


# Comparing Bleeding and Thrombotic Rates in Spine Surgery: An Analysis of 119 888 Patients

Global Spine Journal  
2021, Vol. 11(2) 161-166  
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DOI: 10.1177/2192568219896295  
journals.sagepub.com/home/gsj



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## Abstract

**Study Design:** Retrospective, database review.

**Objectives:** Examine the utilization rate of postoperative deep vein thrombosis (DVT) prophylaxis and compare the incidence and severity of bleeding and thrombotic complications in elective spine surgery patients.

**Methods:** We utilized PearlDiver, a national orthopedics claims database. All patients who underwent elective spine surgery from 2007 to 2017 were included. Patients were stratified by the presence of DVT prophylaxis drug codes, then by comorbidities for postoperative bleeding/thrombosis. The severity of all bleeding and thrombotic complications in each cohort was studied, including the incidence of complications requiring operative washout, diagnosis of pulmonary embolism, intensive care unit admission, and mortality.

**Results:** A total of 119 888 patients were included. The majority of patients (118 720, >99%) were not administered postoperative DVT chemoprophylaxis while a minority of patients (1168) were. The overall rates of bleeding and thrombotic complications within the population not receiving DVT prophylaxis were 1.96% and 2.45%, respectively ( $P < .001$ ). The incidence of surgical intervention for a wound washout was 0.62% compared with 1.05% for pulmonary embolism ( $P < .001$ ). Intensive care unit admission rates related to a wound washout procedure or pulmonary embolism also significantly differed (0.07% vs 0.34%,  $P < .001$ ). There were no observed differences in mortality. When controlling for patient comorbidity, patients with atrial fibrillation, cancer, or a prior history of thrombotic complications experienced the greatest increased risks of postoperative thrombosis.

**Conclusions:** DVT prophylaxis is not routinely utilized following elective spine procedures. We report that there exist specific populations which may receive benefit from these practices, although further study is necessary to determine optimal prevention strategies for both thrombotic and bleeding complications in spine surgery.

## Keywords

chemoprophylaxis, hematoma, deep vein thrombosis, pulmonary embolism, anticoagulant, spine surgery

## Introduction

Among the more serious setbacks in the postoperative period are thrombotic complications. Thrombotic complications such as deep vein thrombosis (DVT) can progress to pulmonary embolism (PE), a potentially life-threatening condition. In order to limit the risk of postoperative venous thromboembolism many surgeons rely on a patient's risk profile to advise the administration of chemical prophylaxis in the postoperative setting.<sup>1</sup>

In patients undergoing spinal surgery, however, the risks associated with suffering a bleeding complication are

intensified, as the development of an epidural hematoma can cause spinal cord compression and irreversible damage to the central nervous system. Historically, the incidence of

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postoperative epidural hematoma has been reported in less than 0.3% of spinal surgery cases, though the effects may be acute and permanent, and negatively affect quality of life.<sup>2,3</sup> This compares to values ranging from 0.8% to 15.5% for a DVT in spine surgery patients.<sup>4-8</sup> The documented risk factors for the rare complication of epidural hematomas include prophylactic anticoagulation after spinal operation, among others, which has been associated in approximately one-third of epidural hematoma cases.<sup>9</sup> Though anticoagulant therapy alone likely does not initiate spontaneous epidural hematoma or spinal hemorrhage, its use represents the second most common association with epidural hematomas second only to idiopathic spinal hematoma.<sup>2,10</sup>

Currently, there are no universally agreed-upon recommendations for anticoagulant administration in spine surgery patients, as present literature remains inconclusive. Small studies have investigated outcomes related to anticoagulant prophylaxis following spine surgeries subsequently documenting a low risk of bleeding complications, including epidural hematomas.<sup>11-15</sup> Furthermore, a meta-analysis and database review by Mosenthal et al<sup>16</sup> described an elevated incidence of pulmonary embolisms relative to epidural hematomas in spine surgery patients, suggesting a possible greater role of chemoprophylaxis. In contrast, in 2009, the North American Spine Society (NASS) published a review and clinical guideline recommending caution with chemoprophylaxis and withholding low molecular weight heparin after routine elective surgery.<sup>17</sup>

In the context of minimizing the likelihood of devastating bleeding complications after spine surgery, patients without thrombotic chemoprophylaxis may carry a potentially increased risk of thrombotic complications, which can be further magnified due to relative postoperative immobility compared to other procedures. Because of the low incidences of severe bleeding and thrombotic complications after spine surgery, a large data sample is required to assess if one type of complication occurs more frequently than the other. We sought to study this question using a large administrative database in order to compare the rates of bleeding and thrombotic complications and their severity in patients who had undergone spinal surgery.

## Materials and Methods

We conducted a retrospective review of the Humana Insurance subset of the PearlDiver national database (PearlDiver Inc, Fort Wayne, IN). This subset contains records from 2007 to 2017 of roughly 25 million patients receiving coverage from the Humana health insurance provider. Records can be accessed with a commercial subscription, and patients within this database can be grouped and filtered based on Current Procedural Terminology (CPT) codes as well as International Classification of Diseases, 9th and 10th Revisions, Clinical Modification (ICD-9, ICD-10) diagnosis coding. Protocol was granted a waiver by our institutional review board under IRB18-0215. Additionally, confidential patient information within the database is blinded and cannot be directly linked to subjects.

For the purpose of our study, we identified an initial patient population using CPT codes for six different operations of the spine, including anterior cervical fusion (22 551, 22 552, 22 845, 22 846, 63 081, 63 082, 22 856), anterior lumbar fusion (22 558, 22 585, 22 851), posterior cervical fusion (22 600, 22 614), posterior cervical laminectomy/laminoplasty (63 001, 63 015, 63 020, 63 043, 63 045, 63 048), posterior lumbar fusion (22 840, 22 842, 22 843, 22 844, 22 612, 22 614, 22 630, 22 632, 22 633, 22 633, 22 634, 22 800, 22 802, 22 804), and posterior lumbar laminectomy (63 012, 63 030, 63 035, 63 042, 63 047, 63 048) (see Appendix A in the Supplemental Material).

In order to ensure that patients were not lost throughout the course of study due to a change or loss of insurance, patients matching the inclusion criteria were required to have active records in the database for at least 6 months following the index procedure. We analyzed 2 groups of patients. The first group was composed of patients who had not received chemoprophylaxis. Exclusion criteria consisted of one or more prescriptions for anticoagulant therapy within the first 5 days after spine surgery, with anticoagulants defined by the generic and brand name drug codes for heparin, enoxaparin (Lovenox, Sanofi, Bridgewater, NJ, USA), enoxaparin sodium (Clexane, Sanofi, Bridgewater, NJ, USA), rivaroxaban (Xarelto, Janssen Pharmaceuticals, Inc, South Raritan, NJ, USA; and Johnson & Johnson, New Brunswick, NJ, USA), apixaban (Eliquis, Bristol-Myers Squibb and Pfizer Inc, New York, NY, USA), edoxaban (Savaysa, Daichii Sankyo, Parsippany, NJ, USA), dalteparin (Fragmin, Pfizer Inc, New York, NY, USA), fondaparinux (Arixtra, Mylan Pharmaceuticals Inc, Canonsburg, PA, USA), dabigatran (Pradaxa, Boehringer Ingelheim Pharmaceuticals Inc, Ridgefield, CT, USA), and warfarin (Coumadin, Bristol-Myers Squibb, New York, NY, USA; Jantoven, Upsher-Smith Laboratories Inc, Maple Grove, MN, USA). The second group included patients who had received any of the aforementioned chemoprophylaxis within 5 days of their procedure.

Complications of interest were separated into the general categories of bleeding or thrombotic. Complications were limited in these patients from the same day of intervention until 3 months postoperation. The rates of these bleeding complications (epidural hematoma, hematoma, seroma) were compared to rates of thrombotic complications (DVT, PE).

We analyzed and compared varying levels of severity of thrombotic and bleeding complications:

1. All bleeding vs. all thrombotic complications:
  - a. Bleeding complications were defined by the ICD-9 and ICD-10 diagnosis codes for epidural hematoma, hematoma, and seroma.
  - b. Thrombotic complications included diagnosis codes for deep vein thrombosis and pulmonary embolism.
2. Bleeding complications requiring operative washout versus pulmonary embolism:
  - a. We restricted our search to only patients with a bleeding complication within 3 months

postoperation who had also had one or more CPT codes for a surgical intervention requiring a wound washout procedure (10 140, 10 180, 11 043, 21 501, 22 010, 22 015, 27 630) within 3 months of index procedure, provided the subsequent procedure was coded either on the same day as or after the ICD-9 or ICD-10 code for the initial bleeding complication.

- b. For the thrombotic complications group, we limited our query to only the ICD-9 or ICD-10 codes for PE, as PE is the most severe complication of thrombosis.
3. Bleeding complications requiring operative washout and associated with ICU admission versus pulmonary embolism associated with ICU admission:
  - a. To accomplish this, we searched for CPT codes for intensive care unit (ICU) admission (99 291, 99 292) within a 7-day window of the severe complication, with the window demarcated 3 days prior, 3 days post, and inclusive of the same day of wound washout or pulmonary embolism diagnosis. The window of time chosen was selected to ideally account for variations in coding by providers while limiting the likelihood that the admission was due to another factor. The ICU admission rates for these respective complications were then compared.
4. Bleeding complications requiring operative washout associated with ICU admission and death versus PE associated with ICU admission and death:
  - a. Using the ICD-9 and ICD-10 diagnosis codes for mortality (ICD-9-D-7981, ICD-9-D-7982, ICD-9-D-7989, ICD-9-D-7999, ICD-10-D-R99), we compared the rates of mortality within 3 months of ICU admission in these two groups.

Proportions of patients who experienced bleeding and thrombotic complications, wound washout and PE, ICU admission associated with wound washout and PE, and mortality after ICU admission were compared using chi-square tests with an alpha level of .05.

To better define a cohort or cohorts of spine patients who may optimally benefit from any change in contemporary practices, patients not administered chemoprophylaxis were stratified by the presence of diagnostic codes for various comorbidities/perioperative factors associated with increased bleeding and thrombotic risks. Variables assessed in this analysis include patient age, atrial fibrillation, cancer, chronic obstructive pulmonary disease, congestive heart failure, gender, hypertension, number of levels treated, obesity, oral contraceptive use, prior history of bleeds, prior history of thrombosis, and tobacco use.

## Results

### Patients Not Administered Chemoprophylaxis

We identified 119 888 patients who fulfilled our inclusion criteria. Of these, the majority of patients (>99%, 118 720) were

**Table 1.** Comparison of Complication Rates Within Spine Surgery Patients Not Administered Anticoagulant Therapy Analyzed at 3 Months Postprocedure

(N = 118 720). <sup>a</sup>	Bleeding Complications	Thrombotic Complications	P
Overall complications	1.96% (2332)	2.45% (2907)	<.001
Severe complications	0.62% (740)	1.05% (1248)	<.001
ICU admission	0.07% (80)	0.34% (404)	<.001
Mortality	–1 <sup>b</sup>	–1 <sup>b</sup>	NA

Abbreviations: ICU, intensive care unit; NA, not applicable.

<sup>a</sup>Overall complications are delineated by bleeding (seroma, hematoma, epidural hematoma) or thrombotic (deep vein thrombosis, pulmonary embolism). Severe complications indicate incidence of wound washout procedure or pulmonary embolism, respectively. ICU admission was tracked within a 7-day window of the severe complication. Mortality is defined by death within 3 months of an ICU admission for a severe complication of the 2 groups.

<sup>b</sup>–1 indicates reported population of less than 11. For patient privacy, values of less than 11 are withheld in the PearlDiver database. For these groups, because both populations of interest reported values smaller than 11, subsequent analysis was not applicable.

not administered DVT chemoprophylaxis within the first 5 days of their spine procedure. Within this group, overall rates of bleeding and thrombotic complications significantly differed (1.96% vs 2.45%;  $P < .001$ ). Additionally, the rate of patients who underwent surgical intervention for a wound washout procedure was 0.62% compared to 1.05% for a diagnosis of pulmonary embolism within 3 months of spine surgery ( $P < .001$ ). ICU admission rates related to a wound washout procedure were 0.07%. The ICU admission rate was 0.34% for the complication of pulmonary embolism ( $P < .001$ ; Table 1). This trend was consistent and observed for subanalyses of all 6 spinal procedures (Table 2).

### Patients Administered Chemoprophylaxis

In contrast, only 1168 patients were placed on anticoagulant therapy following surgical spine procedures, representing 0.97% of all patients who had undergone spinal procedures in this study. Contrary to the above findings, patients in this group experienced much higher rates of overall thrombotic complications compared to bleeding ( $P < .001$ ; Table 3). This trend remained consistent in all 6 spinal surgery type subanalyses. Because of the relatively small sample size represented here, no further analysis was conducted.

### Breakdown by Comorbidity

In subanalyses controlling for the effect of comorbidities on bleeding and thrombotic complications, patients found to be associated with the highest increased risk of thrombotic complications include those with atrial fibrillation, cancer, or prior history of thrombotic complication (Supplemental Tables 1–6). These effects were consistently observed when examining increasing levels of complication severity. In patients without these diagnostic criteria, the majority of

**Table 2.** Subanalysis of Complication Rates for 6 Different Operations of the Spine on Patients Not Administered Anticoagulant Therapy Analyzed at 3 Months Postprocedure.<sup>a</sup>

	Anterior Cervical Fusion n = 31 276	Anterior Lumbar Fusion n = 46 876	Posterior Cervical Fusion n = 21 750	Posterior Cervical Laminectomy n = 40 489	Posterior Lumbar Fusion n = 47 069	Posterior Lumbar Laminectomy n = 77 240
Bleeding complications	1.63% (510) P < .001	2.08% (973) P < .001	3.57% (776) P < .001	2.54% (1028) P < .001	2.79% (1313) P < .001	2.10% (1624) P < .001
Thrombotic complications	2.00% (626)	2.69% (1261)	4.66% (1014)	3.02% (1221)	3.56% (1675)	2.45% (1891)
Surgical intervention	0.46% (143) P < .001	0.63% (297) P < .001	1.18% (256) P < .001	0.89% (361) P < .001	0.91% (453) P < .001	0.70% (538) P < .001
PE incidence	0.91% (284)	1.17% (550)	1.98% (430)	1.37% (555)	1.67% (708)	1.07% (830)
ICU admission—surgery	0.12% (38) P < .001	0.10% (45) P < .001	0.11% (25) P < .001	0.08% (32) P < .001	0.08% (37) P < .001	0.05% (37) P < .001
ICU admission—PE	0.35% (110)	0.39% (182)	0.71% (155)	0.40% (161)	0.49% (230)	0.30% (231)

Abbreviations: ICU, intensive care unit; PE, pulmonary embolism.

<sup>a</sup>Complications defined by bleeding include seroma, hematoma, epidural hematoma, and complications defined by thrombotic events include deep vein thrombosis (DVT) and PE. Surgery refers to operative wound washout procedures due to bleeding complications. ICU admission was tracked within a 7-day window of either surgical intervention or PE, respectively.

**Table 3.** Comparison of Complication Rates Within Spine Surgery Patients Administered Anticoagulant Therapy Analyzed at 3 Months Postprocedure (N = 1168).

	Bleeding Complications	Thrombotic Complications	P
Overall complications	2.65% (31)	10.36% (121)	<.001
Severe complications	0.77% (9)	5.31% (62)	<.001
ICU admission	0.94% (11 <sup>b</sup> )	1.28% (15)	.430/NA
Mortality	—1 <sup>c</sup>	—1 <sup>c</sup>	NA

Abbreviations: ICU, intensive care unit; NA, not applicable.

<sup>a</sup>Overall complications are delineated by bleeding (seroma, hematoma, epidural hematoma) or thrombotic (deep vein thrombosis, pulmonary embolism). Severe complications indicate incidence of a wound washout procedure or pulmonary embolism, respectively. ICU admission was tracked within a 7-day window of the severe complication.

<sup>b</sup>Indicates reported population of less than 11. For patient privacy, values of less than 11 are withheld in the PearlDiver database. For this indicated analysis, we used the value of 11 to represent the highest possible incidence of severe complications related to bleeding complications.

<sup>c</sup>—1: For these groups, because both populations of interest reported values smaller than 11, subsequent analysis was not applicable.

patients either experienced only a marginally increased risk of thrombosis or alternatively, as was the case with patients age less than 60 years, those with a history of prior bleeding complications, or a negative history of prior thrombotic complications in particular, experienced a greater risk of bleeding relative to thrombotic complications. These findings remained consistent in our analysis of severe complications (Supplemental Tables 7-12). For ICU admissions, all cohorts experienced greater incidence of thrombotic complications relative to bleeding (Supplemental Tables 13-18).

When the cohorts experiencing the greatest risk of thrombotic complications (atrial fibrillation, cancer, prior thrombosis history) were excluded from our analysis, the rate of overall bleeding complications was comparatively greater than thrombotic complications (Table 4).

**Table 4.** Comparison of Complication Rates Within Spine Surgery Patients Not Administered Anticoagulant Therapy After Excluding Patient History of Atrial Fibrillation, Cancer, or Prior History of Thrombotic Complication (N = 101 848).<sup>a</sup>

	Bleeding Complications	Thrombotic Complications	P
Overall complications	1.67% (1696)	1.42% (1446)	<.001
Severe complications	0.54% (549)	0.56% (571)	.510
ICU admission	0.05% (50)	0.19% (190)	<.001
Mortality	—1 <sup>b</sup>	—1 <sup>b</sup>	NA

Abbreviations: ICU, intensive care unit; NA, not applicable.

<sup>a</sup>Patients analyzed at 3 months postprocedure. Overall complications are delineated by bleeding (seroma, hematoma, epidural hematoma) or thrombotic (deep vein thrombosis, pulmonary embolism). Severe complications indicate incidence of wound washout procedure or pulmonary embolism, respectively. ICU admission was tracked within a 7-day window of the severe complication. Mortality is defined by death within 3 months of an ICU admission for a severe complication of the 2 groups.

<sup>b</sup>—1 indicates reported population of less than 11. For patient privacy, values of less than 11 are withheld in the PearlDiver database. For these groups, because both populations of interest reported values smaller than 11, subsequent analysis was not applicable.

## Discussion

Unlike other surgery, there is no standard of care in regard to DVT chemical prophylaxis after routine elective spine surgery. Studies have suggested caution with the use of chemoprophylaxis<sup>17</sup> while also acknowledging the dearth of quality literature studying this subject. As a result, the current practice of chemoprophylaxis after spine surgery is largely driven by dogma and not by quality data.

It has been our observation that the majority of spine surgeons do not chemoprophylax in practice. This observation is substantiated by the present study as we observed that greater than 99% of patients who underwent spine surgery did not

receive chemical prophylaxis within 5 days of their surgery. Because of these findings, this analysis largely reflects the rates of bleeding and thrombotic complications in a sample population without chemoprophylaxis.

In the course of comparing bleeding and thrombotic complications, we attempted to identify greater severity of these respective complications. For example, a seroma requiring a return to the operating room for a washout is highly likely to be a more severe complication than a hematoma that required no additional treatment. Similarly, a PE is a more severe complication than a DVT. However, even this level of complication severity may not sufficiently reflect the degree of injury. A PE can be relatively asymptomatic and a seroma requiring a washout may be reflective of poor wound healing with no neurological sequelae. To assess yet another layer of complication severity, we assumed that a severe bleeding complication with neurological sequelae is more likely to be associated with an ICU admission. Similarly, we assumed that a cardiopulmonary compromising pulmonary embolism is more likely to be associated with an ICU admission. Thus, we compared the associated ICU admission rates in these 2 groups. Finally, we added death as an additional inclusive variable to compare even another level of complication severity.

Within this group of patients who did not undergo chemoprophylaxis, we observed that spine surgery patients experienced significantly greater postoperative thrombotic complications when compared with bleeding complications at all levels of severity. Depending on surgical approach, this resulted in anywhere from 1.17 to 1.31 times greater likelihood of developing any thrombotic complication. These risks were magnified when comparing what we defined as more severe complications, increasing to 1.53 to 1.98 times greater risk of thrombotic complications. Furthermore, this patient population experienced a 2.92 to 6.45 times greater risk of ICU admission for thrombotic complications when compared to bleeding complications.

However, when this population was broken down by comorbidity, it became clear that several at risk groups experienced the greatest increase in thrombotic complications. These groups include patients with a diagnosis of atrial fibrillation, cancer, or prior history of thrombotic complication. We report here that patients with these distinct medical histories would potentially be the ideal candidates for DVT prophylaxis following elective spine surgery. This data additionally suggests that patients who do not fit these profiles may not receive such benefit, as when patients with atrial fibrillation, cancer, or prior history of thrombotic complication were excluded from further study, the rate of overall bleeds actually exceeded thrombotic complications. It is worth noting, nonetheless, that while overall and severe complications were relatively similar, all groups continued to experience greater severity of complications associated with thrombosis, evidenced by significantly increased ICU stays due to PE across all cohorts (Table 4).

Consequently, placement on an anticoagulant therapy regimen post-operation has the potential to increase bleeding complications.<sup>18</sup> However, a study by Awad et al<sup>12</sup> found no

association between well-controlled anticoagulant use in the postoperative setting and development of epidural hematoma. Chang et al<sup>19</sup> also reported that the administration of chemical prophylaxis was related to a decrease in DVT and PE, an expected finding, while the rates of hematoma remained unchanged. When we attempted investigated this question in the Humana subset of PearlDiver, however, the experienced rates of thrombotic complications were over 10%. We believe the conflicting nature of the data are artifacts of the relatively small sample size as well as patient populations that were not comparable, as we suspect this represents patients with extenuating circumstances (prior history of thrombosis, hypercoagulable disorders, etc). Based on the 0.97% of patients who received chemoprophylaxis, we are not able to comment on the effect of the chemoprophylaxis. We recognize this as the first limitation of our study.

Second, in the present study the sum of the individual values for the 6 procedures analyzed is greater than the pooled value of total spinal surgeries. This is likely a factor of patients who underwent multiple approaches or procedures and in pooling these values we elected not to count these patients for the final analysis more than once. Third, because of the nature of any large database, our study was also limited by the coding practices of physicians and possible loss of follow-up. We relied on the time frame and chronology of provider coding, which can be skewed or not reported in some cases. While our findings notably persisted in our analysis of anterior cervical fusion, an approach which lends increased risk for catastrophic bleeding complications, given that many anterior cervical fusion procedures are performed as outpatient procedures or procedures with a 23-hour stay, it is possible that a complication outside the hospital environment may not be accurately captured. Finally, the outcomes measures in the study are imperfect. Ultimately, the metric of most interest is bleeding complication threatening paralysis or airway compression and pulmonary embolism with severe cardiopulmonary compromise. While the association of ICU admission makes it more likely that these complications were of this severity, it cannot be wholly known based on the data available to us.

Nevertheless, the large sample size utilized and the national nature of the database provide a useful snapshot into not only the anticoagulant practices of spine surgeons but also the outcomes related to these practices.

## Conclusion

Currently, there is no established standard of care regarding thrombotic chemoprophylaxis after spine surgery. In the present study's patient population, which did not receive DVT chemoprophylaxis, the risks of thrombotic complications were significantly greater than bleeding complications for patients specifically with atrial fibrillation, cancer, or a prior history of thrombotic complications. For those not matching these criteria, the risks of DVT prophylaxis may not outweigh the benefits. This data strongly suggests that additional study is needed to determine optimal thromboprophylaxis strategies. A

similarly powerful analysis and comparison of these complications in patients who have received chemoprophylaxis after spine surgery does not exist, to our knowledge. Such a study would be of great importance in fully defining the role of routine DVT chemoprophylaxis after elective spine surgery.


### Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: MJL has received funding from DePuy Synthes, Stryker Spine, and Globus Medical as a paid consultant. LLS has received funding from DePuy Johnson and Johnson as a paid consultant. The remaining authors certify that they have no commercial associations (e.g., consultancies, stock ownership, equity interest, patent/licensing arrangements, etc.) that might pose a conflict of interest in connection with the submitted article.

### Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

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### Supplemental Material

The supplemental material is available in the online version of the article.

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