prevention rate of 98.3%. The reported complications included technical difficulties (4.6%), lower-extremity swelling (5.2%), caval obstruction (10.1%), and death (0.12%). Decousus, et al.,¹⁵ reported that permanent filters, when used in conjunction with heparin therapy, reduced the occurrence of symptomatic or asymptomatic PE without major complications, but these investigators did not find an effect on long-term mortality rates. Use of IVC filters in patients with spinal cord injury also remains controversial. Morbidity and mortality from a thromboembolic event in these patients remains unacceptably high despite routine use of prophylactic compression devices and low-dose heparin.^{4,8,30,38,65} Placement of IVC filters in patients with paraplegia or quadriplegia from spinal cord injury remains an alternative, with a documented PE rate of 0% after filter placement in one study.⁶⁸ In the retrospective review of major spine surgery at the senior author's institution, the mortality rate associated with symptomatic PE was 1.7% and the case fatality rate was 14% in patients in whom IVC filters were not placed. In the pilot study and with subsequent implementation of the protocol at a second institution, prophylactic filter placement resulted in no patient suffering a PE.

The rationale for prophylactic IVC filter placement in a subset of patients undergoing complex spine surgery was developed from multiple sources. To be considered protective, standard prophylactic measures need to be applied continuously throughout the high-risk period when patients are most prone to suffering a thromboembolic event. Without prophylaxis, DVT develops in one third of patients older than 40 years of age who undergo an elective general surgery procedure.^{9,18,25,35,36,48,67} Staging of procedures only increases the risk and prophylaxis becomes a

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major concern, as does prolonged bed rest.^{20,21} Elastic stockings may not necessarily decrease the risk of DVT.^{9,54} Graduated compression stockings effectively decrease the occurrence of DVT to a certain degree, but prevention of PE is lacking.^{3,19,27,33,51,58} Foot pumps may be the best option.²⁴ Intraoperative intermittent pneumatic compression devices of the calf have proven effective in the prevention of DVT, but not of PE.^{47,59} Although anticoagulation therapy is a possible treatment for DVT and/or PE, surgical patients often cannot be treated with anticoagulant drugs. An alternative then becomes placement of an IVC filter. Although not typically the case with our patients, IVC filter placement can even be temporary, with removal of the device after 2 weeks and even up to 1 year postimplantation.^{43,70} Linsenmaier, et al.,⁴³ report the complication rate from retrieval of temporary IVC filters to be no different from that seen with permanent filters.

Additional indications have recently been identified for prophylactic filters. These devices are currently accepted as the preferred modality for preventing PE when anticoagulation therapy has failed or is contraindicated.^{10,51} Although there have been no randomized trials, it has been suggested that the filters' protection against PE in high-risk patients may be a sufficient reason for their use.²⁹ The risk of a thromboembolic event is not likely to be the same among patients undergoing complex spine surgery. An investigation indicates that the incidence of a thromboembolic event increases in proportion to the number of risk factors present.³⁶ Although no clear indications for prophylactic blood filtering exist, the most prudent approach is to individualize decision making for each patient. Those patients with the highest risk factors would likely benefit the most from prophylactic filtering.

CONCLUSIONS

Pulmonary embolism is one of the most frequent causes of death following complex spine surgery, in which the rate of symptomatic PE can be as high as 12%, with 1 to 2% mortality.⁴¹ In light of the concerns regarding morbidity and mortality rates, combined with the low complication rate of modern IVC filters, a rationale can be used to consider IVC filters prophylactic devices. In this paper we have demonstrated a decrease in the rate of symptomatic PE from 12% (at one institution) to 0% (at two institutions), with a nominal complication rate. This indicates a role for prophylactic IVC filtering in a selected subgroup of patients undergoing complex spine surgery.

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Manuscript received August 16, 2004.

Accepted in final form September 7, 2004.

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