

Prophylactic Inferior Vena Cava Filters Prevent Pulmonary Embolisms in High-Risk Patients Undergoing Major Spinal Surgery

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Abstract

Objective

To demonstrate the efficacy of prophylactic IVC filters in preventing potentially fatal venous thromboembolic event (VTE) in high-risk patients undergoing major spinal surgery.

Methods

All patients undergoing major spinal surgery, with IVC filters placed for VTE prophylaxis from 2006 to 2009 were reviewed. Patients with two or more risk factors for VTE were included and reviewed for perioperative VTE, as well as complications related to use of the IVC filter. Cavograms obtained at the time of attempted filter retrieval identified intercepted emboli, inferring the prevention of a PE. The incidence of intercepted emboli, as well as PE, in our series was compared with rates of PE documented in the literature for similar high-risk populations undergoing similar procedures.

Results

Approximately 17% of patients reviewed had thrombus present at attempted filter retrieval. An additional 17% of IVC filters were unable to be retrieved as they had shifted position within the inferior vena cava. No patients experienced symptomatic PE. One patient developed a DVT requiring pharmacologic treatment. One patient with a retained filter developed a lower extremity phlebitis requiring treatment. There were no other complications related to IVC filter use.

Conclusion

This series shows that IVC filters are safe, as well as efficacious in preventing VTE's in patients undergoing spinal surgery. The observed rate of PE is consistent with the rate of PE in similar populations documented in the literature; however, our study demonstrates objectively that IVC filters prevent embolic events in this patient population. Emboli intercepted by filters more accurately estimate PE's prevented, and may prove to be a standard for future efforts to assess the efficacy of these devices, as their role in spine surgery continues to be defined.

Introduction

Venous thromboembolism (VTE) is a serious cause of morbidity and mortality. Approximately 100 individuals per 100,000 experience a first time VTE each year in America, with patients over eighty experiencing up to 500 per 100,000.¹ More than 250,000 patients are hospitalized annually for treatment of their VTE's,² and the thirty day mortality rate for Pulmonary Embolism (PE) is approximately fifteen percent.³ In addition to the serious medical implications of these complications, there is a tremendous financial burden. The cost per episode of PE averages \$12,795, and additional costs may be incurred by the increased risk of future VTE events and the occurrence of post thrombotic syndrome.⁴

In patients undergoing major spinal surgery, VTE's also present a serious risk.⁵ With the availability of many prophylactic regimens, including observation, pneumatic intermittent compression devices, early ambulation, and pharmacologic agents, there is little uniformity in the surgeon's implementation of prophylactic regimens in these complex patients.⁶ The variation in practice may stem from inconsistent and anecdotal estimates of VTE risks as well as bleeding complications. These inconsistencies are compounded by the lack of standardization of patient populations that make up the current literature. In high-risk patients undergoing major spine surgery, pulmonary embolus (PE) has been shown to be present in up to 12% of patients and fatal in 2% of these individuals.⁷ Major spinal surgery is defined as more than a laminectomy, or as a procedure including instrumentation.⁸ These patients frequently undergo staged procedures, prolonged periods of decreased mobility, anterior surgery with ilio caval manipulation, and may be contraindicated for pharmacologic VTE prophylaxis due to increased risks of bleeding complications. Nevertheless, patients who develop a PE require prompt and aggressive treatment with intravenous heparin sulfate or other similar pharmacologic agent, which carries a risk for bleeding complications, up to 67%.⁹

Bleeding complications may range from wound hematomas requiring drainage, to increased postoperative blood loss requiring transfusion. Non-spinal complications such as gastrointestinal hemorrhage may result from therapeutic anticoagulation as well. However, the most significant of bleeding complication in spinal surgery is compressive epidural hematomas. While epidural hematomas are relatively rare, generally accepted to occur in between 0.1 and 0.7% of cases,^{10,11,12} their effects necessitate immediate surgical intervention, and still may leave patients with permanent neurologic deficits in as many as 37.5% of patients.¹³

Prophylactic Inferior Vena Cava (IVC) filters present a method of prophylaxis that is efficacious in preventing embolic events, without the bleeding risks associated with pharmacologic VTE prophylaxis. They have recently been shown to be a safe and effective method of preventing PE in high-risk patients undergoing major spinal surgery.^{14, 15} Although potentially fatal, PE's are a rare complication; therefore, studies evaluating the efficacy of prophylactic regimens may have difficulty in drawing conclusions with significance. Another difficulty in assessing efficacy in preventing PE is identifying thrombus which would likely have embolized. Methods for diagnosing venous thrombosis in this patient population, such as duplex ultrasonography and venography have shown poor sensitivity for identifying clinically significant PE prior

embolization.¹⁶ In an effort to more fully demonstrate the efficacy of IVC filters in high-risk patients undergoing major spinal surgery, we present data on thrombus captured by indwelling prophylactic IVC filters. In the current study, a group of high-risk patients treated with prophylactic retrievable IVC filters had venography/cavograms performed at the time of attempted filter retrieval and thrombus was documented in order to quantify the potential emboli prevented by these devices.

Methods

The medical records of all patients undergoing major spinal surgery, who had IVC filters placed for VTE prophylaxis from 2006-2009, were reviewed. Patients with two or more risk factors for VTE's were included (*see table 1*).⁹ Records of included patients were then reviewed for perioperative complications, specifically VTE's. Filter retrieval records were also reviewed to identify those patients with significant thrombus harbored in the device, inferring the prevention of a PE. The incidence of intercepted emboli, and PE, in our patients was compared with the incidence of PE in similar high-risk patients undergoing major spinal surgery as documented in the literature.

Table 1. Risk Factors

Contraindication to anticoagulation therapy
Past or concurrent thromboembolism or hypercoagulability
Staged operations
Multiple segments (\geq five levels)
Bedridden for long periods prior to surgery (\geq 2 weeks)
Significant manipulation of abdominal vessels
Active smoking
Obesity
Birth control pills/estrogen replacement therapy
Anesthesia duration estimated at longer than 7.5 hours per surgical intervention
Combined anterior and posterior approach

Results

There was a mean age of 45.8 years (range 26-63 years), 6 patients were men, and 6 were women with a male/female ratio of 1:1; there was an average of 5.9 risk factors per patients (*Table 2*). No patients were immobile prior to surgery due to pain or neurologic deficits, however two patients had limited mobility and ambulated minimally, and only with a walker. Five patients (41.6%) had preoperative neurologic deficits consisting of nerve root irritation, and no motor changes were appreciated on postoperative neurologic examination. Two patients were on aspirin 81mg daily, which was stopped prior to their elective spinal surgery. One patient was on estrogen hormonal replacement therapy (HRT) prior to her operation. Twenty five per cent of patients were active smokers at the time of surgery. According to National Institutes of Health (NIH) 2000 guidelines, BMI's calculated for each patient showed 50 % of patients

to be obese (BMI>30Kg/m²), 25 % were considered overweight (BMI 25-29.9Kg/m²), 25 % were within normal limits (BMI 18.5 – 24.9Kg/m²).

Surgical intervention was indicated for the following diagnoses, deformity (57.1%), pseudoarthrosis (28.6%), osteomyelitis (7.1%), and trauma (7.1%) (Table 3). Fifty percent of procedures were revisions procedures. Eleven of twelve patients had treatment in a staged fashion, with an average of 3(range 3-5 days) days between stages. Surgery included an average of 7.6 vertebral segments (range 3-18). Average anesthetic time for procedure #1 was 4 hours 46 minutes (range 2 h 18 m to 11 h 31 m), and 7 hours 16 minutes (range 1 h 30 m to 11 h 15 m) for procedure #2; average anesthetic time for both procedures was 5 hours 58 minutes. Average blood loss was 441mL (range 100-1400mL) for the first procedure and 960mL (range 50-2700mL) for the second procedure. Significant ilio caval manipulation was felt to have occurred during retraction for anterior exposure in all patients. Radiographs of a representative case are shown in figure 1.

Table 2. Risk Factors per Patient

Patient	Number of Risk Factors
1	5
2	7
3	6
4	6
5	5
6	5
7	7
8	5
9	7
10	7
11	5
12	6
Average risk factors per patient	5.92

Table 3. Percentage of patients by diagnosis

	Number of Patients	Percentage of Patients
Deformity	8	57.1%
Pseudarthrosis	4	28.6%
Osteomyelitis	1	7.1%
Trauma	1	7.1%

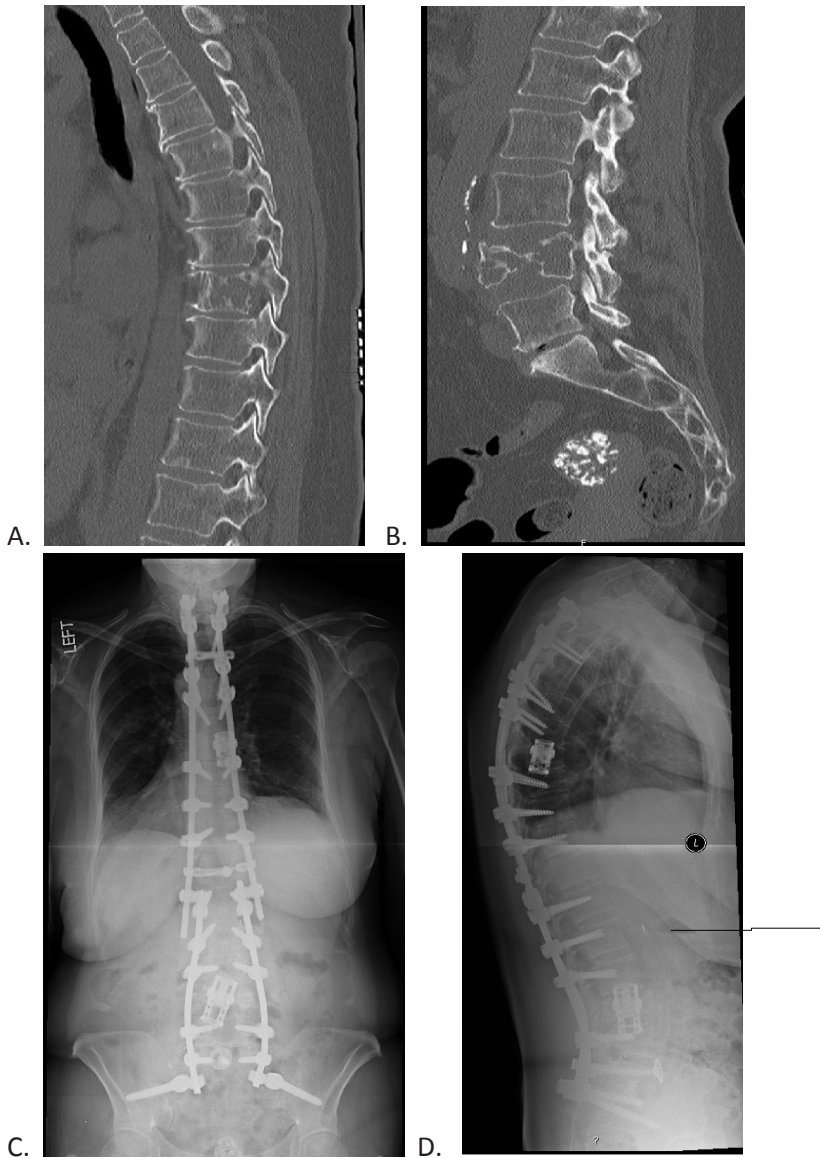


Figure 1. Preoperative sagittal thoracic (A.) and lumbar (B.) computed tomography images of a patient representative of included subjects, demonstrates pathologic thoracic and lumbar compression deformities. Anterior/posterior (C.) and lateral (D.) postoperative radiographs show anteriorly placed interbody devices as well as segmental posterior instrumentation (note indwelling IVC filter – arrow).

Perioperative VTE prophylaxis consisted of intermittent pneumatic compression devices (IPCD) placed intraoperatively, continued through the duration of each patient’s hospitalization when that patient was not ambulating. Placement of IVC filters was before anterior surgery in seven patients, and after anterior surgery in five patients. Filter placement was performed in eleven cases by a board-certified vascular surgeon, and an interventional radiologist in one case. No complications were observed during IVC filter placement. Retrieval of IVC filters was performed by the same board-certified vascular surgeon or interventional radiologist who placed the device at an average of 66.1 days (range 17-94 days) after placement. Venography was performed in all patients prior to attempted filter retrieval. Devices which harbored thrombus or had

experienced a shift in position were identified (*see figure 2*). No complications were encountered during attempted retrieval of any IVC filters.

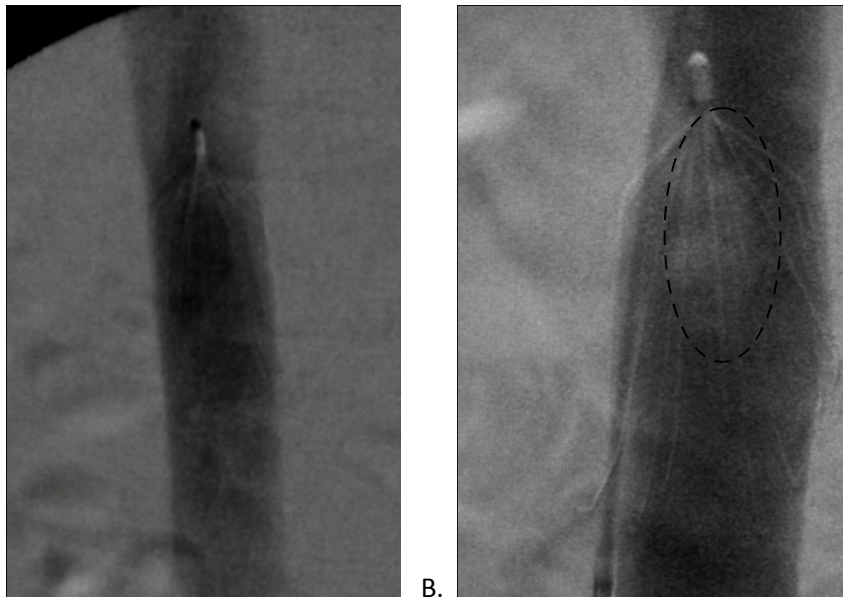


Figure 2. Representative cavograms obtained in study subjects at the time of attempted filter retrieval demonstrate an appropriately positioned, patent IVC filter (A.), and a filter with entrapped thrombus (outlined by dashed oval) – contraindicated for retrieval (B).

Thrombus was present in two filters (16.7%) contraindicating device retrieval (*Table 4*). Two IVC filters were irretrievable due to technical reasons (change of longitudinal filter orientation). Additionally, after noting a change of longitudinal filter orientation, one patient required multiple attempts at retrieval before the device was successfully removed.

Table 4. Patients with Clots

Patient	Diagnosis	Surgery #1	Surgery #2	Days between surgeries	Total risk Factors	Specific Risk Factors
1	Deformity	ALIF L3/4, 4/5, 5/1	PSF T10-S1; Laminectomy L2-S1; SPO L2/3, 3/4	3	7	Staged; AP approach; Time>7.5hr; Multiple Segments; Obesity; IC manipulation; CI to Anticoagulation
2	Trauma	Open treatment of L2 fx; PSF L5-S1	Removal of segmental instrumentation lumbar spine	4	5	Staged; AP approach; Multiple Segments; Prior DVT; CI to Anticoag

ALIF (Anterior Lumbar Interbody Fusion), PSF (Posterior Spinal Fusion), SPO (Smith Peterson Osteotomy, AP (Anterior & Posterior), IC (Iliocaval), Ant (Anterior), CI (Contraindication)

No patients developed a PE in the postoperative period, or at an average of 28.6 months follow-up. One patient was placed on pharmacologic anticoagulation after developing a DVT between stages of his surgical treatment. No additional patients were

anticoagulated postoperatively. One patient with an irretrievable IVC filter due to thrombus developed a local phlebitis which required treatment.

Discussion

Patients undergoing complex, or staged, spinal procedures are often at a significantly increased risk for experiencing VTE events. Oda, in a 2000 study of 134 patients undergoing posterior spinal surgery with no postoperative VTE prophylaxis, observed a 15.5% rate of DVT in all patients and a 26.5% rate in those undergoing lumbar procedures. No patients developed clinical evidence of PE.¹⁷ In his 1999 study, Dearborn et al, reviewed one hundred sixteen patients undergoing major spinal surgery and found an incidence of PE in 2.2% in all patients. However, when analyzing anterior, or combined anterior and posterior, approaches there was a 6% incidence of PE, compared to 0.5% in posterior approaches alone.¹⁸ Demonstrating the safety and efficacy of IVC filters used for VTE prophylaxis in high-risk spinal surgery patients, Rosner et al observed a 12% rate of PE with a 2% mortality rate.⁹ High-risk patients present difficult clinical scenarios for the treating surgeon. They are frequently immobile for a prolonged period of time, due at times to the frequent use of staged treatment, as well as combined surgical approaches.

Patients undergoing major spinal surgery are at an increased risk for bleeding complications postoperatively when chemical VTE prophylaxis is utilized. Bleeding complications such as gastrointestinal hemorrhage and wound complications have been associated with both low-dose heparin and low molecular weight heparin (LMWH).¹⁹ Cain et al observed a 67% rate of bleeding complications for postoperative thoracolumbar spine patients diagnosed with PE who underwent treatment with therapeutic heparin. These authors also noted a relatively lower rate of complications when treatment was with IVC filters, and indicated this as an alternative treatment strategy.³

Of greatest concern is the potential for compressive epidural hematoma with the use of chemical VTE prophylaxis. Yi et al noted 44.4% of epidural hematomas identified in their series as being due to either a medical or pharmacologic coagulopathy.^{3,5,6} Asymptomatic epidural bleeds occur in up to 58% of patients undergoing lumbar decompression²⁰, however the rate of symptomatic epidural hematoma development after a spinal surgery and associated with anticoagulation is approximately 0.1-0.7%.^{4,5}

As in the current study, other authors have observed the efficacy and safety of IVC filters in preventing serious embolic complications in spine surgery.^{3,8,9} However, quantification of the efficacy of these devices has not previously been shown for patients undergoing high-risk spinal surgery. Through the use of routine cavograms in all patients we demonstrate a 16.7% clot burden at the time of attempted filter retrieval. The incidence of thrombus captured by IVC filters in this study is in keeping with the incidence of PE in similar high-risk patients undergoing major spinal surgery.^{8,9} The absence of morbidity associated with insertion and retrieval, and the low incidence of morbidity associated with indwelling, of these devices demonstrates their safety. Because PE are rare, previous studies demonstrating efficacy of IVC filters may have shown this prevention from sampling only patients who would not have developed

emboli regardless of IVC filter. However, our series, while similarly limited by a small sample size, shows objective prevention of embolic events by IVC filters in patients undergoing spinal surgery; none in the series developed a PE.

Several limitations of our study warrant discussion. Inherent to the retrospective nature of the data collection, as well as the small sample size, no statistical significance to the results could be shown, and selection bias could have been present. It is unknown what significance to the patient the thrombus identified on cavogram at the time of attempted filter retrieval would have presented. Also, the use of an IVC filter does not prohibit or inhibit the formation of DVT.

Conclusion

Prophylactic IVC filters are safe when used in high-risk patients undergoing major spinal surgery. This study presents objective data that embolism does take place in this patient population, and that prophylactic IVC filters are effective at preventing these events from becoming a potentially fatal PE. Consideration should be given to using these devices to prevent potentially fatal complications in high-risk patients undergoing major spinal surgery.

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