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Case series of elective instrumented posterior lumbar spinal fusions demonstrating a low incidence of venous thromboembolism

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Abstract

Introduction: Venous thromboembolism (VTE) is a significant cause of morbidity and mortality in orthopaedic surgery. While specific guidelines exist for hip and knee arthroplasty, there is wide variation in VTE prophylaxis in complex spinal surgery. This study sought to determine the incidence of VTE, and risk factors associated with VTE, in patients undergoing elective instrumented posterior lumbar spinal fusion.

Methods: In a single-centre case series study, 107 consecutive patients undergoing elective lumbar spinal fusion were evaluated for VTE by lower limb duplex ultrasonography and/or clinical observation, and where indicated, computed tomography pulmonary angiogram (CTPA). The Caprini model for thrombosis risk factor assessment was retrospectively applied to grade levels of VTE risk, which were compared with overall VTE incidence.

Results: All patients were operated on a spinal frame and received mechanical prophylaxis (thromboembolic deterrent stockings and sequential calf-compression devices). Thirty-seven percent also received chemoprophylaxis with low molecular weight heparin (LMWH). There was no significant relationship between LMWH use and protection from VTE. Risk scores ≥3 (high/highest risk categories) were observed in 96.2% of patients. Four (3.7%) patients encountered a VTE complication (all with no chemoprophylaxis), either deep vein thrombosis (1.9%) or pulmonary embolism (1.9%). No patient sustained an epidural haematoma.

Conclusion: Although patients undergoing elective instrumental posterior lumbar spinal fusion are at high risk of developing VTE, the actual incidence of VTE in these patients is low. Our data support the use of mechanical prophylaxis with thromboembolic deterrent stockings and sequential calf-compression devices to prevent VTE in these patients.

Keywords: DVT, PE, spinal surgery, thromboprophylaxis, VTE

Introduction

Venous thromboembolism (VTE) is a postoperative complication that manifests as either deep vein thrombosis (DVT) or pulmonary embolism (PE). Approximately 30,000 people are hospitalised in Australia each year as a consequence of VTE, and an estimated 2,000 die as a direct result.[1] VTE prevention has been widely acknowledged both internationally and within Australia as a prominent issue amongst hospitalised patients and thus represents a key opportunity to improve patient safety.[1]

VTE is the most common complication following major joint surgery.[2] Whilst there are clear guidelines for VTE prophylaxis in hip and knee arthroplasty, there is a lack of consensus for elective spinal surgery. Patients undergoing spinal surgery are not dissimilar to other orthopaedic surgical patients. They endure periods of extended recumbence and limited mobility after a major operative intervention that may predispose them to thromboembolic disease.[3] Recently, a VTE risk score applied to patients undergoing spinal surgery has established that this is a group of patients at high risk of VTE.[4]

The reported incidence of VTE in elective spinal surgery varies. For DVT, the incidence has been reported to range from 0%[5] to 26.5%[6], while for PE it varies from 0%[5] to 18%[7]. Factors contributing to the variation include differences in prophylactic regimes, the nature of the surgery included and post-operative VTE surveillance methods. Prophylactic measures discussed within the literature include (alone or in combination): thromboembolic deterrent stockings (TEDS), sequential calf-compression devices (SCD), inferior vena cava filters (IVCF) and anticoagulant medication. The variation in scientific studies examining VTE has led to uncertainty regarding thromboprophylaxis.[3]

In light of the lack of consensus regarding prophylaxis in spinal surgery, an investigation was carried out using a prospectively collected database to review the incidence of VTE and prophylactic regimes in 107 consecutive patients undergoing elective posterior instrumented spinal fusions by a single surgeon in rural New South Wales, Australia.

Methods

A database of 107 consecutive patients who underwent elective posterior instrumented lumbar spinal fusion was reviewed. Patients were diagnosed with degenerative spondylosis and/or spondylolisthesis and had, in addition, one or more of the following indications for surgery: spinal canal stenosis, lumbar instability, facet joint disease or degenerative disc disease.

All patients were operated on by a single orthopaedic surgeon from July 2008 to July 2013. Surgery was conducted at two hospitals: the Wagga Wagga Base Hospital, a 220 bed public regional referral hospital, and Calvary Health Care Riverina, a 100 bed private hospital.

All patients were operated on in a prone position using a spinal frame. Patients underwent laminectomy and insertion of pedicle screws (linked with rods) under image intensifier guidance. Harvested bone graft was applied with

Actifuse™ to the appropriately prepared lateral gutters. Rhizolysis, foraminotomy and discectomy were undertaken as required.

Each patient was placed on a VTE prophylactic regime involving pre-operative application of below the knee TEDS and SCD. SCD were applied in the anaesthetic bay over the TEDS and were activated at the time the patient was positioned on the spinal frame. They were temporarily disconnected for transfer to the recovery unit where they were reactivated. SCD continued to operate until patient mobilisation. Patients underwent early post-operative mobilisation (day 1 or 2 post surgery). A group of patients (n=40) was also placed on low molecular weight heparin (LMWH) 4-6 hours postoperatively. There were no clear-cut selection criteria for the application of chemoprophylaxis. During the time period reported on herein, the surgeon discontinued the use of chemoprophylaxis due to the conflicting evidence in the literature and concern regarding possible complications arising from the use of chemoprophylaxis. This change in practice took some time to disseminate amongst the members of the health care teams. All patients were observed for clinical evidence of VTE and two thirds were screened for DVT on day 4 or day 5 post surgery with duplex ultrasound. A CT pulmonary angiogram (CTPA) was performed on all patients with clinical signs and/or symptoms suggestive of PE.

In addition to the presence of DVT or PE for each patient, data were collected regarding age, gender, body mass index (BMI), past medical and surgical history, previous spinal surgery, past history of VTE disease, medication use, levels of spinal fusion, operation time, units of blood transfused, use of LMWH, time to mobilisation and complications. The Caprini model[8] for thrombosis risk factor assessment was retrospectively applied to grade the level of VTE risk for each patient.

Statistical analyses were performed using SPSS Statistics Standard Edition 20 software (IBM, New York, NY, USA). Pearson's chi-square test was used for categorical variables, and independent samples t-tests were used for continuous variables. All tests were two-sided, and a p-value <0.05 was set for statistical significance. Mean (standard deviation) was reported for values with a normal distribution; otherwise median with range was reported.

Ethics approval was granted by the Human Research Ethics Committee of The University of Notre Dame, Australia.

Results

Mean patient age was 58 (± 12) years with a range of 23 to 82 years. Ninety-one percent of the studied population was over 40 years of age. Fifty-eight percent of patients were female. Mean BMI was 29.8 (± 6.1) with 83.2% having a BMI ≥25, and 47.7% a BMI ≥30. Of the cohort, 48.5% had had previous lumbar spinal surgery.

The private hospital hosted 58.9% of the operations performed. Average operating time was 279 minutes, with a range of 162 to 426 minutes. Between one and seven spinal levels were fused (median two levels). A blood

transfusion was administered in 38.3% of patients, with an average of 3.4 (± 1.7) units of packed cells transfused in these patients. All patients in this case series were followed up for a minimum of three months post surgery. No patient developed an epidural haematoma.

Mobilisation before day 3 took place in 91.6% of patients. All patients wore TEDS and SCD, while 37% also received postoperative LMWH and 69.2% received a duplex ultrasound. Figure 1 depicts the change in the pattern of use of LMWH over the studied period, which reflects the change in the practice of the surgeon described earlier. Eight patients underwent CTPA scanning for suspected PE.

Risk factors for each patient were calculated to produce an overall VTE risk score based on the Caprini model (Table 1). On reviewing the risk factors for VTE development in the patient population, 3.7% were at moderate risk, 41.1% were at high risk and 55.1% were at highest risk (Table 2). No patient fell within the low risk category because all patients underwent surgery with an operation time of greater than 45 minutes, which automatically places them above low risk.

From a total of 107 patients, only four (3.7%) had only one risk factor for VTE disease (the length of surgery itself), while 18 patients (16.8%) had two risk factors, and the remaining 85 patients (79.4%) had more than two risk factors. Only two patients (1.9%) developed distal DVTs and two other patients (1.9%) developed PEs, with a total VTE incidence of 3.7% in the studied population. One patient who developed a DVT had an incarcerated inguinal hernia surgically repaired two days after the spinal fusion operation. The DVT was detected five days after the hernia operation. One of the patients with a PE received tranexamic acid intra-operatively. None of these patients had a relevant medical history, hormone replacement therapy or oral contraceptive pill use, present of previous malignancy or history of VTE.

A comparison was undertaken between the groups who did and did not receive LMWH post-operatively. There were no differences between groups in gender, age, BMI, levels of spinal fusion, time to mobilisation or units of blood transfused. All patients sustaining a VTE event had not received LMWH, but this was not statistically significant. There was a statistically significant difference in the VTE investigation rate between the two groups (p=0.006). The group receiving LMWH had a VTE investigation rate of 57.5% compared with an 82.1% rate in the no-LMWH group.

Discussion

The results of the present study have shown that patients undergoing complex elective spinal surgery are at high risk of VTE. The incidence of VTE in these patients was, however, low (four cases in 107), equivalent to a rate of 3.7%. Although there is variability in rates of VTE reported in the literature for patients undergoing spinal surgery, the incidence of cases has generally been reported to be low. Nine recently published journal articles involving case series studies (Table 3) reported incidence rates between 0% and 26.5%, with a mean of 2.65%. Larger retrospective studies

(Table 4) have also found the incidence of VTE to be relatively low (0.1% - 0.45%). The reported incidence of VTE in these studies was probably underestimated, as asymptomatic VTE was unlikely to have been coded and therefore included. [9]

Only one previous study incorporated a comparable group and method of surveillance as the present study. It was carried out by Yoshioka et al.[10] and included 90 patients who underwent elective instrumented posterior lower thoracic or lumbar fusion for degenerative disease. This study also used mechanical VTE prophylaxis (TEDS and SCD), although no patients received chemoprophylaxis. Both studies included methods to screen for and definitively detect a VTE, however the technologies used differed between studies, with Yoshioka et al. using an additional screening tool (lung perfusion scintigraphy) and a more comprehensive imaging tool if VTE was suspected (multidetector CT venography). The incidence of VTE was found to be higher in Yoshioka et al. (13.3%) with eight distal DVTs, two proximal DVTs and two PEs. It should be noted that 16.7% of patients in the study underwent post-operative bed rest for greater than seven days and, in addition, there was a longer mean operating time (327.7 minutes). The more extensive technology used in this study may have also contributed to a higher detection rate of VTE.

Raj and Marshall[11] have described the array of local, general, pharmacological and physiological factors that put patients at an increased risk of developing a VTE. Though the Caprini model risk score may be a valuable tool in assessing individual risk factors, only one other case series looking at VTE incidence in spinal surgery has made use of it (Table 2). This study, conducted by Al-Dujaili et al.[4], included a higher proportion of low risk patients than the current study. Nevertheless, the majority of patients were found to be at high or very high risk and like the present study had a relatively low incidence of VTE (0.6%).

Analysis of the current database demonstrated that, over the time period of the study, there was a change in the pattern of use of LMWH. This provided two patient groups for comparison: one group that received LMWH and another group that had not. Although all cases of VTE in the current series occurred in patients not receiving LMWH, the difference in VTE rate between the two groups was not statistically significant. There may have been additional factors that contributed to the occurrence of VTE in two of the four patients. One VTE event occurred after a subsequent operation for an incarcerated inguinal hernia, and another occurred following administration of tranexamic acid inter-operatively, which may have caused an increased risk[12]. It is possible that chemoprophylaxis in addition to mechanical prophylaxis provides some clinical benefit, particularly in high risk patients, however this study was too small to draw this conclusion.

The current literature is also inconclusive as to whether LMWH should be given to patients undergoing spinal surgery in addition to mechanical thromboprophylaxis. It is well documented that LMWH can increase the risk of developing an epidural haematoma. Gerlach et al.[13] found that the risk of epidural haematoma was nearly eightfold greater than the risk of PE. Ozturk et al.[14] have emphasised the importance of spinal surgeons carefully assessing the

risk of using chemoprophylaxis for VTE prevention, and Sansome *et al.*[15] have concluded that the risk of VTE in spinal surgery is low, and, therefore, the risks of pharmacological prophylaxis outweigh its benefits. In this study, haematoma was not recorded as a post-operative complication in any of the patients.

The limitations of this study include its nature as a case series. Furthermore, not all patients received a duplex ultrasound, and, therefore, there may have been asymptomatic DVTs that were not diagnosed, leading to an underestimate of VTE incidence. Although retrospective application of the Caprini model risk scores may have led to incomplete patient risk scoring, due to the unavailability of some patient data, this would have only led to an underestimate of the VTE risk of the studied population. Pre-operative screening for VTE was not performed in this study. Finally, there was no randomisation involved in the use of LMWH and this limits the conclusions that can be drawn from a comparison of the groups.

There may still be a substantial number of surgeons who do not employ VTE prophylaxis in spinal surgery.[2, 9] A review of the literature and the findings from the current study lead to the conclusion that there is a high risk of VTE in patients undergoing complex spinal surgery. The overall incidence of VTE is, however, low. This suggests that currently employed mechanical prophylactic regimes are effective. Whether or not LMWH should be added to the prophylactic regime is a complex issue, because of the risk of epidural haematoma and the limited evidence of additional positive benefit.

There is a lack of clear and specific guidelines for VTE prophylaxis in elective spinal surgery. The VTE prophylaxis guidelines in Australia, provided by the National Health and Medical Research Council (NHMRC) state that all studies considered were either inconclusive or underpowered and, therefore, do not make a recommendation[1]. According to data obtained from the Australian Institute of Health and Welfare[19], 11 450 spinal fusions were conducted in Australia during the 2009-2010 financial year. Given the potential high risk of VTE in the significant number of patients undergoing spinal fusion in Australia each year, it would appear advisable to consider the use of aggressive mechanical prophylaxis in all such patients. A large, comprehensive randomised controlled trial is required to address the issue of the need for additional VTE chemoprophylaxis.

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Table 1 - VTE risk factors in patients undergoing elective instrumented posterior lumbar spinal fusion as assessed with the Caprini model risk score[4, 8]

Risk factor	Points[†]	Number of patients affected (n=107)	Percentage of population (%)
Overweight and obese (BMI ≥25)	1	89	83
Age 41 - 60 years	1	45	42
Relevant medical history (i.e. IBD, COPD or AMI)	1	13	12
HRT or OCP use	1	9	8
Age 61 - 75 years	2	45	42
Mobilised after day 3	2	9	8
Present or previous malignancy	2	6	6
Major operation (>45 min)	2	107	100
Age >75 years	3	7	6
Past history of VTE	3	5	5

†Point allocation followed the criteria outlined in Caprini *et al.* [8]

BMI, body mass index; IBD, inflammatory bowel disease; COPD, chronic obstructive pulmonary disease; AMI, acute myocardial infarct; HRT, hormone replacement therapy; OCP, oral contraceptive pill; VTE, venous thromboembolism

Table 2 - Patient distribution according to venous thromboembolism (VTE) risk factor score[4, 8]

Risk factor score	0 - 1	2	3 - 4	5+
Level of risk	Low	Moderate	High	Highest
VTE incidence[†] (%)	2	10 - 20	20 - 40	40 - 80
Percentage in studied population (%)	-	3.7	41.1	55.1
Al-Dujaili et al.[4] cohort (%)	-	31.6	55.0	13.4

†Without any prophylaxis

Table 3 - Case series and case-control studies on VTE in spinal surgery

Study	Design	Year	Sample Size	VTE event	VTE Rate (%)	VTE cases	Method of VTE Prophylaxis	Method of VTE Surveillance	Procedure Performed
Yoshioka et al.[10]	Prospective	2013	90	DVT + PE	13.3	12	TEDS + SCD	US + lung scintigraphy ± CT venography (if VTE clincally suspected)	Posterior instrumented spinal fusion
Al-Dujaili et al.[4]	Prospective	2012	158	DVT	0.6[†]	1	TEDS + LMWH ± SCD	Clinical + US	Spinal surgery excludes day procedures but includes 24% cervical
Takahashi et al.[7]	Prospective	2012	100	DVT + PE	19.0	19	TEDS + SCD	CT	Decompression or fusion
Sansone et al.[15]	Meta-analysis	2010	2838	DVT + PE	1.5	43	None or mechanical or aspirin or LMWH or warfarin	US or venography + CT or V/Q scan	Spinal surgery not limited to fusion surgery
Ozturk et al.[14]	Retrospective	2010	129	PE	1.5	2	IVC filter + TEDS + SCD	Clinical ± CT	Complex spinal surgery includes trauma and anterior approaches
			193	PE	4.2	8	Mechanical	Clinical ± CT	Complex spinal surgery includes trauma and anterior approaches
Glotzbecker et al.[3]	Systematic Review	2009	1238	DVT + PE	2.8	35	Not specified	Not specified	Lumbar spinal fusion
Nicol et al.[5]	Retrospective	2009	143	DVT + PE	1.4	2	SCD + TEDS	Clinical from records	Lumbar spinal fusion
			142	DVT + PE	0	0	SCD + TEDS + aspirin/heparin	Clinical from records	Lumbar spinal fusion
Schizas et al.[16]	Prospective	2008	244	PE	2.5	6	TEDS + LMWH	Clinical ± spiral CT	Instrumented spinal fusions
Oda et al.[6]	Prospective	2000	49	DVT	26.5	13	None	Venography	Posterior lumbar surgery
Total			5324			141			
Mean					2.65				

† Three epidural haematomas (1.8%)

VTE, venous thromboembolism; DVT, deep vein thrombosis; PE, pulmonary embolism; TEDS, thromboembolic deterrent stockings; SCD, sequential calf-compression devices; LMWH, low molecular weight heparin; IVC, inferior vena cava; US, ultrasound; CT, computer tomography; V/Q, ventilation perfusion.

Table 4 - Retrospective large medical database studies on VTE in spinal surgery

Study	Design	Year	Sample size	VTE event	VTE rate (%)	VTE cases	Method of VTE prophylaxis	Method of VTE surveillance	Procedure performed
Masuda et al.[17]	Retrospective database	2012	35524	PE	0.1	35	Mechanical	Unknown	Lumbar spinal surgery with mostly posterior approach
Senders et al.[18]	Retrospective database	2012	2107419	PE	0.2	5058	Not specified	Not specified (medical codes used)	Lumbar fusions including for spinal cord injury and fractures
Fang et al.[9]	Retrospective database	2011	80183	DVT + PE	0.45[†]	359	None or mechanical or pharmacological or combination	Not specified (medical codes used)	Spinal fusions
Total			**2223126**			**5452**			
Mean rate					**0.25**				

† rate of epidural haematoma was 1.1%

VTE, venous thromboembolism; DVT, deep vein thrombosis; PE, pulmonary embolism.