

Original Article

Venous Thromboembolism Risk and Prophylaxis in the Acute Hospital Care Setting (ENDORSE study): Thailand Subgroup Analysis

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Abstract : *The incidence of venous thromboembolism (VTE) varies in different countries. Information on the variation in the risk for VTE and extent of prophylaxis practices worldwide is scarce, especially in Thailand. The ENDORSE (Epidemiologic International Day for Evaluation of Patients at Risk for Venous Thromboembolism in the Acute Hospital Care Setting) study is a multinational cross-sectional survey. The study was designed to provide such information by accessing the prevalence of VTE risk in the acute hospital care setting, and to determine the proportion of at-risk patients who receive effective prophylaxis. The eligible patients were those of age 18 years or older admitted to surgical wards or 40 years or older admitted to medical wards. The 2004 American College of Chest Physicians (ACCP) evidence-based consensus guidelines were used to assess VTE risk and to determine whether patients were receiving recommended VTE prophylaxis. Among 358 hospitals across 32 countries worldwide, 1,824 patients from 5 hospitals in Thailand were enrolled in the study, with 1,001 (54.9%) categorized as surgical and 823 (45.1%) as medical patients. A large proportion of Thai patients (56.1%) is at risk for VTE, but the rate of appropriate prophylaxis is very low (1.8%). On the basis of the 2004 ACCP criteria, only 3 (0.5%) out of 618 (61.7%) at-risk surgical patients received VTE prophylaxis compared to 15 (3.7%) out of 406 (49.3%) at-risk medical patients. The data reinforces the rationale for the use of hospital-wide strategies to assess patients' VTE risk and to implement measures that ensure that at-risk patients receive appropriate prophylaxis.*

Key Words : ● Venous thromboembolism ● Prophylaxis ● Thailand

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Venous thromboembolism (VTE) is a common complication in hospitalized patients. Epidemiological studies show that VTE remains a major cause of morbidity and mortality in these patients. Furthermore, these complications contribute substantially to the healthcare cost.

Pulmonary embolism (PE) accounts for 5-10% of deaths in hospitalized patients.¹⁴ While VTE is the most preventable cause of in-hospital mortality, it is frequently underestimated. Failure to provide appropriate thromboprophylaxis puts patients at risk of VTE.

The American College of Chest Physicians (ACCP) publishes regularly updated evidence-based guidelines, based on systematic review of the literature, that provide specific recommendations for thromboprophylaxis of patients at risk for VTE. The guidelines strongly

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recommend that a certain group of patients would gain the benefits from receiving thromboprophylaxis.¹ But to date, the proportion of at-risk patients who should receive prophylaxis remains unknown.

Epidemiologic International Day for the Evaluation of Patients at Risk for Venous Thromboembolism in the Acute Hospital Care Setting (ENDORSE) study was a multinational, observational and cross-sectional study.⁵ A chart audit of surgical and medical patients was performed in a large sample of hospitals. The study was designed to identify the number of patients at risk for VTE in the acute care hospital setting throughout the world and to determine the proportion of these at-risk patients who received effective VTE prophylaxis as recommended by the ACCP evidence-based consensus guidelines.¹ The aim of this paper is to present data specific to the Thai population of patients in this study.

Methods

Procedures

Hospitals, which contained more than 50 patient beds in total, admitted patients for treatment of acute medical illnesses/exacerbations of chronic disease and scheduled routine major surgical procedures, were considered eligible for enrollment. Hospitals dedicated exclusively to psychiatric care, care of children, obstetrics, rehabilitation/hospice care and those with less than 50 beds or not performing routine scheduled major operations were excluded.

A total number of 358 hospitals worldwide were selected at random from authoritative lists of acute care hospitals in 32 participating countries. In Thailand, 5 eligible hospitals were randomly selected by the principal investigator. Ethics committee approval was obtained in accordance with national and local regulations.

Eligible wards are those occupied by acute medical and surgical patients. Psychiatric, pediatric, maternity/obstetrics, neonatal, burn units, geriatric units, eye, ear, nose, throat, dermatology, alcohol/drug treatment, rehabilitation, palliative care and emergency care were ex-

cluded. All eligible wards within enrolled hospital were included in the study. A study log was completed for each ward on the day of the survey.

Patients

The eligible patients were those aged 40 years or more in medical wards or 18 years or more in surgical wards. Patients who were ineligible or excluded from the study were those who met the following criterion: missing hospital chart, patients admitted to an ineligible ward, patients admitted for a solely treatment of VTE, patients admitted for diagnostic testing only.

According to the 2004 ACCP guidelines, all enrolled patients should be assessed for risk for VTE.⁶ This included acutely ill medical patients and patients admitted for major trauma or undergoing a major surgical procedure requiring general or epidural anesthesia for at least 45 minutes. For surgical patients, age, type of surgery and duration of anesthesia were assessed and then classified as being highest, high, moderate, or low risk for VTE.

The recommended types of VTE prophylaxis received by at-risk patients were defined according to the 2004 ACCP guidelines.⁶ Information on both the type of prophylaxis and dose administered were collected. However, only the type of prophylaxis was considered for analysis. Because of different dosing recommendations in each country and lack of data of dosing schedule recommended by ACCP, hence data of dose administered are not declared. Duration of doses could not be assessed because this study was a cross-sectional study.

Patients were considered to have a contraindication to anticoagulant prophylaxis if they have sufficient risk of bleeding presented with, or developed, during hospitalization. Any of the following was considered as a bleeding risk: intracranial hemorrhage; hepatic impairment; bleeding at hospital admission; active gastroduodenal ulcer; or a known bleeding disorder.⁷

Statistical analysis

Quantitative data were summarized as median (IQR)

and the number of non-missing data. Categorical data were summarized into number and percentage of the population. Country rates were calculated from individual patient data. To assess the true occurrence of VTE risk at 25% with a margin of error of 4%, a minimum of 450 patients per analysis group are required. 95% CI and between-country ranges were calculated for the main outcomes. SAS version 9.1 was used for all statistical analyses.

Role of the funding source

The protocol was written by an independent scientific steering committee and revised after discussion with the study sponsor. Data collection was co-ordinated by the Center for Outcomes Research (University of Massachusetts Medical School, Worcester, MA, USA). All statistical analyses were done by the Center of Outcomes Research.

Results

Sixty eight thousand one hundred and eighty three patients were enrolled between August 2006 and January 2007 from 358 hospitals across 32 countries. The five hospitals from Thailand included Ramathibodi hospital, Maharat Nakornratchasima hospital, Chiangmai University hospital, Chiangrai Prachanukroh regional hospital and Prapokklao hospital. Figure 1 shows data from Thailand consisting of the number of beds assessed, reasons for exclusion from assessment together with the number of assessable medical and surgical patients.

General characteristics of the surgical and medical patients and reasons for hospital admission are shown in table 1 and 2, respectively. Patients who are at risk in surgical wards had a median age of 53 years, median body-mass index (BMI) was 23.2 kg/m², median hospital admission to survey date was 7 days and 280 (45.5%) were female. Of the patients in medical ward, the median age was 67 years, median BMI was 19.7 kg/m², median hospital admission to survey date was 4 days and 188 patients (46.4%) were women. In the over-

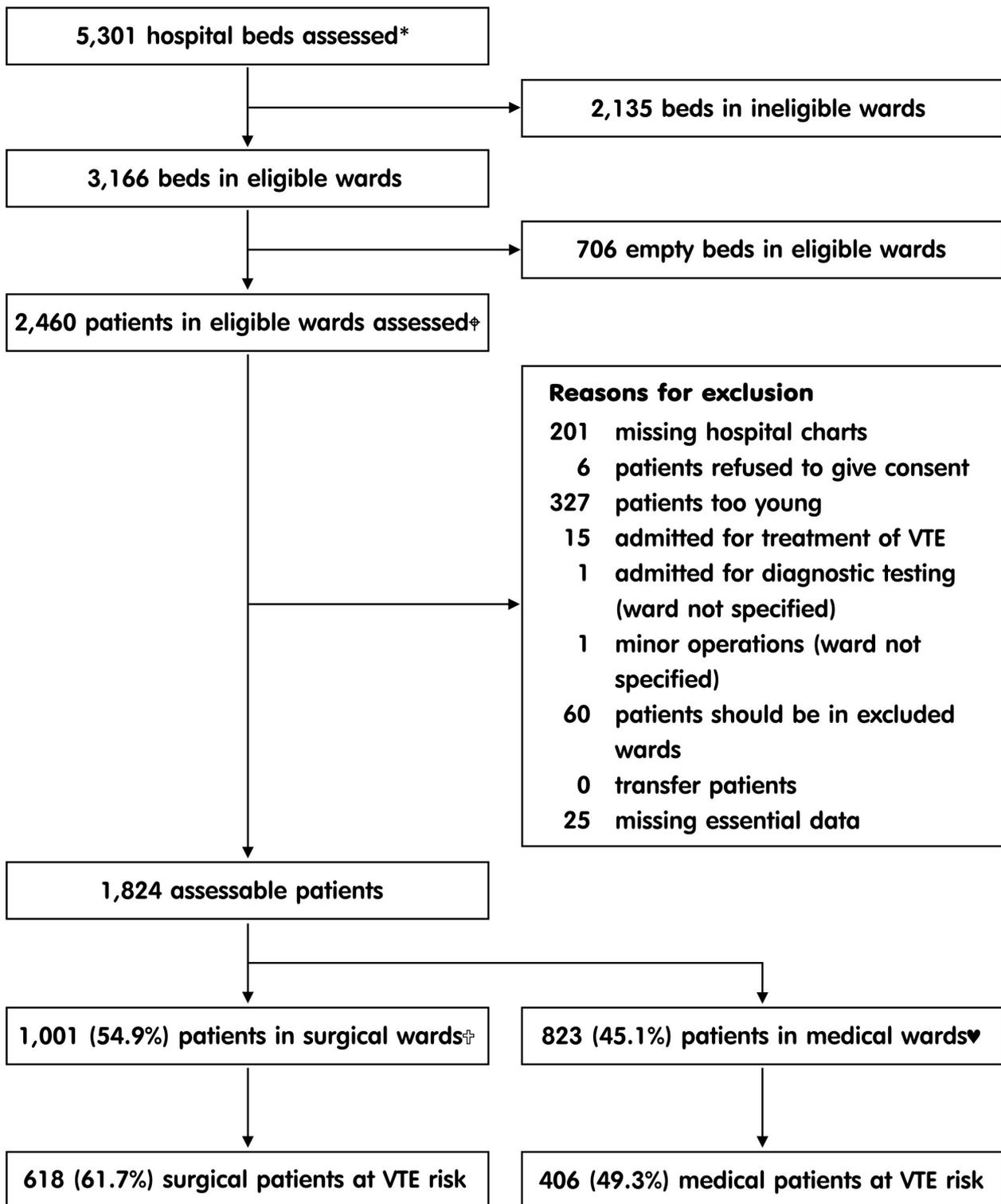
all study population, median length of hospital stay up to the survey date was 6 days.

Risk factors for VTE that were present before admission are shown in table 3. Chronic pulmonary disease was the most common VTE risk before hospitalization in both surgical and medical patients. The second most common VTE risk factor was chronic heart failure. The most common post-admission risk factors for VTE in both surgical and medical patients were complete immobilization, immobilization with bathroom privileges, mechanical ventilation, and admission to an intensive or critical unit.

The most common contraindications to pharmacological prophylaxis in surgical patients were intracranial bleeding followed by bleeding at hospital admission, and clinically relevant hepatic impairment. In medical patients, clinically relevant hepatic impairment followed by bleeding at hospital admission, and intracranial bleeding were the most common contraindications (table 4). Of the population at risk for VTE, 59 (9.5%) surgical patients and 36 (8.9%) medical patients were considered to have a high bleeding risk, sufficient to present a contraindication to anticoagulant prophylaxis.

From a total of 1,824 patients enrolled, 1,024 patients (56.1%) are at VTE risk according to the ACCP 2004 guidelines but only 18 patients (1.8%) received ACCP recommended prophylaxis. Of 1,001 patients on surgical wards, 3 patient out of 618 at-risk patients (0.5%) received ACCP-recommended prophylaxis. Of 823 patients on medical wards, 15 patients out of 406 at-risk patients (3.7%) received ACCP-recommended prophylaxis. Most cases that received prophylaxis were patients with acute heart failure (NYHA Class III or IV), patients with hematologic disease, ischemic stroke, and other cardiovascular disease. Low molecular weight heparin was the most frequently used form of VTE prophylaxis followed by vitamin-K antagonist.

No other types of prophylaxis including mechanical prophylaxis were given for the rest of patients (table 5).



VTE = venous thromboembolism. *On basis of hospital enrolment forms. †On basis of patient enrolment logs, includes patients who did not meet protocol requirements (e.g. age, type of condition, or missing hospital chart). ‡Includes patients in general surgical units, surgical intensive-care units, neurosurgery, gynecology, and orthopedics. ♥Includes patients in other eligible wards.

Figure 1 Selection of study population from Thailand and reasons for exclusion.

Table 1 Characteristics and reasons for hospitalization of assessable surgical patients

	N=618
Patient Characteristics	
Male	337 (54.5%)
Female	281 (45.5%)
Age (years)*	53.0
Body-mass index (kg/m ²)*	23.2
Length of hospitalization up to survey date (days)*	7.0
Reasons for hospitalization	
Hip replacement	11 (1.8%)
Knee replacement	10 (1.6%)
Hip fracture	6 (1.0%)
Curative arthroscopy	1 (0.2%)
Other orthopedic trauma	82 (13.3%)
Colon/small bowel surgery	50 (8.1%)
Urologic surgery	44 (7.1%)
Thoracic surgery	32 (5.2%)
Hepatobiliary surgery	25 (4.0%)
Gynecological surgery	24 (3.9%)
Gastric surgery	17 (2.8%)
Vascular surgery	15 (2.4%)
Rectosigmoid surgery	8 (1.3%)
Other major surgery	192 (31.1%)
Admitted with major trauma but surgery not performed	101 (16.3%)

*Data are medians

Discussion

Globally the proportion of patients at risk for VTE did not vary greatly, with a mean of 52%.⁵ However, the frequency of the use of ACCP-recommended type of prophylaxis was markedly different among different countries.^{1,8,9} Figure 2 shows that the proportion of the patients at risk for VTE ranged from 36% to 73% and the proportion of patients receiving ACCP-recommended prophylaxis ranged from 1.6% to 84%. Thailand is within the range of the proportion of patients at risk for VTE (56.1%), but the proportion of patients receiving prophylaxis is among the lowest (1.6%). Physician awareness seems to be the most important factor influencing the low prophylaxis rate. Other factors include avail-

ability of guidelines, education factors, reimbursement, and national health-care resources.

Although genetic risk factors for VTE are different between Thais and Caucasians, with protein S deficiency and protein C deficiency being more common in the Thai patients and factor V Leiden and G20210A prothrombin gene mutation being more common in Caucasian patients,¹⁰ chronic pulmonary disease and chronic heart failure were the most two common VTE risk factors before hospitalization in Thai patients as well as in Caucasian patients. In Caucasian patients obesity was the risk factor but this is not the case for Thai patients.^{10,11} Complete immobilization, immobilization with bathroom privileges and admission to an

Table 2 Characteristics and reasons for hospitalization of assessable medical patients

	N=406
Patient Characteristics	
Male	218 (53.6%)
Female	188 (46.4%)
Age (years)*	67.0
Body-mass index (kg/m ²)*	19.7
Length of hospitalization up to survey date (days)*	4.0
Reasons for hospitalization	
Pulmonary infection	13 (32.3%)
Infection (non-respiratory)	119 (29.3%)
Other cardiovascular disease	74 (18.2%)
Hematological disease	60 (14.8%)
Renal disease	57 (14.0%)
Acute heart failure (NYHA Class III or IV)	53 (13.1%)
Malignancy (active)	48 (11.8%)
Acute non-infectious respiratory disease	45 (11.1%)
Gastrointestinal/hepatobiliary disease	37 (9.1%)
Ischemic stroke	35 (8.6%)
Endocrine/metabolic disease	33 (8.1%)
Neurological disease	29 (7.1%)
Rheumatologic or inflammatory disease	14 (3.4%)
Hemorrhagic stroke	10 (2.5%)
Other medical conditions	24 (6.0%)

*Data are medians; NYHA = New York Heart Association.

intensive or critical care unit were the most common post-admission risk factors for VTE in both Thai and Caucasian patients.

Worldwide as well as in Thailand, bleeding was the most common contraindication to anticoagulant prophylaxis in both surgical and medical patients. Although the risk of bleeding plays an important role in the decision to provide VTE prophylaxis, anticoagulants especially low molecular weight heparins are solely used in both medical and surgical Thai patients. The use of mechanical prophylaxis was rare among Thai physicians although this procedure could also reduce the incidence of VTE in those cases with contraindications to anticoagulant prophylaxis. This may be due to the

fact that Thai physicians are not familiar with mechanical prophylaxis.

There are several potential limitations in this study. Firstly, the data were captured from the hospital charts. This approach might lead to some inaccuracies and failure to capture the most recent information. Secondly, because ENDORSE was a cross-sectional study, only the quality of treatment up to the date of survey could be assessed. However, the duration of prophylaxis throughout the full hospital stay could not be assessed. Another potential limitation is that even though the risk assessment was done under the 2004 ACCP recommendations, this does not mean that the excluded patients are not at risk. Most Thai physicians recog-

Table 3 Risk factors for venous thromboembolism

	Surgical patients (N=618)	Medical patients (N=406)	Overall (N=1,024)
Before admission			
Chronic pulmonary disease	23 (4.6%)	70 (17.9%)	93 (10.5%)
Chronic heart failure	10 (2.0%)	37 (9.5%)	47 (5.3%)
Long term immobility	8(1.6%)	27 (6.9%)	35 (3.9%)
Previous venous thromboembolism	3 (0.6%)	2 (0.5%)	5 (0.6%)
Obesity (BMI >30 kg/m ²)	2 (0.4%)	3 (0.8%)	5 (0.6%)
Contraceptives	4 (0.8%)	0 (0.0%)	4 (0.5%)
Varicose veins or venous insufficiency	3 (0.6%)	0 (0.0%)	3 (0.3%)
Post-menopausal hormonal replacement therapy	1 (0.2%)	0 (0.0%)	1 (0.1%)
Pregnancy (within 3 months)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Thrombophilia	0 (0.0%)	0 (0.0%)	0 (0.0%)
During hospitalization			
Complete immobilization	302 (48.9%)	219 (53.9%)	521 (50.9%)
Immobilization with bathroom privileges	136 (22.0%)	118 (29.1%)	254 (24.8%)
Mechanical ventilation	98 (15.9%)	118 (29.1%)	216 (21.1%)
Admitted to intensive care unit/critical care unit	95 (15.4%)	96 (23.6%)	191 (18.7%)
Central venous catheter	41 (6.6%)	28 (6.9%)	69 (6.7%)
Cancer therapy	1 (0.2%)	11 (2.7%)	12 (1.2%)
Heparin induced thrombocytopenia	0 (0.0%)	0 (0.0%)	0 (0.0%)

Table 4 Contraindications to anticoagulation

	Surgical patients (N=618)	Medical patients (N=406)	Overall (N=1,024)
Significant renal impairment	60 (9.7%)	90 (22.2%)	150 (14.6%)
Aspirin use	33 (5.3%)	96 (23.6%)	129 (12.6%)
NSAID use (excluding aspirin)	62 (10.0%)	3 (0.7%)	65 (6.3%)
Low platelet count (<100,000 per ul)	7 (1.1%)	33 (8.1%)	40 (3.9%)
Intracranial hemorrhage*	30 (4.9%)	9 (2.2%)	39 (3.8%)
Clinically relevant hepatic impairment*	15 (2.4%)	17 (4.2%)	32 (3.1%)
Bleeding at hospital admission*	15 (2.4%)	9 (2.2%)	24 (2.3%)
Active gastroduodenal ulcer*	4 (0.6%)	5 (1.2%)	9 (0.9%)
Known bleeding disorder (congenital or acquired)*	1 (0.2%)	0 (0.0%)	1 (0.1%)

*Absolute contraindications, defined in accordance with Baglin and colleagues.⁷

Table 5 Type of prophylaxis used in at-risk patients

	Surgical patients (N=618)	Medical patients (N=406)	Overall (N=1,024)
Low molecular weight heparin	1 (0.2%)	15 (3.7%)	16 (1.6%)
Vitamin-K antagonist	2 (0.3%)	0 (0.0%)	2 (0.2%)
Unfractionated heparin	0 (0.0%)	0 (0.0%)	0 (0.0%)
Fondaparinux	0 (0.0%)	0 (0.0%)	0 (0.0%)
Other anticoagulants	0 (0.0%)	0 (0.0%)	0 (0.0%)
Intermittent pneumatic compression	0 (0.0%)	0 (0.0%)	0 (0.0%)
Foot pump	0 (0.0%)	0 (0.0%)	0 (0.0%)
Graduated compression stockings	0 (0.0%)	0 (0.0%)	0 (0.0%)

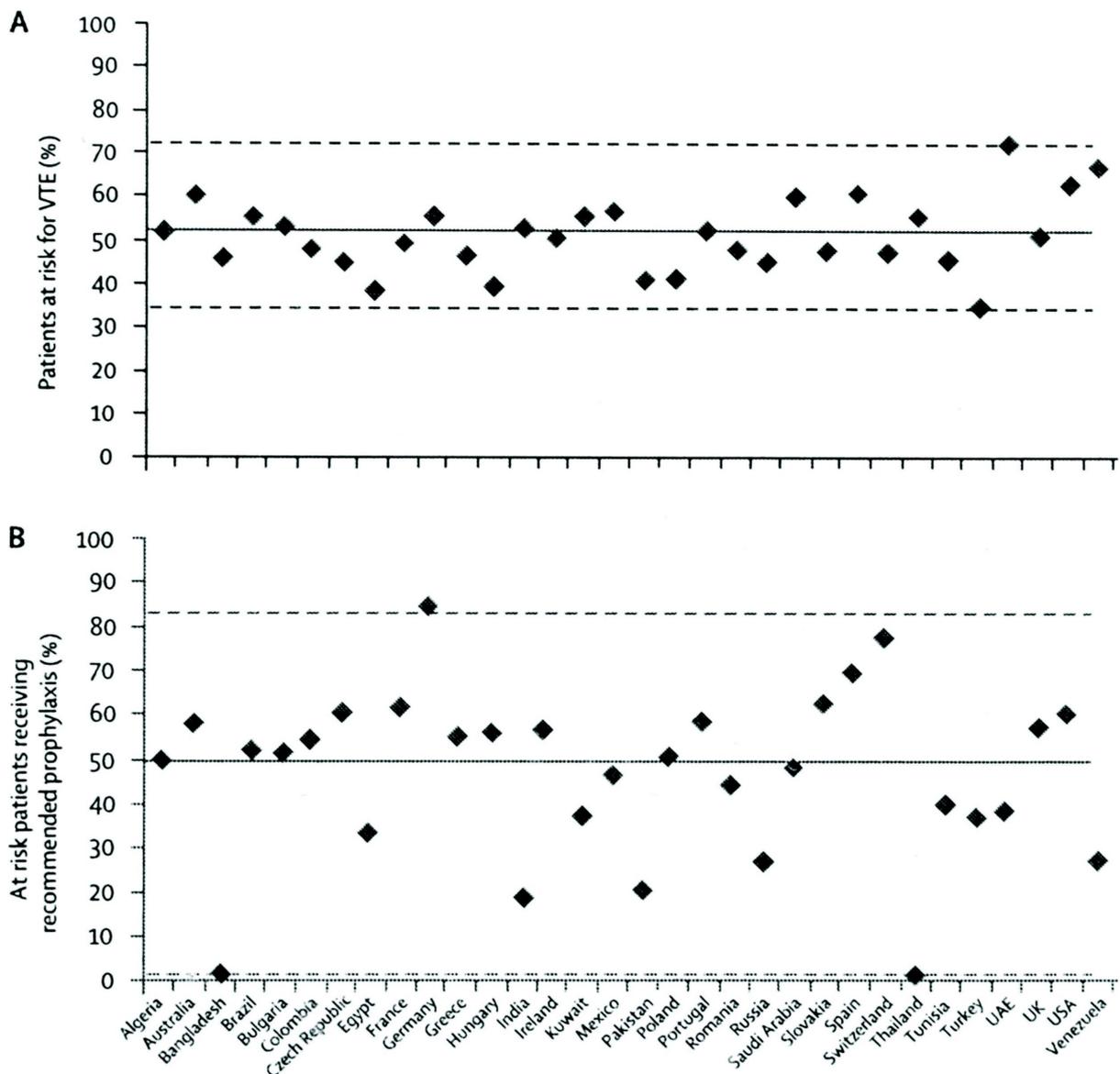


Figure 2: Proportion of patients at risk for VTE (A) and proportion of at-risk patients receiving recommended prophylaxis (B)⁵

nize that the incidence of VTE is increasing, but the risk assessment should be designed for Thai patients. The overall data demonstrate a large gap between ideal and real-world practices in VTE prophylaxis in Thailand.

VTE is a major public health issues.^{12,13} Data from around the world, as well as from Thailand, shows the large proportion of patients at risk for VTE, both surgical and medical. Even though VTE is an easily preventable disease, recommended VTE prophylaxis is still underused, particularly in Asian patients. This is because VTE has been widely perceived to be less common in Thai and other Asian populations than in Western populations. However, the risk of VTE in Asia was challenged by some recent studies which demonstrated that VTE is a relevant clinical problem in Asians.^{14,20}

The purpose of this study is to emphasize and increase physician awareness of the presence of the risk of VTE in Thai patients. The data reinforce the rationale for the use of hospital-wide strategies to assess patients' VTE risk and to implement measures which ensure that at-risk patients receive appropriate prophylaxis. Also further study on the incidence of VTE in hospitalized Thai patients is warranted.

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ความเสี่ยงของภาวะ venous thromboembolism และการให้การป้องกัน ในโรงพยาบาล (การศึกษา ENDORSE) : การวิเคราะห์ข้อมูลของประเทศไทย

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บทคัดย่อ : อุบัติการณ์ของภาวะ venous thromboembolism (VTE) แตกต่างกันในแต่ละประเทศ ข้อมูลเกี่ยวกับความหลากหลายของความเสี่ยงสำหรับภาวะ VTE และการให้การป้องกันทั่วโลกยังมีน้อยโดยเฉพาะในประเทศไทย การศึกษา ENDORSE (Epidemiologic International Day for Evaluation of Patients at Risk for Venous Thromboembolism in the Acute Hospital Care Setting) เป็นการศึกษาแบบ cross-sectional ในหลายประเทศ การศึกษานี้ได้ถูกออกแบบเพื่อให้ได้ข้อมูลดังกล่าวโดยการประเมินอุบัติการณ์ของความเสี่ยงสำหรับภาวะ VTE ในโรงพยาบาลและเพื่อดูจำนวนของผู้ป่วยกลุ่มเสี่ยงที่ได้รับการป้องกันการเกิดภาวะ VTE ที่เหมาะสม ผู้ป่วยที่เข้าเกณฑ์การศึกษาคือผู้ป่วยที่มีอายุ 18 ปีหรือมากกว่าในหอผู้ป่วยศัลยกรรมและอายุ 40 ปีหรือมากกว่าในหอผู้ป่วยอายุรกรรม การประเมินความเสี่ยงของภาวะ VTE และการดูว่าผู้ป่วยได้รับการป้องกันการเกิดภาวะ VTE ที่เหมาะสมใช้ตามคำแนะนำของ American College of Chest Physicians (ACCP) ปี ค.ศ. 2004 มีผู้ป่วยที่เข้าร่วมการศึกษาจากโรงพยาบาล 358 แห่ง ใน 32 ประเทศทั่วโลก ในจำนวนนี้มีผู้ป่วย 1,824 รายจากโรงพยาบาล 5 แห่งในประเทศไทย โดยผู้ป่วย 1,001 ราย (ร้อยละ 54.9) เป็นผู้ป่วยศัลยกรรม และผู้ป่วย 823 ราย (ร้อยละ 45.1) เป็นผู้ป่วยอายุรกรรม ร้อยละ 56.1 ของผู้ป่วยไทยมีความเสี่ยงของภาวะ VTE แต่มีเพียงร้อยละ 1.8 ของผู้ป่วยที่ได้รับการป้องกันภาวะ VTE ที่เหมาะสม ถ้าใช้เกณฑ์ของ ACCP พบว่าจากผู้ป่วยศัลยกรรมที่มีความเสี่ยง 618 ราย (ร้อยละ 61.7 ของผู้ป่วยศัลยกรรมทั้งหมด) มีผู้ป่วยเพียง 3 ราย (ร้อยละ 0.5) ที่ได้รับการป้องกันการเกิดภาวะ VTE เมื่อเทียบกับผู้ป่วยอายุรกรรมที่มีความเสี่ยง 406 ราย (ร้อยละ 49.3 ของผู้ป่วยอายุรกรรมทั้งหมด) พบว่าผู้ป่วย 15 ราย (ร้อยละ 3.7) ได้รับการป้องกันการเกิดภาวะ VTE ข้อมูลนี้บ่งชี้ว่าควรจะมีวิธีการประเมินความเสี่ยงของภาวะ VTE ในผู้ป่วยที่ได้รับการรักษาในโรงพยาบาลเพื่อที่จะได้ให้การป้องกันการเกิดภาวะ VTE ที่เหมาะสมในผู้ป่วยที่เสี่ยงต่อการเกิดภาวะ VTE

Key Words : ● Venous thromboembolism ● Prophylaxis ● Thailand

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