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Investigation of Venous Thromboembolism Prophylaxis Practices in Spinal Fusion Surgery and Outcomes: A Single Center Experience

Spinal Füzyon Cerrahisinde Venöz Tromboemboli Profilaksisi Uygulamalarının ve Sonuçlarının İncelenmesi: Tek Merkez Deneyimi

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Abstract

Aim: Venous thromboembolism (VTE) is among the most common causes of preventable hospital-acquired deaths. VTE is known as deep vein thrombosis (DVT) when it occurs in the veins and pulmonary embolism (PE) when it occurs in the lungs and is common in surgery practice. We aimed to determine the frequency of venous thromboembolism (VTE), the factors affecting the development of VTE, and the types and effectiveness of VTE prophylaxis applications in patients who underwent spinal fusion surgery (SFS).

Material and Methods: The patients aged over 18 who underwent SFS for spinal fracture or thoracolumbar stenosis in our neurosurgery clinic between June, 2020 and December, 2022 were included. The patients records were evaluated retrospectively. VTE prophylaxis was given according to the Caprini risk score.

Results: A total of 137 patients, 85 (62%) of female, with a meanage of 48.6±+8.77 years were included in the study. According to the Caprini risk scores, 90 (65.7%) of the cases were at high risk. VTE was detected in four patients (2.9%) despite prophylaxis (3 cases of DVT and one pulmonary embolism).

Conclusion: Although VTE prophylaxis is performed according to Caprini risk score in SFS, it is seen that embolisms cannot be prevented sufficiently. Therefore, studies with a high level of evidence are needed for the use of these algorithms in SFS.

Keywords: Caprini score, prophylaxis, spinal fusion surgery, venous thromboembolism

Öz

Amaç: Venöz tromboembolizm (VTE), önlenebilir hastane kaynaklı ölümlerin en yaygın nedenlerinden biridir. VTE, damarlarda meydana geldiğinde derin ven trombozu (DVT), akciğerlerde meydana geldiğinde pulmoner emboli (PE) olarak bilinir ve cerrahi pratikte sık görülür. Spinal füzyon cerrahisi (SFS) uygulanan hastalarda VTE sıklığını, gelişimini etkileyen faktörleri ve profilaksisi uygulamalarının türlerini ve etkinliğini belirlemeyi amaçladık.

Gereç ve Yöntem: Nöroşirürji kliniğimizde Haziran 2020 ile Aralık 2022 tarihleri arasında omurga kırığı veya torakolomber darlık nedeniyle SFS uygulanan 18 yaş üstü hastalar dahil edildi. Hasta kayıtları retrospektif olarak değerlendirildi. Caprini risk skoruna göre VTE profilaksisi verildi.

Bulgular: Çalışmaya ortalama yaşları 48.6±+8.77 olan 85'i (%62) kadın olmak üzere toplam 137 hasta dahil edildi. Caprini risk skorlarına göre olguların 90'ı (%65,7) yüksek riskli idi. Profilaksiye (3 DVT ve 1 pulmoner emboli) rağmen dört hastada (%2,9) VTE saptandı

Sonuç: SFS'de VTE profilaksisi Caprini risk skoruna göre yapılmasına rağmen embolilerin yeterince önlenemediği görülmektedir. Bu nedenle bu algoritmaların SFS'de kullanımı için kanıt düzeyi yüksek çalışmalara ihtiyaç vardır.

Anahtar Kelimeler: Caprini skoru, profilaksi, spinal füzyon cerrahisi, venöz tromboembolizm

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INTRODUCTION

Venous thromboembolism (VTE) is among the most common causes of preventable hospital-acquired deaths.[1] VTE is known as deep vein thrombosis (DVT) when it occurs in the veins and pulmonary embolism (PE) when it occurs in the lungs and is common in surgery practice. Increased risk of VTE due to prothrombotic conditions triggered during surgery, perioperative venous stasis and immobility of patients in the postoperative period. In addition, delayed mobilization of patients due to postoperative pain and neurological problems in spinal fusion surgery (SFS) also increases the risk of VTE.[2] Upto 600,000 hospital admissions for DVT and PE and a mortality rate of upto 50,000 occur annually in the United States of America (USA), with a significant portion of these coming from orthopedic surgical procedures.[3]

VTE thromboprophylaxis in SFS is still controversial. In the last decade, several studies have analyzed VTE prophylaxis, but there is no consensus on the timing and effective use of these interventions.[4] The estimated incidence of VTE after spine surgery varies between 0.2-31% according to different studies.[5] This rate has been reported to be 50-100% in traumatic spinal cord injury patients.[6] There are two main categories of risk variables that raise incidence of VTE: patient-related risk factors and surgery-type-related risk factors. Among the factors related to patients, the presence of multiple trauma, active cancer disease, and spinal cord injury are considered high risk.[7] Many other risk factors such as age, hypertension, diabetes mellitus, hyperlipidemia, heart failure, and body mass index may also be effective.[8] Therefore, certain classifications have been made and put into practice to determine the risk of VTE and to apply prophylaxis.[9] There are mechanical and pharmacologic applications in VTE prophylaxis in spinal fusion surgeries. However, bleeding may ocur during or after surgery in pharmacologic VTE prophylaxis applications. Therefore, the decision for VTE prophylaxis is of great importance.[10] Despite the existence of several efficient mechanical and pharmacological thromboprophylaxis therapies, it is stil unclear how these procedures fit into SFS. To balance, the danger of mortality from a thromboembolic consequence, spine surgeons must make a tough choice.[11] However, less is known about ideal applications of chemoprophylaxis for SFS. Due to the relative paucity of good quality evidence on the efficacy and safety of VTE prophylaxis in SFS, surgeons' clinical practice varies widely and is often based on surgeons' experience.[10]

In this study, we sought to reveal the frequency of VTE, the factors affecting the development of VTE and effectiveness of VTE prophylaxis applications in patients who underwent SFS.

MATERIAL AND METHOD

Patient Selection

This study was carried out in compliance with the principles of the Declaration of Helsinki upon the approval dated April 01, 2023 and numbered 2023/01-19 of the Clinical Research Board of Ethics of the Faculty of Medicine. In the present study, the patients aged over 18 who underwent SFS for spinal fracture or thoracolumbar stenosis in our neurosurgery clinic between June, 2020 and December, 2022 were included. The patient's records were evaluated retrospectively.

Exclusion Criteria

Patients with a previous history of VTE and patients under the age of 18 were excluded from the study. In addition, patients with cervical fractures or cervical stenosis who underwent SFS were excluded from the study.

Surgical Method and VTE Prophylaxis

SFS is considered a major surgical procedure. All SFS patients were operated on in the prone position. Patients were divided into short-segment SFS (two levels) or long-segment SFS (≥3 levels).

Compression stockings or elasticbandages were applied to all patients for VTE prophylaxis in the perioperative period. All operated patients were mobilized on the first day of the post operative period (early postoperative period). According to Caprini scoring, LMWH was given to high-risk patients. We did not give LMWH if they were not high-risk and did not have other underlying diseases.

Caprini Risk Assessment Model

The Caprini Risk Assessment Model (RAM) was initially developed for both surgical and medical patients. Despite the fact that there is strong evidence to support its validity in surgical patients.[11] More than 100 clinical trials conducted world wide involving more than 250 000 patients validated the Caprini RAM. The correct completion of the Caprini RAM determines the best course of treatment in the end. In every patient group where it has been fully evaluated, the VTE rate climbs exponentially as the numerical score rises.[12,13] To ensure uniformity and accuracy of scoring, completion guidelines were developed as a result of this procedure. The 2013 Caprini RAM offers a reliable, comprehensive, and effective method for VTE prophylaxis selection and risk stratification.[12]

Data collection

Clinical data and radiological examinations of patients hospitalized in the Department of Neurosurgery who underwent SFS for a spinal fracture, spinal stenosis, or spondylolistesis were retrospectively analyzed. Age, gender, clinical and neurologic status at the time of admission, comorbidities, cause of surgery, type of surgery, duration of surgery, type of VTE prophylaxis, additional risk factors Hypertension (HT), diabetes mellitus (DM), coronary arterial disease (CAD), cerebrovascular disease (CVD), history of antiaggregant drugs, body mass index, platelet level, albumin level and types of medical treatments of VTE were recorded from the hospital information recording system. In addition, the effectiveness of VTE prophylaxis were investigated.

Statistical Method

The IBM SPSS 23 Windows package program was used to analyse this study's data. Demographic and proportional distributions of the subjects included in the study population were calculated as percentages. After using Kolmogorov-Smirnov to determine whether the data were normally distributed, non-parametric analysis techniques were utilized to do the analysis. Mann Whitney U Test was used for comparative statistics of the groups with each other (such as analyzing the length of hospital stay according to gender). The Cross Tabulation Chi-square test was used to reveal the relationships between the groups. "Spearman" test was used in the correlation analysis of the continuous variables in the groups. In the application of correlation tests, each group was separated with a split file and analyzed. Cross Tabulation Chi-square test was used to reveal the relationship between risk factors and Caprini risk groups. In the comparative statistical analysis of hospital stay and surgery duration by gender, the Mann Whitney U test was implemented. Correlation analysis was performed between split file and continuous variables. In the interpretation of statistical results, $p<.05$ values were accepted as significant.

RESULTS

A total of 137 patients, 85 (62%) of female, with a mean age of 48.6±8.77 years were included in the study. VTE was detected in four patients (2.9%) despite prophylaxis. **Table 1** summarizes the characteristics of the patients and the frequency of VTE. The BMI of 69 patients (50.4%) was between 31-35 (**Table 2**).

Table 1. Demographic characteristics of the cases

	N	%
Gender		
Female	85	62.0
Male	52	38.0
Surgery indication		
Vertebral fracture	28	20.4
Spondylosis	109	79.6
Type of surgery**		
Short-segment SFS	23	16.8
Long-segment SFS	114	83.2
VTE subtype		
None	133	97.1
DVT	3	2.2
PE	1	0.7

*DVT: deep vein thrombosis, PE: pulmonary embolism, VTE: Venous thromboembolism, ** Short-segment SFS (two levels) or long-segment SFS (≥3 levels).

Table 2. Distribution of patients according to BMI groups

BMI	N	%
20-25	6	4.4
26-30	30	21.9
31-35	69	50.4
36-40	30	21.9
41 and over	2	1.5

*BMI: body mass index

Hypertension was the most common co-morbidity and it was detected in 51 (37.2%) cases (**Table 3**).

Table 3. Distribution of patients according to underlying co-morbidities

Co-morbidities	N	%
None	43	31.4
HT	51	37.2
DM	16	11.7
CVD	4	2.9
CAD	15	10.9
Antiaggregant use	8	5.8

*CAD: coronary arterial disease, CVD: cerebrovascular disease, HT: hypertension, DM: diabetes mellitus.

According to the Caprini scores, 90 (65.7%) of the cases were at high risk (**Table 4**).

Table 4. Distribution of cases according to Caprini score

Caprini Score	n	%
Very low risk	0	0
Low risk	4	2.9
Moderate risk	43	31.4
High risk	90	65.7

Depending on the type of operation, the included patients were divided into different groups. In long-segment patients, the duration of operation increased, hospital stay increased and albumin levels decreased. In patients who underwent long-segment surgery, the duration of hospital stay increased when the operation time increased ($p<0.01$), and the albumin levels of these patients were also lower $p<0.05$. In patients who underwent short-segment surgery, there was no statistical significance between the duration of hospital stay and albumin levels. There was no significant correlation between Caprini low risk group and operation time, albumin level, platelet count, and length of hospital stay.

In the Caprini medium-risk group, there was a significant correlation in the direction of an increase in the length of hospital stay only as the operation time increased ($p<0.01$). In the Caprini high-risk group, it was observed that the operation time increased with age ($p<0.05$).

Hospital stay and operation times were compared according to gender. It was observed that male (6.9±3.6 days) had a significantly shorter hospital stay than female (8.4±3.2 days) ($p<0.01$). On the other hand, female (3.8±1.2 hours) had a shorter operation times than male (4.0±1.5 hours), but this difference was not statistically significant ($p>0.05$).

According to Kruskal-Wallis test results, there was no significant relationship between the presence of additional risk factors and the development of VTE ($p>0.05$). In addition, there was no significant relationship between additional risk factors and albumin and thrombocyte levels ($p>0.05$). Among subjects without risk factors, the proportion of those with moderate Caprini risk level (n=25, 58%) was significantly higher than those with high Caprini level (n=14, 32.6%) ($p<0.001$).

When the Caprini scores of hypertensive patients were analyzed, the number of patients with high Caprini scores (n=40, 78.4%) was significantly higher than those with moderate risk (n=11, 21.6%) ($p<0.001$). All of those with CAD (n=15, 100%) and a history of antiaggregant use (n=8 ,100%) were in the high-risk group according to the Caprini score ($p<0.001$). Patients with CVD and diabetes mellitus as risk factors had similar Caprini scores, with no noticeable statistically difference ($p>0.05$).

There was no significant relationship between the BMI categories of the subjects with HT, CVD, CAD, or antiaggregant use. However, when the BMI categories of 16 DM cases were compared, BMI=31-35 (n=6, 37.5%) and BMI=36-40 (n=7, 43.8%) were clustered and there was a significant difference between them and the others ($p<0.05$).

DISCUSSION

Statement Of Principal Findings

In our patients included in this study who underwent SFS, we found 4 (3 DVT, 1 PE) VTE in 2.9%, although thromboembolism prophylaxis was performed according to the Caprini score. These VTE incidence results we obtained are relatively lower than the literature. Prophylaxis in SFS operations, even if it is done according to the Caprini score, can reduce VTE even if it does not completely prevent it, so it also helps to reduce morbidity rates.

Interpretation within the Context of the Wider Literature

According to the findings of previous studies, surgical patients appear to be at a higher risk than medical patients for VTE, with over half of all hospitalized patients globally at risk. Moreover, only 50% of at-risk patients got a prophylactic treatment suggested by the American Society of Hematology 2019 guidelines for management of venous thromboembolism: prevention of venous thromboembolism in surgical hospitalized patients.[14] Prior research revealed that rates of total VTE prevention ranged from 13% to 64%.[14-16] Given the varied character of the scant studies that have been published in the literature, it is challenging to estimate the true incidence eventhough DVT and PE are quite uncommon regardless of the kind of prophylaxis. Given the relatively high probability of fatal PE, a new meta-analysis hypothesizes that chemoprophylaxis may be involved.[17] In the USA, PE, DVT, and VTE are the most common avoidable causes of cardiovascular disease and the main cause of preventable mortality after surgery. Many immediate and long-term problems are connected to postoperative VTE.[18] For all these reasons we have planned this study. In our study, we aimed to retrospectively evaluate our VTE prophylaxis practices in SFS, which is considered major surgery and to reveal the characteristics of patients who developed VTE despite these practices. In this study including 137 patients who underwent SFS, VTE was detected in four (3 DVT,1 PE) patients. Mortality did not develop in any patient.

The American Society of Hematology 2019 guideline offered conditional recommendations against inferior vena cava filters, no prophylaxis for mechanical prophylaxis, and graded compression stockings for pneumatic compression prophylaxis for patients undergoing major surgery. Conditional recommendations for patients undergoing total hip or total knee arthroplasty included the use of acetylsalicylic acid or anticoagulants, direct oral anticoagulants rather than LMWH. Using LMWH or unfractionated heparin, the recommendation advocated pharmacologic prophylaxis for major general surgery over no prophylaxis. The use of pharmaceutical prophylaxis prior to major neurosurgery, transurethral prostate resection, or radical prostatectomy is discouraged by this guideline. According to this recommendation, pharmacologic prophylaxis was preferable to no prophylaxis for major gynecologic or trauma surgeries.[14] Patients included in the present study received VTE prophylaxis according to the Caprini RAM. A total of 90 patients (65.7 %) were in the high risk group according to Caprini score. For VTE prophylaxis, LMWH (Nadroparin, is an anticoagulant belonging to a class of drugs called LMWH) was preferred. Compression stockings or elastic bandages were applied to all patients for VTE prophylaxis in the peri-operative period. All operated patients were mobilized on the first day of the postoperative period. Although an increase in the length of hospital stay and a decrease in albumin levels were observed in our long-segment SFS patients, there was no significant relationship between the length of hospital stay and albumin levels in short-segment SFS patients.

In a meta-analysis study conducted by Chao Zhu et al. in 2020 on spinal surgery, it was reported that the prolongation of the operation time was effective in the decrease in hemoglobin and albumin levels and the development of postoperative delirium.[19]

According to a meta-analysis published in 2021 that included a total of 8373 patients, there was a significant difference between groups in the incidence of postoperative DVT, but not in the incidence of VTE. Both groups had a low incidence of serious bleeding episodes and spinal epidural hematomas.[20] The general strategy for non-orthopedic surgery continues to be the evaluation of the thrombosis risk with the advice to utilize a risk assessment instrument like the modified Caprini score. In non-orthopedic surgery, LMWH seems to be more effective for VTE prevention than unfractionated heparin. Recent trials have shown acetylsalicylic acid as a viable choice for VTE prevention following total hip, total knee, and hip fracture surgery in orthopedics. Prolonged prophylaxis with LMWH lowers the risk of symptomatic VTE in high-risk abdominal and pelvic cancer surgeries without noticeably raising the risk of bleeding, and it lowers the risk of symptomatic VTE in major orthopedic surgeries but results in more mild but manageable bleeding.[21] In our study, severe bleeding episodes and spinal epidural hematoma were not detected in any patient receiving LMWH for VTE prophylaxis.

A similar study[21] involving 107 patients found that despite having a high risk of VTE, patients under going elective instrumental posterior lumbar spinal fusion actually have a very low incidence of VTE. In order to prevent VTE complications in these patients, this study's data support use of mechanical prophylaxis with thromboembolic prevention stockings and calf compression devices.[22] Another similar study examined 2366 elective spinal procedures in 2181 adults over all. All patients were provided with anti-embolic stockings, early mobilization, and properhydration. Additionally, 29% of patients (689) received LMWH while they were hospitalized. A peri-operative protocol that includes anti-embolic stockings, hydration, and early postoperative mobilization has been shown to significantly lower the incidence of VTE, and the addition of LMWH is safe in patients who are at high risk of developing VTE.[23] In our study, all patients received mechanical thromboprophylaxis. However, differently, we also applied medical prophylaxis according to the Caprini score. Despite all these, the rate of VTE developed, albeit at a low rate.

The variety in the way that the Caprini RAM is implemented between centers limits its effectiveness. In terms of the number of risk categories employed, the cut points used to define the risk categories, the result being monitored, and the follow-up period, the score-derived VTE risk classification exhibits substantial variety. This influences the clinical and scientific implications of the findings since it causes equivalent risk groups to be linked with differing VTE rates. There is a need for studies that verify the Caprini RAM in a large population of medical and surgical patients, designate standard risk categories, define risk of DVT and PE as different end objectives, and assess outcomes at defined follow-up time periods in order to improve generalize ability.[24, 25]

However, a more effective score other than this score has not been defined in the current literature. Therefore, we examined the relationship between this score and other factors that may be effective in the development of VTE such as underlying diseases, BMI, albumin level, surgical method, length of hospital stay, and gender according to the Caprini score. In the Caprini risk classification, there was no significant correlation between low risk and operation time, albumin level, platelet count, and length of hospital stay. However, our cases with BMIs between 31 and 40 had high Caprini scores, and this elevation also leads to an increase in the risk of VTE. It is known that high BMI is one of the factors that increase the risk of VTE, and our result was compatible with the literature.[26,27] However, there was no significant relationship between the patients' BMI categories and the use of HT, CVD, CAD and antiaggregant use.

Implications For Policy, Practice And Research

In the Caprini medium-risk group, there was a significant correlation in the direction of an increase in the length of hospital stay only as the operation time increased. In the Caprini high-risk group, the duration of surgery was observed to increase significantly with age. It is seen that Caprini scores of patients with history of antiaggregant use and hypertension are higher.

Limitations and Advantages

This retrospective study was a single-center study and one of the most prominent limitations of the study is the small sample size. However, the fact that there is no similar study published in our country is the superiority of the study. Therefore, prospective observational studies are needed.

CONCLUSION

In conclusion, early postoperative patient mobilization and using mechanical anti-embolic stockings are effective in lowering the incidence of VTE. For the vast majority of patients having elective spinal surgery, this protocol seems to be safe. However, it is safe to administer LMWH while a patient is hospitalized if they have risk for VTE. The VTE risk can be calculated using the Caprini RAM. Despite all precautions, VTE can not entirely be avoided. Therefore, prospective observational studies of large series are needed.

ETHICAL DECLARATIONS

Ethics Committee Approval: The study was carried out with the permission of Çanakkale Onsekiz Mart University Clinical Researches Ethics Committee (Date: 04.01.2023, Decision No: 2023/01-19).

Informed Consent: All patients signed the free and informed consent form.

Referee Evaluation Process: Externally peer-reviewed.

Conflict of Interest Statement: The authors have no conflicts of interest to declare.

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