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Adherence to Venous Thromboembolism Prophylaxis in High-Risk Gynecologic Cancer Patients during the Enhanced Recovery after Surgery Era

Sirada Tachatiemchan, M.D.*,
Atcharaporn Prathumsuwan, M.N.S.**,
Dittakarn Boriboonhirunsarn, M.D.*,
Tarinee Rungjirajittranon, M.D.***,
Vuthinun Achariyapota, M.D.*,
Atthapon Jaishuen, M.D.*,
Vitcha Poonyakanok, M.D.*

** Department of Obstetrics and Gynecology, Faculty of Medicine Siriraj Hospital, Mahidol University*
*** Obstetrics and Gynaecological Nursing Division, Department of Nursing Siriraj Hospital*
**** Division of Hematology, Department of Medicine, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand.*

ABSTRACT

Objectives: Venous thromboembolism (VTE) is a common complication in patients with gynecologic cancer, reducing survival and increasing the financial burden. This study aimed to assess the adherence to VTE prophylaxis and factors that influence physician decisions.

Materials and Methods: This descriptive cross-sectional study was conducted in the Department of Obstetrics and Gynecology, Siriraj Hospital, Thailand. We included patients with gynecologic malignancies undergoing abdominopelvic surgery who were at high risk for VTE (Caprini score ≥ 5). Patient demographics, clinical profiles, and the adherence of the physician to the thromboprophylaxis protocols were evaluated.

Results: From October 2023 to October 2024, 231 patients met the inclusion criteria. The median age was 59 years (interquartile range (IQR) 50–66) and the median body mass index was 24.4 kg/m² (IQR 21.1–28). Most patients (83.2%) had Caprini scores of 5 or 6. 219 (96.5%) patients received mechanical and/or pharmacological prophylaxis. However, only 50 patients (22%) received prophylaxis in accordance with the guidelines. The surgical route was the only factor significantly associated with guideline adherence.

Conclusion: The adherence rate to VTE prophylaxis in perioperative gynecologic malignancy patients was low (22%). Further research is needed to understand barriers to adherence and the clinical consequences of noncompliance.

Keywords: venous thromboembolism, anticoagulants, female genital neoplasms, guideline adherence.

Correspondence to: *Vitcha Poonyakanok, M.D., Department of Obstetrics and Gynecology, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok 10700, Thailand. E-mail: vitcha.poo@mahidol.ac.th*

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อัตราการปฏิบัติตามแนวทางป้องกันการเกิดภาวะลิ่มเลือดอุดตันหลอดเลือดดำในผู้ป่วยมะเร็งนรีเวชที่เข้ารับการผ่าตัดและมีความเสี่ยงต่อการเกิดลิ่มเลือดอุดตันหลอดเลือดดำในช่วงโปรแกรม ERAS

ศิรดา เตชะเทียมจันทร์, อัชราภรณ์ ประทุมสุวรรณ, ธาริณี รุ่งจิรจิตรานนท์, ดิฐกานต์ บริบูรณ์หิรัญสาร, วุฒินันท์ อัจฉริยะโพธา, อรรถพล ใจซื่น, วิชชา ปุณยกนก

บทคัดย่อ

วัตถุประสงค์*: ภาวะลิ่มเลือดอุดตันในหลอดเลือดดำเป็นภาวะแทรกซ้อนที่พบบ่อยในผู้ป่วยมะเร็งนรีเวช ซึ่งส่งผลให้อัตราการรอดชีวิตลดลงและเพิ่มภาระค่าใช้จ่ายทางการแพทย์ งานวิจัยนี้มีวัตถุประสงค์เพื่อประเมินการปฏิบัติตามแนวทางการป้องกัน การเกิดภาวะลิ่มเลือดอุดตันหลอดเลือดดำและปัจจัยที่มีผลต่อการปฏิบัติตามแนวทาง*

วัสดุและวิธีการ*: การศึกษานี้เป็นการศึกษาแบบตัดขวางเชิงพรรณนา ทำการศึกษาในผู้ป่วยที่เป็นมะเร็งนรีเวชและเข้ารับการผ่าตัดในช่องท้องหรืออุ้งเชิงกราน ซึ่งมีความเสี่ยงสูงต่อการเกิดการเกิดภาวะลิ่มเลือดอุดตันหลอดเลือดดำ (คะแนน Caprini ≥ 5) ที่โรงพยาบาลศิริราช ตัวแปรข้อมูลทั่วไป ประวัติทางคลินิก และการปฏิบัติตามแนวทางการให้ยาป้องกันการเกิดลิ่มเลือดอุดตันของแพทย์ ถูกจัดเก็บและนำมาประเมิน*

ผลการศึกษา*: การศึกษานี้รวบรวมข้อมูลระหว่างเดือนตุลาคม พ.ศ. 2566 ถึงตุลาคม พ.ศ. 2567 โดยมีผู้ป่วยจำนวน 231 รายที่เข้าเกณฑ์ อายุมัธยฐานอยู่ที่ 59 ปี (พิสัยระหว่างควอร์ไทล์ 50–66) ค่าดัชนีมวลกายมัธยฐาน 24.4 กก./ม² (พิสัยระหว่างควอร์ไทล์ 21.1–28) ผู้ป่วยส่วนใหญ่ (ร้อยละ 83.2) มีคะแนน Caprini เท่ากับ 5 หรือ 6 มีผู้ป่วย 219 ราย (ร้อยละ 96.5) ได้รับการป้องกันด้วยวิธีกลและ/หรือการใช้ยาต้านการแข็งตัวของเลือด อย่างไรก็ตาม มีผู้ป่วยเพียง 50 ราย (ร้อยละ 22) ที่ได้รับการป้องกันตรงตามแนวทางที่กำหนด ปัจจัยเดียวที่สัมพันธ์อย่างมีนัยสำคัญกับการปฏิบัติตามแนวทางคือช่องทางการผ่าตัด*

สรุป*: อัตราการปฏิบัติตามแนวทางการป้องกันการเกิดภาวะลิ่มเลือดอุดตันหลอดเลือดดำในผู้ป่วยมะเร็งนรีเวชช่วงก่อนและหลังผ่าตัดมีเพียงร้อยละ 22 ควรมีการศึกษาวิจัยเพิ่มเติมเพื่อทำความเข้าใจอุปสรรคที่ทำให้ไม่ปฏิบัติตามแนวทาง และผลลัพธ์ทางคลินิกที่เกิดจากการไม่ปฏิบัติตาม*

คำสำคัญ*: ภาวะลิ่มเลือดอุดตันในหลอดเลือดดำ, ยาต้านการแข็งตัวของเลือด, เนื้องอกในอวัยวะสืบพันธุ์สตรี*

Introduction

Venous thromboembolism (VTE), which includes deep vein thrombosis (DVT) and pulmonary embolism (PE), is one of the leading causes of morbidity and mortality in gynecologic oncology. Patients with malignancies and those undergoing pelvic surgery have an elevated risk of VTE, making gynecological oncology patients a particularly high-risk population[1]. The RISTOS study is a prospective observational study involving more than 2,000 surgical patients; 20% underwent gynecologic procedures with a VTE incidence of 2%. Notably, 40% of the events occurred more than 21 days after surgery[2]. The prognosis of patients who develop malignancy-associated VTE is poorer than that of those who do not, across all gynecological cancer types[3]. For instance, in one large 7-year study of cervical cancer patients, the 5-year survival rate was nearly 80% in those without VTE, compared to just under 40% in those who developed VTE[4].

The randomized controlled trial by Bergqvist et al in 2002 showed that enoxaparin prophylaxis for four weeks after surgery for abdominal or pelvic cancer significantly reduced the rate of VTE compared to a one-week regimen[5]. The guidelines from the American College of Chest Physicians (ACCP) in 2012, the American College of Obstetricians and Gynecologists (ACOG) in 2021, the American Society of Clinical Oncology (ASCO) in 2023, and the European Society for Medical Oncology (ESMO) in 2023 recommend the use of low molecular weight heparin (LMWH) combined with intermittent pneumatic compression, followed by extended LMWH for 4 weeks in patients at high risk for VTE[6-9].

In 2001, the Enhanced Recovery After Surgery (ERAS) Society developed a protocol to improve surgical patient outcomes through a multimodal, multidisciplinary approach, with VTE prophylaxis included as part of the care bundle. ERAS protocols have been shown to reduce the length of hospital stay by 30% to 50%, along with similar reductions in complication rates[10]. Building on this in July 2023, our department launched an ERAS protocol and a local VTE prophylaxis guideline for malignancy patients. Most high-risk patients received mechanical prophylaxis, but the use of pharmacological prophylaxis varied depending on physician preference. Additionally, data from a multinational registry study conducted in Latin America, Africa and the Middle East reported that prescriptions adhered to ACCP guidelines in 73.9% of patients during hospitalization, but only 18.9% after discharge[11]. The primary objective of this study was to evaluate adherence to VTE prophylaxis in high-risk gynecologic cancer patients during the ERAS period. The secondary objective was to identify factors that influence medical decisions about prophylaxis.

Materials and Methods

This was a single-center cross-sectional descriptive study conducted from October 2023 to October 2024 in the Department of Obstetrics and Gynecology of Siriraj Hospital. The study received approval from the Siriraj Institutional Review Board (CoA No. 950/2024). Based on a review of electronic medical records, the study included patients who were preoperatively diagnosed with gynecologic malignancy, admitted for abdominopelvic surgery and identified as a high risk of VTE defined by a Caprini score of 5 or higher. Patients with a prior diagnosis of deep vein thrombosis or pulmonary embolism, those currently using anticoagulant therapy, and those whose tumors were diagnosed as benign after surgery were excluded. The characteristics of the patients including clinical details and operation profiles, and adherence to the prescribed thromboprophylaxis protocols were assessed. Radical surgery was defined as an extensive procedure that carries an increased risk of complications. For example, radical hysterectomy or vulvectomy, lymphadenectomy, peritonectomy, tumor debulking, and bowel or bladder surgery.

On July 1, 2023, the Department of Obstetrics and Gynecology at Siriraj Hospital adopted an ERAS protocol along with a local VTE prophylaxis guideline. As part of the preoperative evaluation, all patients with

gynecologic malignancy were assessed using the Siriraj DVT scoring system to identify those at high risk of asymptomatic DVT[12]. High risk patients underwent a lower extremity Doppler ultrasound. Those diagnosed with DVT received appropriate treatment and their surgery was postponed. On the day of admission before surgery, each patient was evaluated using the Caprini score to determine the appropriate VTE prophylaxis. For high-risk patients with a Caprini score of 5 or higher, a combination of mechanical methods, such as intermittent pneumatic compression and extended duration anticoagulation therapy, was recommended. The choice of prophylaxis was ultimately determined by the surgeon. During the postoperative period, leg circumference was measured daily until discharge. If the circumference difference exceeded 2 cm or if the patient experienced desaturation - both potential signs of VTE - further evaluation with Doppler ultrasound and/or chest CT angiography was performed.

Complete adherence to thromboprophylaxis for high-risk patients was defined according to our local guideline as the combined use of mechanical and pharmacological prophylaxis, with an extended regimen of 28 days post-operation. Partial adherence was defined as the use of mechanical or pharmacological prophylaxis alone, or the incomplete use of either.

The sample size was calculated based on a previous study, which reported a thromboprophylaxis compliance rate of 73%[11] with a 10% margin of error. A total of 231 atients were included in the study, accounting for an anticipated 10% data loss.

Data were analyzed using IBM SPSS Statistics for Windows, version 29 (IBM Corp., Armonk, NY). Baseline characteristics and data on prophylaxis use were presented using the median and interquartile range for continuous variables and number and percentage for categorical variables. Factors associated with complete adherence to the VTE prophylaxis protocol were analyzed using the Chi square test or Fisher's exact test. To identify independent predictors of adherence, variables with a p value < 0.1 in the univariate analysis were included in a multivariate analysis using logistic regression. A p value less than 0.05 was considered statistically significant.

Results

Data were retrieved from 231 patients between October 2023 and October 2024. After excluding 4 patients without malignancies, a total of 227 patients remained for analysis The median age was 59 years (interquartile range (IQR) 50-66) and the median body mass index (BMI) was 24.4 kg/m² (IQR 21.1-28). Approximately two-thirds of the patients had at least one chronic illness, primarily hypertension. Additionally, 6.6% of patients were using antiplatelet drugs. The most common primary cancer site was the endometrium (58.6%), followed by the ovary (30.4%) and cervix (10.6%). Half of the patients were at stage 1 of the disease, while 16.7% were at stage 4. The Caprini score was used to evaluate perioperative DVT risk in all patients: 87 (38.3%) had a score of five, 102 (44.9%) had a score of six, 30 (13.2%) had a score of seven, and 8 (3.6%) had a score of eight.

Of the 227 patients included in the analysis, 219 (96.5%) received at least one form of VTE prophylaxis. Combined mechanical and pharmacological prophylaxis was administered to 59.4% of patients, while 38.4% and 5.0% received mechanical or pharmacological prophylaxis alone, respectively. Among the 135 patients who received both mechanical and pharmacological prophylaxis, 80 (59.3%) were prescribed anticoagulants only preoperatively, 50 (37.0%) received extended anticoagulation for 4 weeks, 4 (3.0%) were prescribed anticoagulants for less than four weeks, and 1 (0.7%) received pharmacological prophylaxis solely during hospitalization. Enoxaparin was the exclusive pharmacological agent utilized. Complete adherence to the local guideline, defined as receiving anticoagulants both preoperatively and for 28 days postoperatively, in addition to mechanical prophylaxis, was observed in only 50 patients (22.0%). The baseline characteristics of the patients are summarized in Table 1, and the utilization of prophylaxis among gynecologic cancer patients undergoing surgery is presented in Table 2.

Table 1. Baseline characteristics of patients with gynecological cancer who underwent surgery (n = 227).

Characteristics	n = 227 (%)
Age (years)	
> 60	102 (44.9)
≤ 60	125 (55.1)
BMI (kg/m^2)	
≥ 25	100 (44.1)
< 25	127 (55.9)
History of chronic illness	150 (66.1)
Diabetes mellitus	45 (19.8)
Hypertension	82 (36.1)
Cardiovascular disease	7 (3.1)
Current antiplatelet drug use	15 (6.6)
Primary cancer organ	
Ovary	69 (30.4)
Endometrium	133 (58.6)
Cervix	24 (10.6)
Vulva	1 (0.4)
Stage of the disease	
1	114 (50.2)
2	31 (13.7)
3	44 (19.4)
4	38 (16.7)
Blood loss (ml)	
≤ 500	180 (79.3)
> 500	47 (20.7)
Radicality of surgery	
Yes	193 (85)
No	34 (15)
Residual disease	
Yes	49 (21.6)
No	178 (78.4)
Caprini score	
5	87 (38.3)
6	102 (44.9)
7	30 (13.2)
8	8 (3.6)

* Data are presented as number (%).
BMI: body mass index

Table 2. Usage of prophylaxis in gynecologic cancer patients undergoing surgery (n = 227).

VTE prophylaxis	n = 227 (%)
No VTE prophylaxis	8 (3.5)
Any VTE prophylaxis	219 (96.5)
Type of VTE prophylaxis*	
Mechanical prophylaxis alone	84 (38.4)
Pharmacological prophylaxis alone	5 (2.3)
Mechanical and pharmacological prophylaxis	130 (59.4)
Type of Pharmacological prophylaxis†	
Only pre-operative	80 (59.3)
Only hospitalization	1 (0.7)
Duration of post-operative anticoagulant (weeks)	
< 4 weeks	4 (3)
4 weeks	50 (37)

VTE: venous thromboembolism
* n = 219
† n = 135

The univariate analysis of patient factors associated with complete adherence to the VTE prophylaxis guideline is presented in Table 3. Among the variables analyzed, the only factor that was significantly associated with adherence was the surgical approach. Patients who underwent laparotomy were more likely to receive appropriate prophylaxis compared to those who underwent laparoscopic surgery. Other factors, including age, BMI, presence of chronic illness, primary cancer site, stage of the disease, and Caprini score, were not significantly associated with adherence to the prophylaxis protocol. Notably, factors such as the radical nature of the surgery and intraoperative blood loss were also found to be associated with adherence to the prophylaxis protocol. A multivariate analysis was not conducted because only one factor demonstrated a p value less than 0.1 in the univariate analysis.

Table 3. Factors associated with complete adherence to VTE prophylaxis guidelines.

Factors	VTE adherence to guideline		p value
	Yes (%)	No (%)	
Age (years)			0.144
> 60	27 (54)	75 (42.4)	
≤ 60	23 (46)	102 (57.6)	
BMI (kg/m^2)			0.513
≥ 25	20 (10)	80 (45.2)	
< 25	30 (60)	97 (54.8)	
Chronic illness			0.317
Yes	36 (72)	114 (64.4)	
No	14 (28)	63 (35.6)	
Organ			0.149
Ovary	17 (34)	52 (29.4)	
Cervix	1 (2)	23 (13)	
Endometrium	32 (64)	101 (57.1)	
Vulva	0	1(0.6)	
Stage			0.754
Early stage (1-2)	31 (62)	114 (64.4)	
Advance stage (3-4)	19 (38)	63 (35.6)	
Route of surgery			0.034
Laparotomy	45 (90)	135 (76.3)	
Laparoscopy	5 (10)	42 (23.7)	
Blood loss(ml)			0.497
≤ 500	40 (80)	139 (78.5)	
> 500	10 (20)	38 (21.5)	
Radical surgery			0.504
Yes	44 (88)	149 (84.2)	
No	6 (12)	28 (15.8)	
Caprini score			0.148
5-6	45 (91.8)	144 (81.4)	
More than 6	5 (10.2)	33 (18.6)	

VTE: venous thromboembolism

Discussion

Our study aimed to evaluate the rate of adherence to VTE prophylaxis in the era of ERAS. In Thailand, ERAS has been shown to significantly reduce length of stay and improve recovery in the first 24 hours after surgery[13, 14]. While many professional societies have promoted the implementation of clinical guidelines and the ERAS society has included VTE prophylaxis as part of its recommended care bundle to accelerate patient recovery, we found that adherence remains suboptimal. In our cohort of patients with high-risk gynecologic cancer who underwent surgery, only 22% received VTE prophylaxis in full accordance with the guidelines.

The main reason for incomplete adherence was the failure to provide the full recommended duration of pharmacological prophylaxis with LMWH. VTE occured in approximately 4% of patients undergoing gynecologic cancer surgery, with approximately three-quarters of these events detected more than seven days postoperatively[15]. Based on these findings, a randomized controlled trial conducted in 2002 demonstrated that a four-week course of enoxaparin following abdominal or pelvic cancer surgery significantly reduced the incidence of venographically confirmed thrombosis compared to a one-week regimen, without compromising safety[5]. In our institution, we have implemented a VTE prophylaxis protocol that includes extended medical prophylaxis that aligns with international recommendations. In addition, the Gynecologic Cancer Society of Thailand is developing a new guideline that may have a significant impact on national practice.

Schemeler et al demonstrated that the incidence of VTE within 20 days postoperatively decreased from 2.7% to 0.6% following the implementation of VTE prevention guidelines[16]. Extended duration thromboprophylaxis has also been shown to be cost-effective in abdominal oncologic surgeries. According to Iannuzzi et al (2014), it was the dominant strategy when the probability of VTE exceeded 2.39%, based on a willingness-to-pay threshold of $50,000 per quality-adjusted life year (QALY)[17]. Despite strong evidence supporting extended prophylaxis, adherence to these recommendations remains poor. The compliance rate was only 18.9% for abdominal and pelvic cancer surgeries in Latin America, Africa, and the Middle East[11]. In the U.S. Medicare population consisting of individuals aged 65 and older, as well as younger people with disabilities or end-stage renal disease undergoing major abdominal cancer operations, 8.9% received extended prophylaxis[18]. Our study, which focused specifically on high-risk gynecologic cancer patients, found a compliance rate of 22%.

Currently, there are no data on the incidence of VTE in perioperative gynecologic oncology patients considered to be at high risk of VTE in Thailand. However, two studies conducted in Thailand reported a 7% incidence of DVT among critically ill medical patients[19] and a notably higher 21% incidence of VTE among hospitalized cancer patients with clinically suspected VTE[20]. These findings underscore the need for further research to determine the true incidence of VTE in high-risk perioperative gynecologic oncology patients in Thailand. The incidence in this specific group may differ from that reported in other regions. If this is true, current VTE prophylaxis guidelines may need to be adapted to reflect local epidemiological and clinical characteristics.

Several explanations for the underuse of thromboprophylaxis have been proposed, including the perceived lack of evidence, brief periods of postoperative immobilization, shorter operative times, and notably, the increasing use of minimally invasive (laparoscopic) surgical techniques[21]. While laparoscopic approaches are associated with less blood loss, fewer complications, and faster recovery, the use of the Trendelenburg position and potentially longer operative times may increase the risk of VTE[22]. A study involving 301 patients undergoing laparoscopic surgery for colorectal cancer found that VTE occurred in 11 of 113 patients who received

short-duration prophylaxis, whereas no events occurred among the 112 patients who received extended prophylaxis, supporting the safety and efficacy of prolonged anticoagulation[23]. Currently, international guidelines such as those of the ASCO and the ESMO do not differentiate between surgical modalities when recommending extended VTE prophylaxis after cancer surgery. In our study, however, patients who underwent laparotomy were more likely to receive appropriate thromboprophylaxis compared to those who underwent laparoscopic surgery.

Obesity is a factor that increases postoperative complications, elevates the risk of VTE, and prolongs hospital stay[24, 25]. However, in our study, obesity was not associated with a lack of adherence to the thromboprophylaxis protocol. Similarly, surgical factors that might be expected to influence adherence to prophylaxis, including intraoperative blood loss and the radicality of the operation, were not associated.

The final significant barrier to compliance with postoperative VTE prophylaxis protocol is the requirement for daily, and sometimes twice-daily, subcutaneous injections of LMWH or unfractionated heparin. Direct oral anticoagulants (DOACs) offer a major advantage over LMWH, as they are administered orally rather than parenterally, which may improve patient adherence[26]. The VALERIA trial, which compared rivaroxaban to enoxaparin for thromboprophylaxis following major gynecological cancer surgery, supported the hypothesis that DOACs could be a promising alternative to LMWH in this high-risk population. However, the statistical power of the study was limited due to not reaching the intended sample size[27]. However, DOACs are not currently reimbursed in Thailand and remain relatively expensive, limiting their accessibility. Despite this, DOACs offer greater convenience and may significantly improve patient compliance, particularly among those who prefer oral medication to daily injections.

Based on our finding of poor adherence, additional strategies are needed to improve compliance with VTE prophylaxis protocols. These include conducting audits after the implementation of ERAS protocols, which are associated with a reduced risk of perioperative complications, including VTE[28], quality improvement initiatives within gynecologic oncology services[29] and the integration of risk assessment and risk-based prophylaxis systems into electronic medical records for all surgical patients[30]. Additionally, factors unique to Thailand, such as patient acceptance of prolonged home injections and physician awareness or attitudes toward guideline adherence, should be further explored.

The limitations of our study included its retrospective nature and the absence of data on the actual incidence of VTE in our cohort. A key strength was that the study reflects real-world adherence rates at our institution following the implementation of the ERAS protocol.

Despite strong international guidelines and robust clinical evidence supporting extended-duration VTE prophylaxis in high-risk gynecologic cancer patients, especially in the ERAS period, adherence remains suboptimal. Our study revealed that only 22% of patients received complete prophylaxis as recommended. Improving adherence will require a multifaceted approach, particularly the implementation of new strategies and systems within our institution. Strengthening these measures is essential to improve patient safety and reduce the incidence of postoperative VTE in this high-risk population.

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Potential conflicts of interest

The authors declare no conflicts of interest.

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