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Incidence of venous thromboembolism in post-operative gynecologic patients at Srinagarind Hospital

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Abstract

Venous thromboembolism (VTE) after gynecologic surgery shows high mortality rate but has not been yet extensively investigated in Thailand. The authors aimed to investigate the incidence and risk factors of VTE in post-operative benign gynecologic patients. A retrospective cohort study was conducted in all gynecologic surgeries for benign indications between 2014 and 2018 at Srinagarind Hospital, Khon Kaen University, Thailand. Individual patient's characteristics were reviewed based on information from the electronic medical record system and outpatient medical records to detect venous thromboembolism that occurred from the post-operative admission period until follow up with a scheduled visit to the health care providers at 30 days after surgery. The study included 2,678 patients. Post-operative venous thromboembolisms were detected in only 2 patients (one being alive, the other died of a VTE-related problem). Incidence proportion of post-operative venous thromboembolism was 0.07% (95% CI, 0.009-0.26) leading to the incidence rate of 15 per 100,000 person-year (95% CI, 2-52). There was no significant risk factor identified due to low event rate. Post-operative venous thromboembolism appeared rare in benign gynecologic patients, but showed high death-to-case rate. Institutional thromboprophylaxis guidelines have been used since 2019, however, a study to monitor its safety and efficacy is still required.

Keywords: Venous thromboembolism, Deep vein thrombosis, Pulmonary embolism, Gynecologic surgery

1. Introduction

Venous thromboembolism (VTE) is a lethal complication of surgery [1-3]. It generally comprises deep vein thrombosis (DVT) and pulmonary embolism (PE). The American College of Chest Physicians (ACCP) developed clinical practice guidelines for thromboprophylaxis in surgical patients including gynecologic surgery [1]. With patients at very low risk for VTE (Caprini score = 0), no specific pharmacologic or mechanical prophylaxis was recommended [1,4]. For patients with low risk for VTE (Caprini score = 1-2), the guideline suggested only mechanical prophylaxis with intermittent pneumatic compression (IPE) [1,4]. Patients at moderate risk for VTE (Caprini score = 3-4) without high risk for major bleeding, pharmacological prophylaxis with low molecular weight heparin, low dose unfractionated heparin, or mechanical prophylaxis with IPE were recommended [1,4]. Moreover, for patients at high risk for VTE (Caprini score ≥ 5) without high risk for major bleeding, the guideline recommends pharmacological prophylaxis adding mechanical prophylaxis [1,4].

The VTE (DVT+PE) incidences ranges from 0-7.6% [5-9]. Its occurrence seems to be relatively constant, or even increasing. The overall incidence is 0.2% for all gynecologic surgeries, and less likely to be found in minimally invasive surgery [6]. The incidence of PE ranged from 0-1.9 % [7]. In the West, these might be higher than [8] or equal with Asia [9]. Known clinical risk factors included age, race, BMI, principle diagnoses, operation types, operative time, comorbidities, hormonal uses, and length of stay [10-12]. DVT incidence in Thai intensive care unit (ICU) setting and major abdominal surgery were both 3.6% [11,12], while PE incidence was 1.8% [12], similar to the above mentioned [5-9]. Nevertheless, routine thromboprophylaxis for VTE after surgery in Thai institutions has not been commonly practiced [11,12]. Also, before 2019 there had been no institutional thromboprophylaxis guideline in place at the Srinagarind Hospital. Only routine elastic bandages to

both legs, but neither elastic stockings nor IPE, were applied to all patients, perioperatively. No other pharmacological prophylaxis was used in combination with the mentioned mechanical prophylaxis. Incidence of VTE is believed to be rare but no study was conducted in the institution to prove the assumption. In addition, some sporadic cases of VTE occurred, inspiring the authors to conduct this study.

In 2014, an electronic medical record (EMR) system was successfully implemented in the Srinagarind Hospital. This kind of electronic archiving has made retrieving and analyzing large number of data from medical records possible. Therefore, investigating the incidence of VTE has been possible since then. Since 2019, the institutional thromboprophylaxis guidelines, similar to the ones mentioned above [1-4], has also been in place. As a result, the incidence of VTE might be changing. Therefore, the primary objective of this study was to investigate the incidence of VTE in post-operative benign gynecologic patients who had undergone surgeries from 2014 to 2018, a period prior to initiation of guidelines for VTE prophylaxis. The secondary objective was to identify risk factors of post-operative venous thromboembolism at the Srinagarind Hospital, in the Northeast of Thailand.

2. Materials and methods

A retrospective cohort study was conducted to investigate the incidence and risk factors of post-operative VTE in all gynecologic surgeries for benign indications between January 1, 2014 and December 31, 2018. There were neither institutional thromboprophylaxis guidelines nor routine screening for post-operative VTE risk factors in place during the study period at the Srinagarind Hospital, Khon Kaen University, Thailand. The study was approved by the Khon Kaen University Ethics Committee in Human Research, Reference No. HE621032.

Sample size calculation was based on the reported incidence of symptomatic VTE in Chinese patients after gynecologic surgery at 0.5% [9], by the level of significance at 95%, study power of 80%, and acceptable error of 0.1%. Calculations were based on samples from 1,912 patients. From 2014-2018, there were about 500 gynecologic surgeries per year recorded for benign indications at the Srinagarind Hospital (in total about 2,500). Hence, we decided to analyze all of them according to the study's inclusion and exclusion criteria.

Procedure codes assigned to each medical record according to the International Classification of Disease, 9th revision (ICD-9) were used to search all gynecologic surgeries in EMR during the study period. ICD-10 disease codes were maintained to exclude all oncologic patients. The author (TT) retrospectively reviewed individual patient's data on the EMR system (Praxticol^{TM}) for collecting important data including age, race, BMI, gynecologic disease, operation types, operative time, comorbidities, length of stay, clinical presentation and investigation of venous thromboembolism during admission period, and from pre-operative until complete post-operative treatment and discharge. Outpatient medical records were analyzed to detect symptomatic VTE at the time of follow up in order to schedule health care provider visits 30 days after surgery.

Post-operative VTEs were defined as deep vein thrombosis (DVT) or pulmonary embolism (PE) that occurred starting at the post-operative admission period until follow up 30 days after the surgery. DVT was declared when clinical leg swelling, pain, and diagnosis had been confirmed by Doppler ultrasonography. PE was assessed when clinical dyspnea, chest pain, hypoxemia, and diagnosis were confirmed by pulmonary angiography or computer tomography angiography. Patients who had shown VTEs signs before surgery, or who had no follow up after surgery, or had displayed malignancy confirmed by pathological report after surgery, together with those who had incomplete important medical records, were excluded.

Statistical analysis was performed using commercial statistical software STATA version 10.1 (Stata Corp college Station, Texas, USA). The incidence proportion and rate and its 95% CI of post-operative venous thromboembolism were calculated. Univariate analysis with exact logistic regression were calculated with odd ratio and its 95% CI, for the associated factors of VTEs, such as age, BMI, operative time, oral combine contraceptives, pregnancy, comorbidities, and Caprini score. A *p*-value of less than 0.05 from univariate analysis was regarded as statistically significant.

3. Results and discussion

Between January 1, 2014 and December 31, 2018, a total of 2,801 patients had undergone gynecologic surgeries for benign indications at the Srinagarind Hospital. One hundred and twenty-three patients were excluded due to incomplete medical records (4 patients), pathological confirmed malignancy after surgery (16 patients), venous thromboembolism presented before surgery (13 patients), and the inability to follow up 30 days after surgery (90 patients). As a result, 2,678 patients were recruited for analysis in this study (Figure 1).

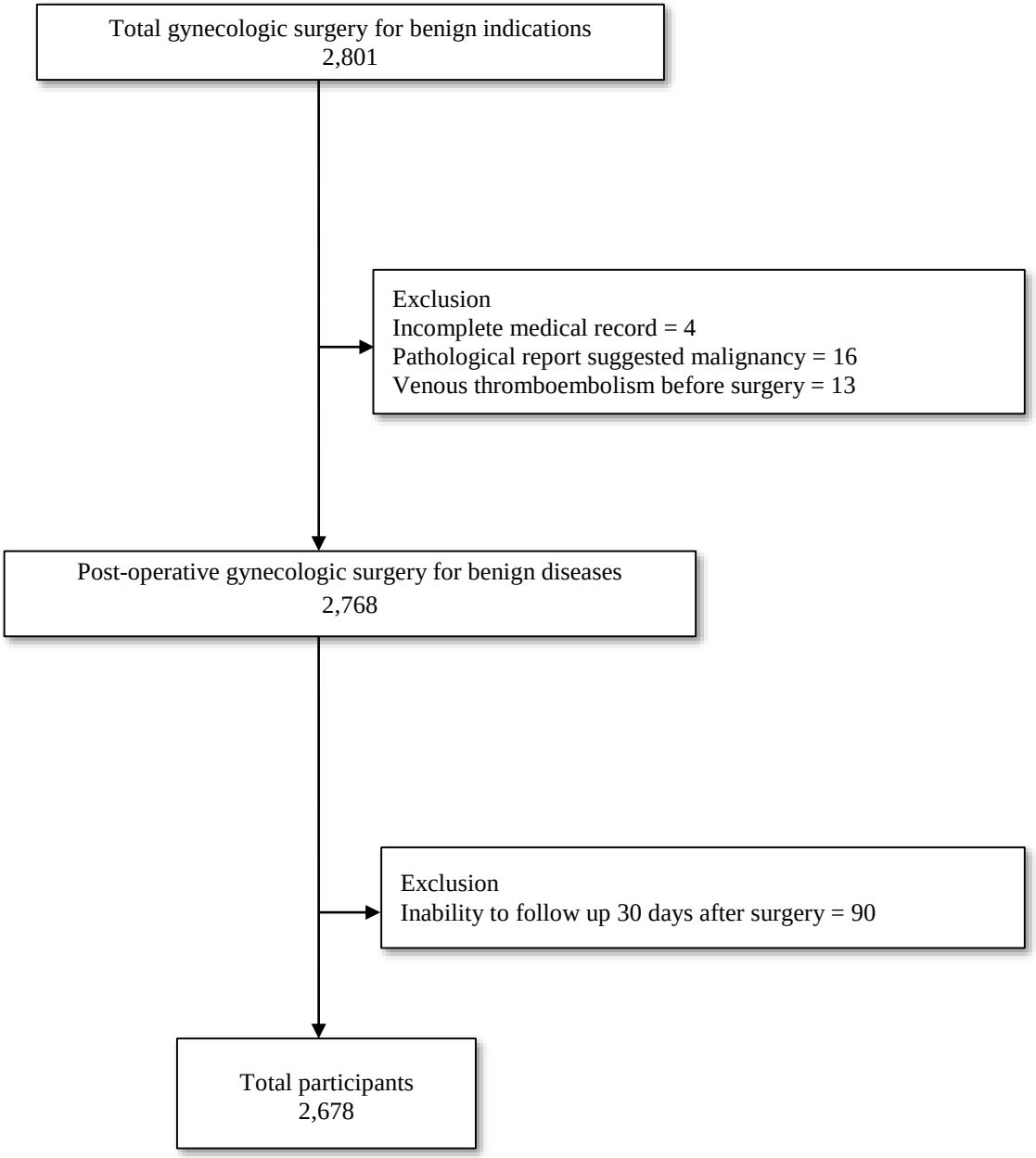

Figure 1 Flow diagram of the participants.

All patients belonged to the Southeast Asian Nationalities: 2,642 Thai, 34 Laotians, 1 Vietnamese, and 1 Cambodian. Their ages ranged from 12 to 95 year-old (mean 42 year-old). Eight hundred and forty one (31.4%) patients had BMI ≥ 25 kg/m^2. Only 36 (1.3%) patients had used oral combined contraceptives until the time of surgery (currently). Top three comorbidities were hypertension (11.6%), diabetes mellitus (5.6%), and dyslipidemia (5.1%). Most diagnoses were myoma uteri, in 906 of the patients (33.8%). Most operations were abdominal hysterectomy, performed on 1,116 patients (41.7%). Among the 786 laparoscopic cases in the complete follow-up group, 74 were diagnostic while 712 were operative with 376 LOC (laparoscopic ovarian cystectomy), 108 TLH (total laparoscopic hysterectomy), 82 SO (salpingo-oophorectomy) or salpingectomy, 55 RAVH (radical-laparoscopic assisted hysterectomy), 43 LAVH (laparoscopic assisted hysterectomy), 18 myomectomy, 18 TR (tubal resection), and 12 adhesiolysis. In the loss follow-up group, there were no diagnostic but only 26 operative; 13 LOC, 5 LAVH, 4 TLH, 3 SO, and 1 myomectomy. Almost all patients (95.6%) had operative time of more than 45 minutes. Length of stay in hospital ranged from 2 to 49 days (mean 5 days). When using Caprini risk assessment, there were 915 patients (34.2%) having Caprini score = 2, 962 patients (35.9%) having Caprini score = 3, 599 patients (22.4%) having Caprini score = 4, and 111 patients (4.1%) having Caprini score ≥ 5. Patients' characteristics are shown in Table 1.

Table 1 Patient characteristics.

Characteristics	Complete FU N=2,678 (%)	Loss FU N=90 (%)	*P*-value
Age (years)			0.485
< 40	1,183 (44.17)	35 (38.89)	
40-60	1,274 (47.57)	51 (56.67)	
61-75	186 (6.95)	3 (3.33)	
> 75	35 (1.31)	1 (1.11)	
Nationalities			0.746
Thai	2,642 (98.65)	90 (100)	
Laotian	34 (1.27)	0	
Vietnamese	1 (0.04)	0	
Cambodian	1 (0.04)	0	
BMI			0.342
< 25	1,837 (68.6)	66 (73.33)	
≥ 25	841(31.4)	24 (26.67)	
Current oral combine contraceptive use	36 (1.34)	1 (1.11)	0.807
Pregnancy	13 (0.49)	0	0.507
Comorbidities			0.882
Hypertension	311 (11.61)	10 (11.11)	
Diabetes mellitus	150 (5.60)	6 (6.67)	
Dyslipidemia	136 (5.08)	3 (3.33)	
Thyroid disease	76 (2.84)	1 (1.11)	
Asthma	51 (1.90)	0	
Valvular heart disease	47 (1.76)	0	
Hepatitis	35 (1.31)	5 (5.56)	
Chronic kidney disease	24 (0.90)	0	
Atrial fibrillation	16 (0.60)	3 (3.33)	
HIV infection	13 (0.49)	1 (1.11)	
Stroke	12 (0.45)	0	
Rheumatoid arthritis	11 (0.41)	0	
SLE	8 (0.30)	0	
Osteoporosis	7 (0.26)	0	
Respiratory failure	5 (0.19)	1 (1.11)	
Varicose vein	1 (0.04)	0	
Diagnoses			0.325
Myoma uteri	906 (33.83)	35 (38.89)	
Endometrioma	546 (20.39)	20 (22.22)	
Ovarian tumor	249 (9.30)	4 (4.44)	
Adenomyosis	219 (8.18)	5 (5.56)	
Pelvic organ prolapse	187 (6.98)	3 (3.33)	
Dermoid cyst	181(6.76)	13 (14.44)	
Desired fertility	66 (2.46)	6 (6.67)	
HSIL	57 (2.13)	1 (1.11)	
Hydrosalpinx	52 (1.94)	0	
Tubo-ovarian abscess	34 (1.27)	1 (1.11)	
Endometrial hyperplasia	34 (1.27)	1 (1.11)	
Desired female sterilization	23 (0.86)	0	
Endometrial polyp	10 (0.37)	0	
Others*	114 (4.25)	1 (1.11)	
Operations			0.152
Laparoscopy	786 (29.35)	26 (28.89)	
Abdominal hysterectomy with salpingo-oophorectomy	685 (25.58)	31 (34.44)	
Abdominal hysterectomy	416 (15.53)	11 (12.22)	
Salpingo-oophorectomy (SO)	203 (7.58)	4 (4.44)	
Vaginal hysterectomy	187 (6.98)	2 (2.22)	
Cystectomy	157 (5.85)	8 (8.89)	
Open myomectomy	101 (3.77)	2 (2.22)	
Tubal reanastomosis	66 (2.46)	6 (6.67)	
Salpingectomy	17 (0.63)	0	
Abdominal hysterectomy with SO with omentectomy	15 (0.56)	0	
Others**	41 (1.53)	0	
Operative time (minutes)			0.127
< 45	119 (4.44)	1 (1.11)	
≥ 45	2,559 (95.56)	89 (98.89)	
Caprini score			0.324
1	91 (3.40)	0	
2	915 (34.17)	35 (38.89)	
3	962 (35.92)	31 (34.44)	
4	599 (22.37)	22 (24.44)	
≥ 5	111 (4.14)	2 (2.22)	

Notes: *Other diagnoses were; pelvic endometriosis (24), chronic pelvic pain (14), pelvic adhesion (13), pelvic pseudocyst (9), Down's syndrome (6), mental retardation (6), transverse vaginal septum (5), bicornuate uteruS (5), abnormal uterine bleeding (5), autism (4), global delay development (3), ectopic pregnancy (2), primary infertility (2), vaginal stenosis (2), tuberculosis peritonitis (2), subcutaneous endometriosis (1), pelvic congestion syndrome (1), Swyer syndrome (1), cerebral palsy (1), Lennox-Gastaut syndrome (1), uterine scar fistula with pelvic abscess (1), polycystic ovarian syndrome (1), primary amenorrhea (1), imperforate hymen (1), mosaic Turner syndrome

(1), androgen insensitivity syndrome (1), and Williams syndrome (1) in the complete follow-up group. Only 1 autism case was found in the loss follow-up group.
**Other operations were; exploratory laparotomy with drainage (12), adhesiolysis (9), vaginal septum excision (6), exploratory laparotomy (6), exploratory laparotomy with ovarian drilling (2), tubal resection (2), perineorrhaphy (2), hymenal incision (1), and subcutaneous endometriosis excision (1) in the complete follow-up group.

Post-operative venous thromboembolisms were detected in 2 patients. One of them had left leg edema and hypoxemia 14 days after surgery. The diagnosis was DVT based on Doppler ultrasonography and PE from computed tomography pulmonary angiography. The patient received treatment with heparin immediately after diagnosis. Unfortunately, two days after the treatment, patient went into sudden cardiac arrest followed by death despite immediate CPR. The other one had pulmonary embolism 3 days after surgery with clinical hypoxemia. The diagnosis was confirmed by computed tomography pulmonary angiography. This patient also received treatment with Heparin immediately after diagnosis. In June of 2020, the patient has been reported alive and free from disease. Characteristics of the two patients who developed post-operative VTEs are shown in Table 2.

Table 2 Characteristics of patients who developed post-operative venous thromboembolism

Patient	Age	BMI	Diagnosis	Operation	OR time (minutes)	Comorbidities	Caprini score	VTEs	Outcome
1	51	28.7	Myoma uteri	TAH with BSO	75	Type2 DM Hypertension	4	DVT PE	Death
2	53	26.9	Myoma uteri	TAH with BSO	150	Thalassemia	4	PE	Alive

TAH with BSO: Total abdominal hysterectomy with bilateral salpingo-oophorectomy
PE: pulmonary embolism
DVT: Deep vein thrombosis

From these two incidental cases, the incidence proportion of post-operative venous thromboembolism was 0.07% (95% CI, 0.009-0.26) and incidence rate was 15 per 100,000 women-years (95%CI, 2-52). However, death-to-case rate was 50% (1/2). Unfortunately, due to scanty events, there were no any other risk factors identified as reaching statistical significance in this study. All univariate analyses of known clinical risk factors associated with VTE are shown in Table 3. The only nearest factor to a statistical significance was "BMI ≥ 25" (*p*-value = 0.19). Therefore, multivariate analysis was not practiced.

Table 3 Univariate analysis of clinical factor associate with venous thromboembolism.

Variables	Non-VTE (n=2,676)	VTE (n=2)	OR (95% CI)	*P*-value
Age				
< 40	1,183	0	Reference	
40-60	1,272	2	2.24 (0.17-inf)	0.53
61-75	186	0	1 (0-inf)	0
≥75	35	0	1 (0-inf)	0
BMI				
< 25	1,837	0	Reference	
≥ 25	839	2	5.27 (0.41-inf)	0.19
Oral contraceptive use	36	0	0.03 (0.002-inf)	1
Pregnancy	13	0	0.01 (0.0008-inf)	1
Comorbidities				
Diabetes mellitus	149	1	0.59 (0.0007-4.66)	0.21
Hypertension	310	1	0.13 (0.001-10.31)	0.43
Dyslipidemia	136	0	0.12 (0.01-inf)	1
Gynecologic disease				
Myoma uteri	904	2	3.91	0.86
Adenomyosis	219	0	1.71 (0-22.05)	1
Pelvic organ prolapse	187	0	2.01 (0-25.83)	1
Endometrioma	546	0	0.68 (0-8.83)	1
Ovarian tumor	249	0	1.51 (0-19.39)	1
Operative time (minutes)				
< 45	119	0	Reference	
≥ 45	2557	2	0.11 (0.008-inf)	1
Caprini score				
1	91	0	Reference	
2	915	0	1	0
3	962	0	1	0
4	599	2	0.36 (0.02-inf)	1
≥ 5	111	0	1	0

In this study, the incidence proportion of post-operative venous thromboembolism was 0.07% (95% CI, 0.009-0.26) and incidence rate was 15 per 100,000 women-years (95% CI, 2-52). These were lower than those in the previous studies, which were 3.6% in Thai ICU [11] and 3.6% in Thai major abdominal surgeries [12]. These were also lower than those in overall Chinese (0.5%) [9] or American (0.2%) [6] gynecologic surgeries. However, these were still in the range of 0-7.6% from the literatures reviewed [5-9]. These might be due to the fact that most patients in this study were low to moderate risks for VTEs and the nature of a retrospective study's inability to detect asymptomatic VTE.

There was no risk factor associated VTE identified as having statistical significance because of scanty events. Both of the patients diagnosed as having myoma uteri had undergone total abdominal hysterectomy with salpingo-oophorectomy, they had BMI greater than 25 cm/m2, Caprini score was 4 and operative time of more than 45 minutes. The only nearest factor to statistical significance was "BMI $\geq$ 25" (p-value = 0.19). In this group of patients with high BMI but without high risk for major bleeding, pharmacological prophylaxis with low molecular weight heparin, low dose unfractionated heparin, or mechanical prophylaxis with IPE were recommended [1,4]. One of the two cases died from PE causing death-to-case rate to be 50% in this study, but in general, one third of VTE are PE which would be fatal in almost 10% of cases [13]. Unfortunately, only elastic bandages were supplied as there was no institutional guideline during the study period.

In 2017, Feng et al. suggested that IPC significantly lowered the DVT risk (RR = 0.33, 95% CI, 0.16-0.66) [14]. In 2019, after the above-mentioned incidences, the institutional thromboprophylaxis guidelines have been established and IPC was routinely used at the Srinagarind Hospital for indicated perioperative gynecologic patients. However, the post-operative incidence of symptomatic VTE should exceed 3% to warrant pharmacological prophylaxis [1,15,16]. From this study, even if we strictly consider patients with Caprini score of 4-5, the VTE incidence would be only 0.3%. Pharmacological prophylaxis is also not without risk, therefore, a monitoring study for the guideline's safety and efficacy is still needed.

In 2018, although most Canadian hospitals and the UK National Institute for Health and Care Excellence (NICE) have implemented guidelines [17,18] based on ACCP [1]. Kotaska suggested that VTE prophylaxis may cause more harm than benefit [19]. In asymptomatic VTE, the estimates of benefit or harm magnitudes from low molecular weight heparin (LMWH) are still lacking. Most hospitalized patients have the symptomatic VTE risk equal to or lower than the bleeding risk from LMWH. Therefore, they should not receive LMWH until randomized trials have shown more benefit than harm. Prophylaxis is not indicated if patient is fully mobile and will have only brief length of stay [17]. In addition, it is contraindicated if patient is in active bleeding or high risk of bleeding [17]. In our institute, these indications and contraindications are also strictly adhered. Nevertheless, the judgment depends on the authorized surgeon.

Strength of this study is that it is the first Thai study investigating incidence of VTE in postoperative benign gynecologic patients. It also has large and adequate sample size to summarize the incidence, although not enough to summarize the risk factors. Limitations of the study included nature of the retrospective design, its inability to detect VTE in patients who were unable to trace for a follow up or patients who went to another hospital for post-operative venous thromboembolism diagnosis and treatment.

4. Conclusion

Post-operative venous thromboembolism was rare (0.07%) in benign gynecologic patients after surgeries, but resulted in high death-to-case rate. A monitoring study for the institutional guideline's safety and efficacy in terms of VTE prophylaxis is still needed.

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