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Research Paper

Outcomes after implementation of prophylactic protocol for venous thromboembolism in surgical patients: A retrospective cohort study

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ABSTRACT

Introduction: Venous thromboembolism (VTE) in surgical patients is a preventable cause of hospital death. In previous studies, the prevalence of VTE decreased after implementing a prophylactic protocol. Because of the low rate of VTE prophylaxis in Thailand, we studied the outcomes after the implementation of a VTE prophylactic protocol in our hospital.

Methods: A retrospective cohort single-center study was conducted from November 2019 to November 2020 in the Department of Surgery. We established the VTE prophylactic protocol using a multidisciplinary team approach and the Caprini score risk assessment model. The outcomes were the incidence of symptomatic VTE, VTE-related death, risk factors, and safety.

Results: In total, 6983 patients were admitted to the surgical department during the study period. After excluding patients with current VTE and missing data, 4579 patients were enrolled in this study, and 1579 (34.5%) patients at high risk for VTE were identified. The use of pharmacological prophylaxis, mechanical prophylaxis, and early ambulation in the entire cohort was lower than that in high-risk patients (7.99%, 19.81%, and 21.56% vs. 15.77%, 31.10%, and 46.55%, respectively). In the comparison of before and after implementation, the prevalence of symptomatic VTE and 30-day mortality of VTE decreased from 1.20% to 0.37% and from 0.11% to 0.02%, respectively. No major bleeding occurred.

Conclusions: After protocol implementation, the prevalence of symptomatic VTE and VTE-related death decreased. The VTE prophylaxis was safe. We highly recommended using a multidisciplinary team approach VTE prophylaxis in high-risk surgical patients.

1. Introduction

Venous thromboembolism (VTE), including deep venous thrombosis (DVT) and pulmonary embolism (PE), is a common cause of preventable death in surgical patients. The annual incidence of VTE reportedly ranges from 104 to 183 in every 100,000 people [1]. The estimated risk of VTE is 20% for general surgical patients, and the prevalence of VTE in surgical patients ranges from 0.15% to 1.18% [1,2]. Fatal PE is the form of VTE with the highest mortality. The VTE-associated mortality rate ranges from 2.1% to 4.7% [3]. Up to 50% of patients with DVT develop post-thrombotic syndrome. One of the most serious consequences of PE is chronic thromboembolic pulmonary hypertension, the incidence of which is about 1.0%–3.8% within 2 years [4].

In 1991, Caprini et al. [5] created a perioperative VTE risk assessment model and classified surgical patients as low risk (score of ≤4), moderate risk (score of 5–8), or high risk (score of ≥9); this scoring system was then modified in 2013 [6,7]. The 2012 American College of Chest Physicians (ACCP) guideline recommended VTE prophylaxis in non-orthopedic surgery using pharmacological and mechanical prophylaxis [8], and the 2019 American Society of Clinical Oncology (ASCO) guideline recommended that all patients

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with malignant disease undergoing major surgical intervention should be offered pharmacologic thromboprophylaxis [9]. The prophylaxis consisted of both pharmacological and mechanical prophylaxis. The pharmacological prophylaxis included the administration of low-molecular-weight heparin (LMWH) and unfractionated heparin, and the mechanical prophylaxis included the use of graduated compressive stockings (GCS) and an intermittent pneumatic compression (IPC) device. After thromboprophylaxis, the incidence of VTE and PE were decreased to 84% and 55%, respectively [10].

The ENDORSE study, a multinational cross-sectional study, showed that 58.5% of all surgical patients at risk received ACCP-recommended VTE prophylaxis, whereas this proportion in Thailand was only 0.2% [11]. Concerning the risk of bleeding complications in surgical patients, the rate of pharmacological prophylaxis was low. No VTE prophylaxis protocol was currently applied in our hospital, and VTE prophylaxis adherence was low. The VTE prophylaxis method was dependent upon the surgeon's preference, and most patients receive no prophylaxis. This study was performed to reduce the incidence of VTE and VTE-related death after the implementation of a VTE prophylaxis protocol using a multidisciplinary team approach according to ACCP-recommended VTE prophylaxis.

2. Methods and material

2.1. Study design

This retrospective cohort single-center study was conducted at the Department of Surgery from November 2019 to November 2020. The nature of our institute is academic and public university hospital. The study population included all adult patients who were admitted to the Department of Surgery. Patients were aged <15 years, patients who had been diagnosed with or were undergoing current treatment for VTE before admission, and patients whose data were lost were excluded from the study. The study protocol was approved by the Human Research Ethics Committee. This study was approved by the ethical committee of Hospital approval; COA.No.MURA 2020/1751 and registered with the TCTR committee TCTR20211213001 (https://www.thaiclinicaltrials.org/page_user/). This study has been reported in line with the STROCSS criteria [12].

2.2. Multidisciplinary team approach in VTE prophylaxis protocol

The patients were educated on VTE and VTE prophylaxis at the outpatient clinic. After admission, VTE risk assessment was performed using the Caprini score, and the patients were classified as being at very low, low, moderate, or high risk for VTE. The contraindications for pharmacological and mechanical prophylaxis were assessed. The surgeons then chose each patient's VTE prophylaxis regimen according to his or her VTE risk and contraindications for VTE prophylaxis.

Pharmacological prophylaxis was administered by subcutaneous injection of 40 mg of enoxaparin every 24 h for patients with normal kidney function and was stopped 12 h before surgery. In patients with impaired kidney function (creatinine clearance rate of <30 mL/min), 5000 units of unfractionated heparin were subcutaneously injected every 8 h and was stopped 8 h before surgery. The dosage and type of anticoagulant were rechecked by the pharmacologist. The surgical safety checklist, including the VTE risk and method of prophylaxis, was completed before, during, and after surgery with the surgeon, scrub nurse, and anesthesiologist.

For the patients who received mechanical prophylaxis, an IPC device was preferred over GCS. The patients underwent application of the IPC device during the intraoperative period. An early ambulation protocol and calf exercises were conducted postoperatively. The patients underwent IPC therapy until they could ambulate well. They were monitored for signs and symptoms of VTE and complications of VTE prophylaxis every day by the surgeon and the nurse. For the patients who were not able to ambulate well, the rehabilitation team would take care of these patients. For the high-risk VTE patients who could not self-care by themselves or their families, home health care service was activated.

Minor bleeding was defined as the development of a wound hematoma, drain site bleeding, or hematuria. Major bleeding was defined as the need for an intervention and transfusion of >2 units of packed red blood cells [13]. Adverse events and complications of IPC therapy and GCS included sensory impairment, allergy to the stocking material, skin irritation, and pressure injury.

2.3. Outcomes

The primary outcomes were the incidence of symptomatic VTE and 30-day VTE-related death. The secondary outcomes were VTE risk factors and complications after VTE prophylaxis.

2.4. Statistical analyses

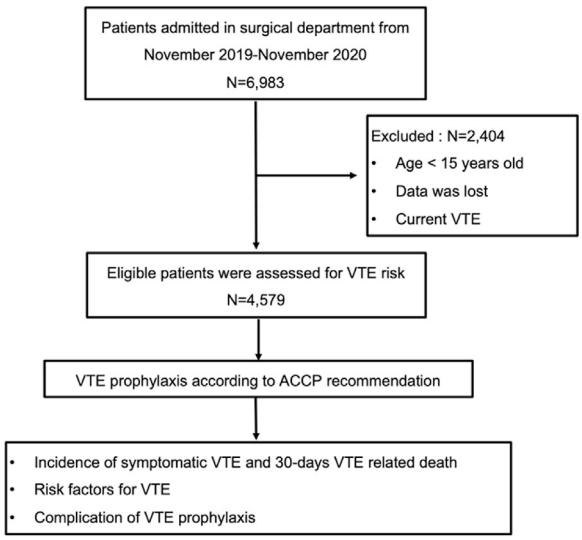
Categorical variables are presented as count and percentage and were compared using the chi-squared test or Fisher's exact test according to the sample size. Normally distributed continuous variables are presented as mean ± standard deviation and were compared using the unpaired *t*-test. Non-normally distributed variables are presented as median and interquartile range and were compared using the Mann–Whitney test. A P-value of <0.05 was considered statistically significant. Logistic regression was used to analyze the variable risk factors of VTE. The analyses were performed using STATA version 15.1 (StataCorp, College Station, TX, USA). The present study protocol was approved by our institutional review board.

3. Results

In total, 6983 patients were admitted to the Department of Surgery during the study period. We excluded 2404 patients who met the exclusion criteria; therefore, 4579 surgical patients were enrolled in this study and assessed for Caprini VTE risk assessment as shown in Fig. 1. The baseline characteristics of the entire cohort and patients at high risk for VTE were shown in Table 1. The patients' mean age was 59 ± 17 years, 33% were undergoing surgical cancer treatment, their median Caprini score was 4 (interquartile range [IQR], 2–5), and 34.5% were at high risk for VTE. The VTE prophylaxis methods in the high-risk for VTE surgical patients were pharmacological prophylaxis in 15.82%, postoperative mechanical prophylaxis in 31.14%, and early ambulation in 46.58% (Table 1). The rate of intraoperative IPC therapy was 100%.

The incidence of symptomatic VTE and 30-day VTE-related mortality were 17 (0.37%) patients and 1 (0.02%) patient, respectively. The median (IQR) time from admission to the occurrence of symptomatic VTE was 6 (4–12) days, and that from the operation to the occurrence of VTE was 4 (2–14) days. The complications of pharmacological prophylaxis included minor bleeding in 4 (1.25%) of 319 patients, such as a hematoma or ecchymosis at the injection site, hematuria, or gastrointestinal bleeding. No patients developed major bleeding that required a reoperation or blood transfusion. Complications of mechanical prophylaxis occurred in 61 (7.67%) of 795 patients, and all pressure injuries were grade 1 and 2 as shown in Table 2.

The univariate analysis showed that the risk factors associated with VTE in surgical patients were age, serious infection, lung



Abbreviations: VTE = venous thromboembolism, ACCP = American College of Chest Physicians 2012 guideline

Fig. 1. Flow chart of study, including enrollment and outcomes
Abbreviations: VTE = venous thromboembolism, ACCP = American College of Chest Physicians 2012 guideline.

disease, a bedridden state or restricted mobility, current or past malignancy, a planned major operation lasting >45 min, and confinement to bed for >72 h. The multivariate analysis confirmed that the risk factors were serious infection, current or past malignancy, a planned major operation lasting >45 min, and confinement to bed for >72 h. Serious infection was the strongest risk factor for VTE. VTE risk assessment was the only factor significantly associated with the prevention of VTE, as shown in Tables 3 and 4.

4. Discussion

More than 20% of all postoperative hospitalized patients have particular risk factors for VTE [13]. Many surgical patients possess all three components of Virchow's triad (stasis, hypercoagulability, and endothelial injury), leading to thrombus formation [14]. VTE is a preventable cause of death in surgical patients. International guidelines [8,13] recommend VTE risk stratification and provision of thromboprophylaxis according to the risk of VTE in non-orthopedic surgical patients, especially those with cancer [9,15,16].

The two main methods of thromboprophylaxis in the present study were pharmacological prophylaxis with LMWH and mechanical prophylaxis with IPC therapy or GCS. The recommendation for patients with no contraindications for anticoagulation is prophylactic anticoagulation and mechanical prophylaxis. Patients with contraindications for anticoagulation should receive IPC therapy and/or GCS; of these, IPC therapy is preferable. Until the risk of bleeding has decreased, pharmacologic prophylaxis can be initiated. After discharge, it is recommended that patients with cancer who have undergone an operation receive anticoagulation for up to 4 weeks postoperatively [4,9,16].

Despite the fact that worldwide data support the benefit of thromboprophylaxis in surgical patients, the rate of at-risk surgical patients receiving ACCP-recommended prophylaxis is reportedly only 0.2% in Thailand [11]. There are four main reasons for this low rate [17]. First, many surgeons are concerned about bleeding complications, especially fatal bleeding, when patients receive pharmacological prophylaxis, although Asian VTE guidelines indicate that the rate of major bleeding is <1% following pharmacological prophylaxis with either LMWH or the new oral anticoagulants [13]. The second reason is the lack of awareness regarding VTE even though the incidence of VTE, DVT, PE, and fatal PE in colorectal surgery without VTE prophylaxis ranges from 0.18% to 42.0% [18–21]. Third, the benefits of prophylaxis as revealed in clinical trials might not be applied in subsets of patients. Fourth, individual risk assessment makes the protocol difficult to reinforce.

We were distressed to discover the high rate of VTE and VTE-related death (1.77% and 0.15%, respectively) in our hospital in 2019. We regarded this as an opportunity to improve the standard of care. We thus developed a VTE prophylaxis protocol and implemented this protocol in our hospital. The protocol involves mandatory VTE risk assessment and risk-stratified prophylaxis for all admitted patients. Implementation of this protocol along with the rising awareness of VTE, standardized early postoperative mobilization, mechanical prophylaxis, and pharmacological prophylaxis resulted in excellent adherence to prophylaxis guidelines and a dramatic reduction in postoperative VTE events among our patients. With the cooperation of the multidisciplinary team led the rate of VTE decreased and the complication of the prophylaxis was minimized. In the present study, 4579 patients were analyzed. Compared with our previous data in 2019 (before the development of the VTE prophylaxis protocol), the incidence of VTE in our surgical department dramatically decreased from 1.77% to 0.37% per year after implementation of the VTE prophylaxis protocol. Not only did the incidence of VTE decrease, but the VTE-related mortality rate dropped from 0.15% to 0.02% per year as shown in Fig. 2.

Despite the existence of the multidisciplinary team, there was 28.54% of surgical patients received some form of VTE prophylaxis in all cohort. There was low rate of early ambulation (21.56%), mechanical VTE prophylaxis (19.81%) and pharmacological prophylaxis (7.99%). To explain these, first, due to our establishment that high-risk patients should receive the VTE prophylaxis so the threshold for VTE prophylaxis in our study for non-high-risk group

Table 1
Baseline characteristics of surgical patients.

Variable	Entire cohort	Patients at high risk for VTE
	n = 4579	n = 1579
Age, years	59 ± 17	67 ± 13
Male sex	2294 (50.11)	769 (48.70)
Unit		
1. General surgery	678 (14.84)	283 (17.92)
2. ACS/Trauma	538 (11.77)	115 (7.28)
3. Breast and endocrine surgery	533 (11.66)	294 (18.62)
4. Hepato-pancreato-biliary surgery	481 (10.53)	187 (11.84)
5. Vascular surgery	428 (9.37)	129 (8.17)
6. Neurosurgery	487 (10.66)	172 (10.89)
7. Cardiovascular thoracic surgery	366 (8.01)	127 (8.04)
8. Urology surgery	656 (14.35)	212 (13.43)
9. Plastic surgery	403 (8.82)	60 (3.80)
VTE risk assessment	4193 (91.57)	1573 (99.62)
History of major surgery (>45 min) within last month	123 (2.93)	40 (2.53)
Visible varicose veins	18 (0.43)	10 (0.63)
Current swollen legs	13 (0.31)	7 (0.44)
Overweight (body mass index of >25 kg/^{2})	83 (1.98)	38 (2.41)
Heart attack	9 (0.21)	5 (0.32)
Congestive heart failure	22 (0.52)	15 (0.95)
Serious infection	34 (0.81)	23 (1.46)
Lung disease	22 (0.52)	17 (1.08)
Bedridden or restricted mobility	38 (0.90)	23 (1.46)
Current use of birth control or hormonal replacement therapy	4 (0.10)	0 (0.00)
Current or past malignancy	1401 (33.34)	1087 (68.84)
Planned major surgery lasting >45 min	2540 (60.45)	1295 (82.01)
Central venous access	14 (0.33)	14 (0.89)
Confined to bed for >72 h	298 (7.09)	241 (15.26)
History of deep vein thrombosis or pulmonary embolism	48 (1.14)	46 (2.91)
Family history of venous thrombosis	3 (0.07)	3 (0.19)
Broken hip, pelvis, or leg	5 (0.12)	5 (0.32)
Serious trauma	11 (0.26)	11 (0.70)
Spinal cord injury resulting in paralysis	6 (0.14)	6 (0.38)
Experience of stroke	24 (0.57)	24 (1.52)
Caprini score	4 (2–5)	6 (5–6)
Implementation of VTE prophylaxis	1307 (28.54)	964 (61.05)
Pharmacological prophylaxis	319 (7.99)	249 (15.77)
Mechanical prophylaxis	795 (19.81)	491 (31.10)
Early ambulation	855 (21.56)	735 (46.55)
VTE	17 (0.37)	17 (1.08)
VTE-related death	1 (0.02)	1 (0.06)

Data were presented as mean ± standard deviation, n (%), or median (interquartile range).
Abbreviations: VTE = venous thromboembolism, ACS = acute care surgery.

Table 2
Complications.

Complication	Mechanical prophylaxis group (n = 795)
Complication from IPC therapy	61 (7.67)
- Pressure injury grade 1, 2	42 (5.28)
- Pressure injury grade 3, 4	0 (0.00)
- Numbness	2 (0.25)
Complication	**Pharmacological prophylaxis group (n = 319)**
Bleeding	
- Minor bleeding	4 (1.25)
- Major bleeding	0 (0.00)

Data were presented as n (%).
Abbreviation: IPC = intermittent pneumatic compression.

was low. Nearly sixty-five percent of our patients were non-high-risk for VTE. Second, the definition of early ambulation was the patients could ambulate out of bed independently within 3 days after the operation. Some of our patients could not walk independently by themselves within 3 days after surgery, some still admitted in intensive care unit where the activity was limited and some were high risk for fall. Third, the postoperative IPC usage was low because of the character of patients in our study which were cardiovascular thoracic, infection or wound at the leg and peripheral arterial disease patients. These brought to the low VTE prophylaxis in all cohort.

Despite the low rate of VTE prophylaxis in all cohort, the incidence of VTE and VTE related mortality was decreased. Focusing on the high-risk patients in our protocol, the rate of VTE prophylaxis in this group was 61%. In addition, all patients who had hospital-acquired-VTE in our surgical department were high risk for VTE. These confirmed our protocol which selected the high-risk patients receiving VTE prophylaxis. Bahl et al. [22] demonstrated the greatest likelihood of VTE in patients with scores of >5. Furthermore, there was a significant increase in the likelihood of VTE in patients with scores of 7 and 8 (2.58%) and scores of ≥9 (6.51%). The risk of VTE in patients with scores of <5 was quite low (<1%). Therefore, the Caprini score was useful for predicting the risk of VTE and the score ≥5 should be the trigger for multidisciplinary team approach for VTE prophylaxis in our hospital.

In high-risk VTE patients, the high incidence of VTE (1.08%) was occurred corresponding to the low rate of pharmacological prophylaxis in the high-risk group (15.8%) because of concerning regarding postoperative bleeding. All of our VTE cases did not

Table 3
Risk factors associated with VTE and outcomes.

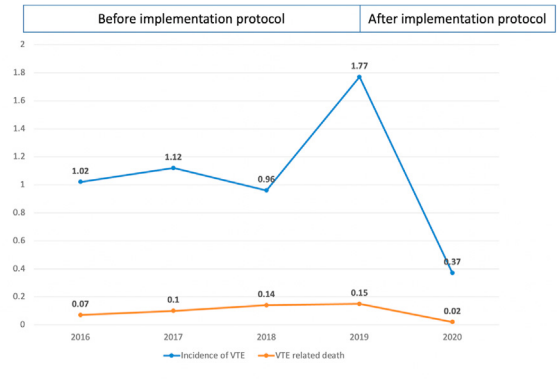
Variable	VTE	No VTE	P-value
	n = 17	n = 4563	
Age, years	67 ± 14.15	59 ± 17.15	0.046
Male sex	9 (52.94)	2285 (50.10)	0.815
Doctor access	11 (64.71)	4182 (91.67)	0.002
History of major surgery (>45 min) within last month	0 (0.00)	123 (2.94)	0.999[b]
Visible varicose veins	0 (0.00)	18 (0.43)	0.999[b]
Current swollen legs	0 (0.00)	13 (0.31)	0.999[b]
Overweight (body mass index of >25 kg/m^2)	1 (5.88)	82 (1.96)	0.288[a]
Heart attack	0 (0.00)	9 (0.22)	0.999[b]
Congestive heart failure	0 (0.00)	22 (0.53)	0.999[b]
Serious infection	3 (17.65)	31 (0.74)	<0.001[b]
Lung disease	1 (5.88)	21 (0.50)	0.086[b]
Bedridden or restricted mobility	1 (5.88)	37 (0.88)	0.143[b]
Current use of birth control or hormonal replacement therapy	0 (0.00)	4 (0.10)	0.999[b]
Current or past malignancy	13 (76.47)	1388 (33.17)	<0.001
Planned major surgery lasting >45 min	15 (88.24)	2526 (60.33)	0.019
Central venous access	0 (0.00)	14 (0.33)	0.999[b]
Confined to bed for >72 h	6 (35.29)	292 (6.98)	0.001
History of deep vein thrombosis or pulmonary embolism	0 (0.00)	48 (1.15)	0.999[b]
Family history of venous thrombosis	0 (0.00)	3 (0.07)	0.999[b]
Broken hip, pelvis, or leg	0 (0.00)	5 (0.12)	0.999[b]
Serious trauma	0 (0.00)	11 (0.26)	0.999[b]
Spinal cord injury resulting in paralysis	0 (0.00)	6 (0.14)	0.999[b]
Experience of stroke	0 (0.00)	24 (0.57)	0.999[b]
Caprini score	6 (5–7)	4 (2–5)	<0.001[a]

Data are presented as mean ± standard deviation, n (%), or median (interquartile range).
Abbreviations: VTE = venous thromboembolism.
[a] Mann-Whitney *U* Test.
[b] Fisher's exact test.

Table 4
Univariate and multivariate analyses of risk factors for VTE.

Variable	VTE	No VTE	P-value	Univariate	P-value	Multivariate	P-value
	n = 17	n = 4563		OR (95% CI)		OR (95% CI)	
Age, years	67 ± 14.15	59 ± 17.15	0.046	1.03 (1.00–1.07)	0.049	1.03 (0.97–1.09)	0.285
Doctor access	11 (64.71)	4182 (91.67)	0.002	0.17 (0.06–0.45)	<0.001	0.001 (0.000–0.006)	<0.001
Serious infection	3 (17.65)	31 (0.74)	<0.001[a]	28.71 (7.86–104.94)	<0.001	18.86 (2.09–170.55)	0.009
Lung disease	1 (5.88)	21 (0.50)	0.086[a]	12.39 (1.57–97.74)	0.017	4.75 (0.33–68.01)	0.251
Bedridden or restricted mobility	1 (5.88)	37 (0.88)	0.143[a]	7.01 (0.91–54.21)	0.062	2.38 (0.05–111.75)	0.659
Current or past malignancy	13 (76.47)	1388 (33.17)	<0.001	2.56 (1.46–4.49)	0.001	2.23 (1.16–4.26)	0.015
Planned major surgery lasting >45 min	15 (88.24)	2525 (60.33)	0.019	2.22 (1.06–4.65)	0.034	3.30 (1.22–8.96)	0.019
Confined to bed for >72 h	6 (35.29)	292 (6.98)	0.001	2.70 (1.63–4.45)	<0.001	3.52 (1.81–6.85)	<0.001

Data are presented as mean ± standard deviation or n (%).
Abbreviation: VTE = venous thromboembolism, OR = odds ratio, CI = confidence interval.
[a] Fisher's exact test.



Abbreviations: VTE, venous thromboembolism

Fig. 2. Incidence of VTE and VTE-related death from 2016 to 2020
Abbreviations: VTE, venous thromboembolism.

receive pharmacological prophylaxis. Five of 17 patients were neurological patients which were at high risk from bleeding. Three patients were active bleeding and 5 patients had a large solid tumor which beware of tumor bleeding. From this result, we encouraged to use pharmacological prophylaxis in high-risk patients if they did not have the contraindication.

The high awareness of VTE in surgical patients, the obvious protocol in the term of the multidisciplinary team, the identification of high-risk patients, and the increased application of VTE prophylaxis were the keys leading to a lower incidence of VTE and VTE-related death. Most cases of VTE occurred in the early postoperative period; the median (IQR) time from admission to the occurrence of VTE was 6 (4–12) days, and that from the operation to the occurrence of VTE was 4 (2–14) days. We encourage clinicians to follow a prophylactic protocol extremely early in the postoperative period.

The factors predicting the occurrence of VTE in our study were serious infection, current or past malignancy, a planned major surgery lasting >45 min, and confinement to bed for >72 h. The strongest risk factor for VTE was a serious infection. Most cases of serious infections with VTE occurred in patients with end-stage cancer who were undergoing palliative care. The preventive factor was VTE risk assessment for identifying patients at risk.

The rate of complications of VTE prophylaxis was quite low; only minor complications occurred because of our closed monitoring protocol indicating that VTE prophylaxis in surgical patients is safe.

The main limitation of this study is its retrospective observational nature. Because the basis of our work is quality improvement founded on standardization, we believe that it is necessary to implement the program for all of our surgical patients at the same time. Our prospective direction may focus on the specific subgroup patients such as neurological and cancer patients who have an extreme risk of VTE and high bleeding risk of the procedure.

5. Conclusions

Our VTE prophylaxis protocol emphasizes high-risk patient identification, early postoperative mobilization, intraoperative and postoperative intermittent IPC application, and pharmacological prophylaxis using a multidisciplinary team approach. This protocol significantly reduced the likelihood of VTE complications among our patients.

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Consent

Not applicable since it was a retrospective study.

Registration of research studies

TCTR20211213001.

Ethical approval

Ethical approval was obtained from the Human Research Ethics Committee, Faculty of Medicine Ramathibodi Hospital, Mahidol University, COA. MURA2020/1751 and registered with the TCTR committee TCTR20211213001.

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Author contribution

This manuscript was carried out in collaboration among all authors. NK contributed to the conception and design of the study, acquired; analyzed and interpreted the data drafted and revised the manuscript. PP, SH, CP, GT, CC, CG and CS participated in reviewing the design and methods of data collection. PP, SH, CP and GT performed the interpretation and preparation of the manuscript. All authors participate in preparation and critical review of the manuscripts. In addition, all authors read and approved the manuscript.

Guarantor

Nutsiri Kittitirapong.

Declaration of competing interest

The author declares there is no conflict of interest.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijso.2022.100453.

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