

Risk Factors for Lower Limb Deep Vein Thrombosis in Patients With Single-Level Lumbar Fusion: A Prospective Study of 710 Cases

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Abstract

Lower limb deep vein thrombosis (DVT) is not an uncommon postoperative complication of spinal fusion surgery. However, the related risk factors identified in previous studies remain controversial. This study aimed to investigate risk factors for lower limb DVT in patients with single-level lumbar fusion surgery. Between January 2010 and December 2016, a total of 710 patients undergoing lumbar fusion were recruited for this study, including 172 males and 538 females (aged 18-75 years). Deep vein thrombosis was detected by ultrasonography. Accordingly, patients were divided into the DVT group and the non-DVT group and compared in terms of operative data, underlying diseases, and biochemical data. Additionally, logistic regression analysis was performed to identify risk factors for lower limb DVT. The incidence of lower limb DVT was 11.8% (84 of 710 cases). Five patients were symptomatic, with lower limb pain and swelling. Two patients developed pulmonary embolism and 1 died. Binary logistic regression indicated that advanced age ($P = .001$, odds ratio [OR] = 2.86, 95% CI: 1.85-5.12), hypertension ($P = .006$, OR = 4.10, 95% CI: 1.09-2.30), and increased D-dimer ($P < .001$, OR = 3.49, 95% CI: 2.05-6.36) were risk factors for postoperative DVT. In conclusion, for patients with single-level lumbar fusion, advanced age, increased D-dimer, and hypertension may contribute to DVT development after spinal fusion surgery. Therefore, patients with these risk factors should be protected during the perioperative period.

Keywords

risk factor, thrombosis, lumbar fusion, DVT, VTE

Introduction

To the best of our knowledge, venous thromboembolism (VTE) is a common clinical ailment and potentially fatal to patients, comprising deep vein thrombosis (DVT) and pulmonary embolism (PE).¹ Venous thromboembolism may potentially result in a high morbidity rate, poor quality of life, and even sudden death by PE. In fact, VTE and related complications impose a heavy burden on the national health-care system.² Thus, VTE has drawn much attention and has been well studied in the past few years. Some previous studies have indicated that VTE is correlated with obesity, smoking, high blood pressure (HBP), advanced age, blood transfusion, immobilization, hospitalization, trauma, major surgery, neurological deficits, hypercoagulability, malignancy, D-dimer level, and oral contraceptive use.³⁻⁵

A study based on 2454 consecutive patients with PE reported that the 3-month mortality rate was 15%.⁶ This study revealed that risk factors relevant to death may include the

following: advanced age (at least 75 years), congestive heart failure, cancer, and chronic obstructive pulmonary disease. A later study of 15 520 consecutive patients with acute VTE, including both patients with PE and DVT, found that 6264

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patients developed symptomatic but nonmassive PE, while 248 patients developed symptomatic and massive PE.⁷ Apart from those patients, the study indicates that the predisposing factors for mortality include prolonged immobility due to neurological disorders, an age <75 years, and tumors.

It has been reported that the incidence of VTE is 25% (20/80 patients) after spinal surgery.⁸ The most important risk factor for developing postoperative VTE is reportedly preoperative walking disability. Another retrospective study reported the prevalence of VTE to be 17% (147/861 patients) after spinal surgery, and the important risk factors for developing postoperative VTE were advanced age, increased D-dimer, and hypertension.⁵ In addition, Japanese researchers reported that the incidence of VTE (n = 79) was 10.1% among patients with single-level lumbar spondylolisthesis treated with spinal fusion surgery.⁹ In addition, the prevalence of VTE after degenerative spinal surgery in patients differs by surgical site and surgical procedure, such as in patients with cervical or thoracolumbar degenerative disease, lumbar spinal stenosis, or single-level lumbar spondylolisthesis treated with single posterior decompression surgery or fusion surgery. However, few prospective studies with large samples have focused only on single-level lumbar fusion and DVT risk.

As such, this study was prospectively designed to focus on the current occurrence of lower limb DVT among patients undergoing only single-level lumbar fusion surgery, identify the risk factors related to lower limb DVT, and provide a better understanding of lower limb DVT in patients with single-level lumbar fusion.

Methods

Patient Population

This study was performed in our hospital with approval from the institutional ethics board, and written informed consent was obtained from all the patients. Between January 2010 and December 2016, patients undergoing single-level lumbar fusion were recruited for this study. Medical data, including baseline population demographics and characteristics, operative data, underlying diseases, and routine biochemical parameters, were collected. Biochemical parameters were analysed before surgery. All enrolled patients were routinely inspected via lower extremity ultrasonography preoperatively and 7 days postoperatively. After spinal fusion surgery, surgical site drainage was normally adopted. All patients received prophylactic treatment with 5000 UI low-molecular-weight heparin (LMWH) per day until they could walk. Meanwhile, the patients were encouraged to perform lower limb exercises to improve blood circulation. The exclusion criteria included the following: (1) no lumbar interbody fusion; (2) preoperative DVT; and (3) anticoagulant drug use within 1 week before surgery. Patient age, sex, disease history, biochemical data, surgical data, and VTE data were all collected and analyzed in this study.

Table 1. Clinical Characteristics of All Patients.

Items	DVT Group	Non-DVT Group	P Value ^a
No. of patients (%)	84 (11.8%)	626 (88.2%)	–
Age, years	64 (IQR: 10)	53 (IQR: 8)	.015
Sex (M:F)	23:61	149:477	.662
BMI, kg/m ²	24.53 (IQR: 4.18)	22.15 (IQR: 4.24)	.098
Hospital stay, days	14 (IQR: 5)	12 (IQR: 6)	.635

Abbreviations: BMI, body mass index; DVT, deep vein thrombosis.

^aMann-Whitney *U* test was applied for data analysis of age, BMI, and hospital stay. χ^2 test was applied for data analysis of sex.

Statistics

Statistical analyses were carried out with SPSS software 18.0 (IBM SPSS Inc, Chicago, Illinois). All measurement data are expressed as the mean (standard deviation) or median (interquartile range [IQR]) when applicable. Statistical analyses were performed by Student *t* test or the Mann-Whitney *U* test when applicable. All count data are presented as frequencies, and the χ^2 test was applied for data analysis when applicable. Logistic analysis was used to determine the relationship between VTE and potential risk factors. The regression conditions were as follows: backward (likelihood ratio [LR]) and stepwise probability (entry, 0.10; removal, 0.15). The logistic regression equation is presented as $\text{logit } P = X_0 + A \times X_1 + B \times X_2 + C \times X_3$, (X_0 = constant; X_1, X_2, X_3 = risk factors). The equation was statistically determined by the Pearson χ^2 test. Two-tailed *P* values <.05 were considered significant.

Results

General Patient Data

A total of 710 patients who underwent single-level lumbar fusion surgery were identified and included in this study, including 172 males and 538 females (aged 18-75 years). For all patients, the median hospital stay was 12 (IQR: 5) days. Of all included patients, 84 (11.8%) developed postoperative DVT. Five (0.7%) patients were symptomatic, with lower limb pain and swelling. Two (0.3%) patients developed PE and 1 died. The rest of all the 84 patients with DVT were asymptomatic.

As shown in Table 1, the patient's age in the DVT group was 64 (IQR: 10) years, which was different from that in the non-DVT group, at 53 (IQR: 8) years ($P = .015$). Of the 84 patients with postoperative DVT, 23 were males and 61 were females. There was no significant difference regarding sex ($P = .662$) between the DVT and non-DVT groups. The body mass index (BMI) was applied as a weight to height ratio in all patients and was 24.53 (IQR: 4.18) in the DVT group and 22.15 (IQR: 4.24) in the non-DVT group ($P = .098$). In addition, there was no significant difference regarding hospital stay between the 2 groups ($P = .635$). Other information regarding the 84 postoperative patients with DVT is shown in Table 2.

Table 2. Information of the 84 Postoperative Patients With DVT.

Items	Data in Detail
No. of DVT sites	68 patients with single site; 10 with double sites; 6 with 3 or more
Distribution of DVT	DVT in calf intermuscular veins with 65 patients; femoral vein 1 patient; popliteal vein 2 patients; anterior tibial veins 6 patients; posterior tibial veins 12 patients; fibular veins 23 patients
Fusion levels	41 cases with L4-5 level, 32 with L5-S1 level, 5 with L3-4 level, 4 with L2-3 level, and 2 with L1-2 level

Abbreviation: DVT, deep vein thrombosis.

Table 3. Comparison of Operation Data Related to Postoperative DVT.

Items	DVT Group (84 Cases, 11.8%)	Non-DVT Group (626 Cases, 88.2%)	Mann-Whitney U Test	
	Median (IQR)	Median (IQR)	Z Value	P Value
Surgical duration	165 (101) min	172 (75) min	-0.237	.813
Blood loss	600 (525) mL	600 (500) mL	-0.048	.961
Blood transfusion	325 (400) mL	300 (400) mL	-0.167	.867
Incision length	15 (10) cm	16 (5) cm	-0.911	.362

Abbreviations: DVT, deep vein thrombosis; IQR, interquartile range.

Table 4. Comparison of Underlying Disease History Associated With Postoperative DVT.

Diseases	DVT Patients (84 Cases, 11.8%)	Non-DVT Patients (626 Cases, 88.2%)	P Value ^a
HBP	25 (3.5%)	95 (13.4%)	.001
DM	8 (1.1%)	58 (8.2%)	.912
HD	14 (2.0%)	107 (15.1%)	.922

Abbreviations: DVT, deep vein thrombosis; DM, diabetes mellitus; HBP, high blood pressure; HD, heart disease.

^a χ^2 test was applied for data analysis.

Comparison of Surgical Data

The operative data included the duration of the operation, perioperative blood loss volume, need for blood transfusion, and surgical incision length; there were no significant differences between the DVT and non-DVT groups in any of the above-mentioned surgical parameters (all $P > .05$) as shown in Table 3.

Underlying Disease History

As shown in Table 4, comparisons were made regarding underlying diseases between the 2 groups, including HBP, diabetes mellitus (DM), and heart disease (HD). The HBP distribution

Table 5. Biochemical Analyses Related to Postoperative DVT.

Items	DVT Group (84 Cases, 11.8%)	Non-DVT Group (626 Cases, 88.2%)	P Value ^a
PTA	112% \pm 15%	112% \pm 16%	.862
HDL	1.23 \pm 0.24 mmol/L	1.12 \pm 0.25 mmol/L	.133
LDL	3.07 \pm 0.80 mmol/L	3.16 \pm 0.77 mmol/L	.689
FIB	3.05 (0.62) g/L	2.82 (0.97) g/L	.239
TT	14.95 (2.75) s	14.7 (1.5) s	.674
D-BIL	3.80 (1.25) μ mol/L	3.55 (1.90) μ mol/L	.970
I-BIL	8.80 (3.58) μ mol/L	8.30 (4.00) μ mol/L	.861
TC	4.76 (1.37) mmol/L	4.76 (1.09) mmol/L	.891
T-BIL	12.20 (5.98) μ mol/L	12.00 (5.50) μ mol/L	.945
D-dimer	0.23 (0.19) mg/L	0.13 (0.12) mg/L	.018

Abbreviations: DVT, deep vein thrombosis; PTA, prothrombin time activity; HDL, high-density lipoprotein; LDL, low-density lipoprotein; SD, standard deviation; FIB, fibrinogen; TT, thrombin time; TC, total cholesterol; T-BIL, total bilirubin; D-BIL, direct bilirubin; I-BIL, indirect bilirubin.

^aStudent t test was applied for data analysis of PTA, HDL, and LDL. Mann-Whitney U test was applied for data analysis of FIB, TT, D-BIL, I-BIL, TC, T-BIL, and D-dimer.

was different between the DVT and non-DVT groups ($P = .001$), while no significant differences were found between the DVT and non-DVT groups in the other parameters, including DM and HD (all $P > .05$).

Biochemical Data Analyses

As shown in Table 5, biochemical data were compared between the DVT and the non-DVT groups. The D-dimer level was found to be significantly different between the 2 groups ($P = .018$), while there were no differences in any of the other biochemical parameters (all $P > .05$).

Logistic Regression Analysis

In this analysis, all patients were grouped into 4 categories according to their age (~ 45 , $45 \sim 54$, $55 \sim 64$, and $65 \sim$ years). The regression conditions were as follows: backward (LR) and stepwise probability (entry, 0.10; removal, 0.15). As shown in Table 6, binary logistic regression indicated that advanced age ($P = .001$, odds ratio [OR] = 2.86, 95% CI: 1.85-5.12), hypertension ($P = .006$, OR = 4.10, 95% CI: 1.09-2.30), and increased D-dimer ($P < .001$, OR = 3.49, 95% CI: 2.05-6.36) were risk factors for postoperative DVT. The logistic regression equation was as follows: $\text{logit } P = -3.12 + 1.05 \times X_1 + 1.41 \times X_2 + 1.25 \times X_3$ ($X_1 =$ age; $X_2 =$ hypertension; $X_3 =$ D-dimer). The equation was statistically significant by the Pearson χ^2 test ($P < .001$).

Discussion

In our study, the incidence of lower limb DVT was 11.8% (84 out of 710 cases) among patients who underwent single-level lumbar fusion; this result is similar to the incidence reported in a previous study. Yang et al⁵ revealed that the DVT incidence was 17% (147/861 patients) after spinal surgery, including

Table 6. Binary Logistic Regression Analysis Regarding VTE Development.

No.	Items	B	Exp (B)	P Value	95% CI for Exp (B)
X1	Age	1.05	2.86	.001	1.85-5.12
X2	HBP	1.41	4.10	.006	1.09-2.30
X3	D-dimer	1.25	3.49	<.001	2.05-6.36
X4	Incision	-0.15	0.86	.228	0.53-1.56
X5	FIB	-0.05	0.95	.847	0.65-1.43
X6	HDL	0.09	1.09	.319	0.79-1.82
X7	BMI	0.34	1.40	.237	0.92-2.63
X0	Constant	-3.12	0.04	.000	—

Abbreviations: BMI, body mass index; CI, confidence interval; DVT, deep vein thrombosis; FIB, fibrinogen; HBP, high blood pressure; HDL, high-density lipoprotein; VTE, venous thromboembolism.

fusion and nonfusion surgery. However, they reported in another study¹⁰ that the rate of lower limb DVT detection by ultrasonography was 22.4% (223/995) in patients who underwent lumbar interbody fusion; the same authors reported 2 different results regarding the incidence of lower limb DVT. Perhaps they performed different surgical procedures for various spinal diseases, such as cervical spondylopathy, thoracic diseases, and lumbar disc degenerative diseases, which were evaluated together. Herein, it is apparent that ultrasonography is a crucial screening method for the detection of DVT in clinical situations. With the help of ultrasonography, clinicians can identify DVT at an early stage and take appropriate measures, which are especially helpful in cases of lethal, asymptomatic DVT that may lead to PE. Hence, the regular use of ultrasonography pre- and postoperatively is warranted for the early detection of DVT.

Yoshioka et al⁹ reported that the incidence of VTE was up to 10.1% among patients with lumbar spondylolisthesis who underwent 1-level lumbar interbody fusion surgery. They also found that advanced age, the female sex, the spinal level, and neurological deficits were possible risk factors for VTE development. Our study was expected to identify possible risk factors related to lower limb DVT and to assess the risk of this condition in patients after single-level fusion surgery. Interestingly, our results are consistent with those above, with no differences in terms of DVT incidence among patients undergoing 1-level fusion surgery. As we have observed in clinical practice, most cases of DVT form and develop in distal regions, consistent with the results of a previous study by Yoshioka et al⁹ They reported a distal DVT incidence of 85.7% (30/35). In addition, we have found in our daily clinical work that most DVT cases occur in calf intermuscular and fibular veins as reported in this study.

As a consequence, the incidence of DVT detected by ultrasonography in this study was 11.8% (84 of 710 cases) among patients after single-level lumbar fusion surgery. Five patients were symptomatic with lower limb pain and swelling. Two patients developed PE and 1 died. All comparisons of operative data, including the operation duration, perioperative blood loss volume, and surgical incision length, revealed no differences

between patients with or without DVT. In addition, no significant differences were found in other variables, including biochemical parameters, between the 2 groups. However, binary logistic regression indicated that advanced age, HBP, and increased D-dimer were risk factors for postoperative DVT, which is an interesting result that could be explained by the following. First, older patients generally move less after spinal fusion surgery, which is a contributing factor for the development of DVT. Second, prolonged HBP damages the vessel endothelium, contributing to the formation of DVT. In addition, a high D-dimer level indicates a state of hypercoagulability, which is undoubtedly another contributing factor for DVT development. However, these are not novel risk factors that may fill a knowledge gap; instead, they represent the strong confirmation of previous findings.

Regarding risk factor analyses, Yang et al^{5,10} found that the possible risk factors contributing to postoperative VTE development are advanced age, increased D-dimer level, hypertension, high visual analogue scale score, and blood transfusion, while the region distribution and high-density lipoprotein level are likely to be protective factors. A recent study¹¹ reported that DVT was detected in 9.4% (269/2861) of patients after posterior lumbar surgery. Advanced age, preoperative D-dimer level, and history of rheumatoid arthritis were identified as risk factors related to DVT development after posterior lumbar surgery. In a multicenter study including only elderly (>80 years) patients who underwent lumbar decompression, increased age was correlated with some minor complications, including VTE development.¹²

A recent retrospective study¹³ investigated 43 777 patients who underwent thoracolumbar surgery. Among these patients, 202 (0.5%) cases of PE and 311 (0.7%) cases of DVT were identified. Multiple risk factors for VTE were identified in the study, including disseminated cancer, length of stay (LOS) ≥ 6 days, paraplegia, albumin < 3 , white blood cell count > 12 , BMI > 40 , American Society of Anesthesiologists class 4 or greater, and operative time > 193 minutes; LOS < 3 days was considered a protective factor. Interestingly, another study¹⁴ reported similar results; this study included a large group of patients who underwent spinal surgery ($n = 22\ 434$). The rate of VTE in the cohort was 1.1% (PE, 0.4%; DVT, 0.8%). Why does the incidence of DVT in these 2 studies seem so low? These results seem low because the studies only identified cases of symptomatic DVT and never investigated asymptomatic DVT. In contrast, our study screened all patients for DVT by ultrasonography regardless of whether they were symptomatic. Thus, the DVT incidence is much higher (11.8%) in comparison.

In a prospective study¹⁵ of 100 children, no cases of DVT were found by ultrasound in 91 patients; the other 9 patients were lost to follow-up. While the study may be underpowered for generating a definitive incidence, the obtained data suggest that the risk of VTE is very low in children who undergo elective neurosurgical procedures. Therefore, prophylactic protocols designed for adults should not be applied to pediatric patients.

Most previous studies performing a risk assessment of VTE development have focused on hospitalized patients. However, 3 of 4 VTE events arise outside hospitals.¹⁶⁻¹⁸ Furthermore, factors that affect VTE are often found to be associated with a previous hospital stay.¹⁹ Thus, when investigating risk factors for VTE, the continuity of VTE development should be considered. It is essential and very important to establish a complete prophylaxis strategy for VTE after an operation regardless of the hospital stay duration and time since discharge from the hospital. As previously reported, patients at a moderate or high risk of VTE development require regular prophylaxis, typically with preventive doses of anticoagulant agents, such as LMWH.³

The current situation regarding VTE prophylaxis is not optimistic. Nearly two-thirds of all VTE events are due to hospitalization, but only one-third of all hospitalized patients with risk factors are prophylactically treated to an adequate extent.²⁰ Currently, there are 2 types of prophylactic treatment for VTE: one is mechanical prophylaxis, which can provide intermittent pneumatic compression to lower limb muscles and the vasculature to promote blood circulation, and the other is pharmacological prophylaxis, primarily including anticoagulant drugs, such as LMWH.²¹ However, the effect of prophylactic LMWH treatment for VTE remains a matter of debate^{4,5,22} and requires further investigation. Additionally, there is a lack of appropriate prophylactic protocols for DVT after spinal surgery. We generally use different methods to prevent DVT after spinal surgery, including mechanical prophylaxis (intermittent pneumatic compression and compression stockings) as well as anticoagulant drugs (often LMWH). An additional effective method is to encourage patients to undergo rehabilitation training as early as possible.²³ This training includes 2 different types of procedures: one is regular physical activity, such as walking and the other is lower limb rehabilitation training gymnastics on a daily basis, which has been reported to be effective prophylactically for DVT after spinal surgery.²³

In summary, advanced age, increased D-dimer, and hypertension may contribute to DVT development after single-level lumbar fusion surgery. This study contributes to a better understanding of the risk of lower limb DVT.

Compliance With Ethical Standards

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

Authors' Note

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Declaration of Conflicting Interests

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