

Venous thromboembolism risk and prophylaxis in the acute hospital care setting – results of the ENDORSE study in Poland

Jacek Musiał, Wojciech J. Sydor, and ENDORSE Investigators – Poland

Department of Medicine, Jagiellonian University School of Medicine, Kraków, Poland

KEY WORDS

ENDORSE study, Poland, venous thromboembolism, venous thromboembolism prophylaxis, venous thromboembolism risk factors

ABSTRACT

INTRODUCTION Venous thromboembolism (VTE) is the most common preventable cause of in-hospital death. However, the risk of VTE and prophylaxis practices in Polish hospitals are not known.

OBJECTIVES The ENDORSE study in Poland was part of the global cross-sectional Epidemiologic International Day for the Evaluation of Patients at Risk for Venous Thromboembolism in the Acute Hospital Care Setting survey with the objective to assess the prevalence of VTE risk in acutely ill medical and surgical patients and to determine the proportion of at-risk patients who receive recommended prophylaxis.

PATIENTS AND METHODS In 10 non-academic Polish hospitals, a chart review was performed in all inpatients aged 40 or older admitted to medical wards, and in patients at the age of ≥ 18 admitted to surgical wards. The VTE risk and recommended prophylaxis were assessed according to the 2004 American College of Chest Physicians (ACCP) guidelines.

RESULTS The study enrolled 2673 patients (1092 in surgical wards, 1581 in medical wards). Out of these, 1111 were judged to be at risk for VTE (597 surgical patients, 514 medical patients). Only 51.8% of all at-risk patients received ACCP-recommended VTE prophylaxis (54.7% of surgical patients, 32.5% of medical patients).

CONCLUSIONS In Polish hospitals more than 40% of patients hospitalized for acute illness are at risk of VTE, but only a small proportion of them receives appropriate prophylaxis. These results call for decisive actions to ensure that at-risk patients receive recommended VTE prophylaxis.

INTRODUCTION Many surgical and medical inpatients are at markedly increased risk of venous thromboembolism (VTE). Such patients often have more than one risk factor for VTE, and these factors are usually combined. Approximately 5–10% of all deaths in hospitalized patients are accounted for by pulmonary embolism making VTE the most common preventable cause of in-hospital death.^{1,2} There are over 370,000 estimated VTE-related deaths per year in 6 European Union (EU) countries; 75% of them from hospital-acquired VTE.³ Extrapolation of American data indicates that in Poland pulmonary embolism may account annually for up to 25,000–33,000 deaths.⁴ Deep vein thrombosis and its long-term complications (post-thrombotic

syndrome, chronic thromboembolic pulmonary hypertension) contribute to increased long-term patient morbidity and raise the costs for public healthcare systems.^{5,6}

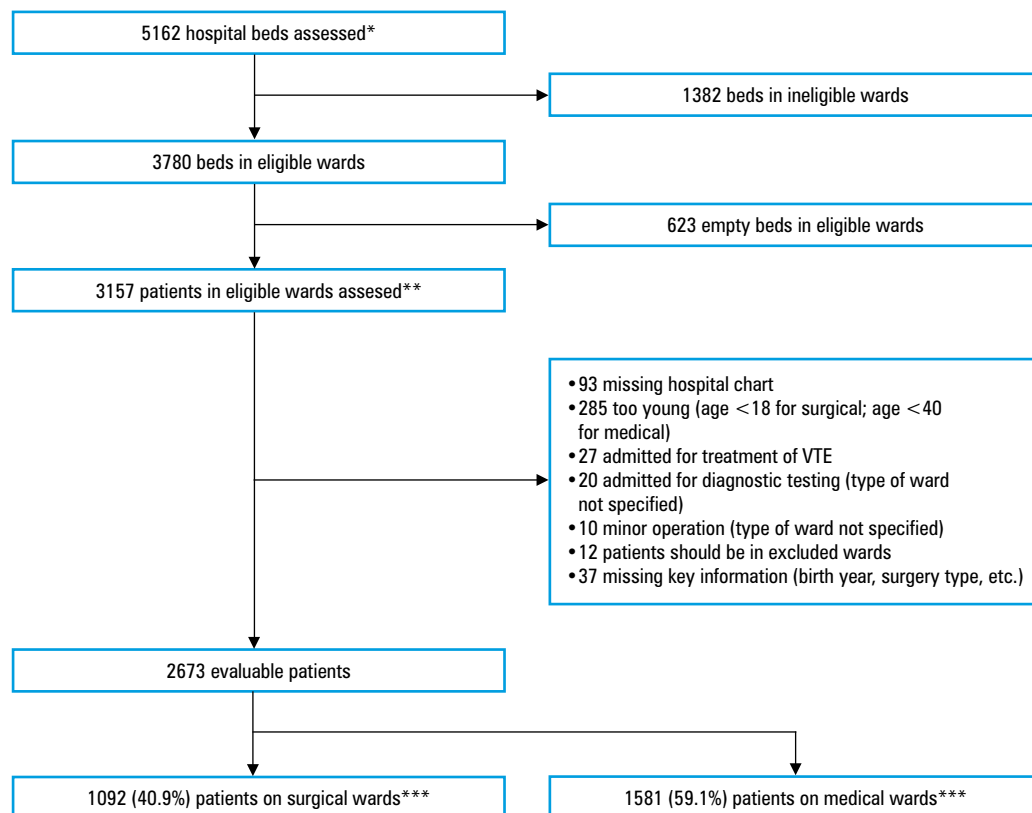
Despite the availability of evidence-based consensus guidelines^{1,7} thromboprophylaxis is often not implemented, due to underestimation of the risk or variable risk of hemorrhagic complications related to antithrombotic agents. Several epidemiologic studies have addressed the problem in defined countries and institutions outside Poland.^{8–10} Such studies have not been published in Poland yet.

Until now global data on the proportion of at-risk inpatients who should receive thromboprophylaxis have been unavailable. Recently,

Correspondence to:
prof. Jacek Musiał, MD, PhD,
II Katedra Chorób Wewnętrznych,
Uniwersytet Jagielloński,
ul. Skawińska 8, 31-066 Kraków,
phone: +48-12-293-42-13,
fax: +48-12-293-40-30,
e-mail: mmmusia@cyf-kr.edu.pl
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FIGURE 1 Selection of study population and reasons for exclusions

* Based on hospital enrollment forms.
 ** Based on patient enrollment logs, includes patients who did not meet protocol requirements (e.g. age, type of condition, or missing hospital chart).
 *** Surgical patients include patients in general surgical units, surgical intensive care units, neurosurgery, gynecology, and orthopedics. Medical patients include patients in other eligible wards.
 Abbreviations: VTE – venous thromboembolism



Cohen et al.¹¹ published the results of the multinational, observational, cross-sectional ENDORSE (Epidemiologic International Day for the Evaluation of Patients at Risk for Venous Thromboembolism in the Acute Hospital Care Setting) study, conducted between August, 2006 and January, 2007. The study assessed the number of patients at risk for VTE in the acute care hospital setting in 358 hospitals across 32 countries on 6 continents and established the proportion of patients who received thromboprophylaxis according to the recommendations of the American College for Chest Physicians (ACCP) guidelines.¹ Poland took part in this study. This paper presents the country-specific data from 10 Polish hospitals participating in the ENDORSE study.

PATIENTS AND METHODS Detailed procedures have been described in the primary ENDORSE report.¹¹ Briefly, hospitals with >50 beds, admitting patients with acute medical illnesses and exacerbations of chronic diseases, and scheduled routine major surgical procedures were included in the study. In Poland, 10 non-academic hospitals were randomly selected from the Polish Hospital Register. According to the national rules, the approval of the Ethics Committee (Chamber of Physicians, Kraków) was obtained for the study in Poland. Signed patient consent was not required. Patients' data, including demographics, admission and post-admission diagnoses, risk factors associated with VTE, bleeding risk factors for, the duration of a stay and the type of VTE prophylaxis, were collected from a review of hospital charts on standard case report forms by trained physicians.

For inclusion, each patient had to be hospitalized in an eligible ward on the predetermined day of survey. In large hospitals it was possible to survey one ward or floor on any particular day.

Patients aged ≥40 years in eligible medical wards, or ≥18 years in eligible surgical wards were screened. The assessment of VTE risk (according to the 2004 ACCP guidelines) included acutely ill medical patients, patients hospitalized for major trauma or undergoing a major surgical procedure requiring general or epidural anesthesia for at least 45 minutes. Following the 2004 ACCP guidelines, surgical patients were classified as being at highest, high, moderate or low risk for VTE. Only information about types of venous thromboprophylaxis included in the ACCP guidelines recommendations was collected, and only these types were taken into account for ACCP compliance determination. Anticoagulant prophylaxis was considered contraindicated if the patient presented with or developed during hospitalization any of the following: intracranial hemorrhage, liver impairment, bleeding at hospital admission, an active peptic ulcer, bleeding disorders of a known cause.

Statistical analysis Statistical analyses are discussed in detail in the global primary ENDORSE report.¹¹ Briefly, quantitative data were presented as median, and the number of non-missing data. Categorical data were given as the number and percentage of the population. The SAS version 9.1 was used for all statistical analyses.

TABLE 1 Characteristics and reasons for hospitalization of eligible patients in Poland

	Surgical risk (n = 597)	Medical risk (n = 514)	All risk (n = 1111)
Patient characteristics			
Male	289 (49.7)	256 (51.2)	545 (50.4)
Female	292 (50.3)	244 (48.8)	536 (49.6)
Age (years)*	62	73	68
BMI (kg/m ²)*	26.1	27.5	26.5
Hospital admission to survey day (days)*	6	7	6
Reason for hospitalization			
Acute heart failure (NYHA class III/IV)	8 (1.3)	176 (34.2)	184 (16.6)
Other cardiovascular disease	80 (13.4)	155 (30.2)	235 (21.2)
Ischemic stroke	2 (0.3)	31 (6)	33 (3)
Hemorrhagic stroke	3 (0.5)	6 (1.2)	9 (0.8)
Pulmonary infection	9 (1.5)	186 (36.2)	195 (17.6)
Acute non-infectious respiratory disease	9 (1.5)	93 (18.1)	102 (9.2)
Rheumatologic or inflammatory diseases	6 (1.0)	3 (0.6)	9 (0.8)
Hematologic disease	3 (0.5)	21 (4.1)	24 (2.2)
Malignancy (active)	56 (9.4)	26 (5.1)	82 (7.4)
Infection (non-respiratory)	21 (3.5)	22 (4.3)	43 (4.0)
Neurologic	12 (2)	19 (3.7)	31 (2.8)
Renal	14 (2.3)	45 (8.8)	59 (5.3)
Endocrine/metabolic	39 (6.5)	58 (11.3)	97 (8.7)
Gastro-intestinal/hepatobiliary	65 (10.9)	31 (6)	96 (8.6)
Other medical conditions	99 (16.6)	35 (7.0)	134 (12.1)

* Data are shown as a median.

Data are shown as number (percentage). Denominators may vary due to missing data.

Abbreviations: BMI – body mass index

RESULTS In the global ENDORSE study¹¹, a total number of 68,183 patients were enrolled from 358 hospitals across 32 countries (Algeria, Australia, Bangladesh, Brazil, Bulgaria, Colombia, Czech Republic, Egypt, France, Germany, Greece, Hungary, India, Ireland, Kuwait, Mexico, Pakistan, Poland, Portugal, Romania, Russia, Saudi Arabia, Slovakia, Spain, Switzerland, Thailand, Tunisia, Turkey, United Arab Emirates, UK, USA, and Venezuela). Out of this number, 30,827 (45%) of the eligible patients were categorized as surgical and 37,356 (55%) as medical. According to the ACCP criteria, 35,329 (51.8%; between country range 35.6–72.6) patients were at risk for VTE, including 19,842 (64.4%; 44.1–80.2) surgical patients and 15,487 (41.5%; 21.1–71.2) medical patients. Of the surgical patients at risk, 11,613 (58.5%; 0.2–92.1) received ACCP-recommended VTE prophylaxis, compared with 6,119 (39.5%; 3.1–70.4) at-risk medical patients.

In Poland, a total number of 2,673 patients were enrolled from 10 hospitals, 1,092 (40.9%) on surgical and 1,581 (59.1%) on medical wards. The total number of beds assessed, together with reasons for exclusion, and the number of analyzed medical and surgical patients are shown in [FIGURE 1](#). The median number of beds per hospital was 369.4 (range 233–565 beds). The median

time to identify and enroll the eligible patients was 6 days.

The median age of patients in medical wards was 73 years and in surgical wards 62 years. The patient's characteristics and causes of hospitalization are shown in [TABLE 1](#).

Risk factors for VTE that were present before hospital admission are shown in [TABLE 2](#). Chronic heart failure was the most common VTE risk factor before admission both in medical and surgical patients (46.3% and 10.3%, respectively). The second most frequent VTE risk factor in medical patients was chronic pulmonary disease (24.4%) and in surgical patients varicose veins/venous insufficiency (7.9%). The most common post-admission risk factor for VTE in both medical and surgical patients was complete immobilization, followed by immobilization with bathroom privileges for surgical patients, and admission to an intensive or critical care unit in medical patients ([TABLE 2](#)).

Risk factors for bleeding were more common in medical than surgical patients. This risk in medical patients was mainly due to aspirin use and significant impairment of renal function, while in surgical patients the bleeding risk was due to use of non-steroidal anti-inflammatory drugs ([TABLE 3](#)).

TABLE 2 Risk factors for VTE venous thromboembolism

	Surgical risk (n = 597)	Medical risk (n = 514)	All risk (n = 1111)
Before admission			
Previous venous thromboembolism	5 (0.9)	15 (3.0)	20 (1.9)
Thrombophilia (laboratory documented)	1 (0.2)	2 (0.4)	3 (0.3)
Varicose veins or venous insufficiency	42 (7.9)	89 (17.5)	131 (12.6)
Postmenopausal hormone replacement therapy	2 (0.4)	0	2 (0.2)
Chronic pulmonary disease	22 (4.1)	124 (24.4)	146 (14)
Long-term immobility	10 (1.9)	59 (11.6)	69 (6.6)
Pregnancy (within 3 months)	0	0	0
Obese (based on physician's note)	34 (6.4)	85 (16.7)	119 (11.4)
Oral contraceptives	4 (0.7)	1 (0.2)	5 (0.5)
Chronic heart failure	55 (10.3)	235 (46.3)	290 (27.8)
During hospitalization			
Admitted to ICU/CCU	20 (3.4)	94 (18.3)	114 (10.3)
Central venous catheter	34 (5.7)	44 (8.6)	78 (7)
Mechanical ventilation	50 (8.4)	27 (5.3)	77 (6.9)
Immobile with bathroom privileges	99 (16.6)	78 (15.2)	177 (15.9)
Complete immobilization	225 (37.7)	142 (27.6)	367 (33.0)
Cancer therapy	0	5 (1)	5 (0.5)
Heparin-induced thrombocytopenia	0	0	0

Data are shown as number (percentage). Denominators may vary due to missing data.

Abbreviations: CCU – critical care unit, ICU – intensive care unit

Out of 2673 analyzed patients, 1111 (41.6%) were deemed as being at VTE risk. Among 1,092 patients on surgical wards (see [FIGURE 1](#)), 597 (54.7%) were deemed to be at VTE risk. Four-hundred four (67.7%) of these at risk patients received any VTE prophylaxis and 396 (66.3%) received ACCP recommended prophylaxis. Among 1581 patients on medical wards (see [FIGURE 1](#)), 514 (32.5%) were deemed to be at risk of VTE. Out of these 514 patients, 239 (46.5%) received any VTE prophylaxis; 179 (34.8%) received ACCP-recommended prophylaxis. Altogether, in Poland, out of 1111 inpatients at VTE risk, 575 (51.8%) received ACCP-recommended prophylaxis.

There was a substantial difference between participating hospitals in terms of percentages of at-risk patients among all analyzed surgical (range from 39.3% to 100%) and medical (range from 15.5% to 45.6%) patients. Such a marked difference was also typical of the everyday practice of administering ACCP-recommended VTE prophylaxis (from 45.2% to 90.8 % for surgical patients, and from 8.7% to 55.6% for medical patients, respectively).

For comparison, the proportion of patients at risk for VTE and the use of ACCP-prophylaxis in the EU countries are shown in [FIGURE 2](#). In EU countries, the proportion of hospitalized medical patients at VTE-risk ranged from 31% (Hungary) to 63% (France) and the proportion of patients receiving ACCP-recommended prophylaxis from 18% (Romania) to 70% (Germany). In

surgical patients, these proportions were 55% (Greece) to 78% (France), and 55% (Portugal) to 92% (Germany), respectively.

Anticoagulant agents (mainly heparins) were used in Poland as the preferred mode of VTE prophylaxis (92.1% of medical patients and 99.2% of surgical patients who received the ACCP recommended prophylaxis), followed by antivitamins K and other anticoagulants (see [TABLE 4](#)). The use of mechanical prophylaxis (foot pump, graduated compression stockings, and intermittent pneumatic compression) was limited to surgical patients only (<2% of all prophylactic measures).

Contraindications to anticoagulant prophylaxis were observed in 6.4% of both surgical and medical patients.

DISCUSSION The ENDORSE is by far the largest cross-sectional study assessing VTE risk and thromboprophylaxis in the acute hospital care setting.¹¹ On a global scale 358 hospitals across 32 countries completed the study. Out of 340 hospitals which provided characteristic data, 44% were categorized as academic. In all hospitals participating in the study the number of assessable patients approached 70 thousand. About 50% of them were deemed to be at risk for VTE (64.4% of surgical patients and 41.5% of medical patients). The ACCP-recommended prophylaxis was received only by about 50% of patients at risk of VTE (58.5% of surgical patients; 39.5%

TABLE 3 Risk factors for bleeding in evaluable patients

Risk factors for bleeding present at current admission	Surgical risk (n = 597)	Medical risk (n = 514)	All risk (n = 1111)
Significant renal insufficiency	16 (2.7)	44 (8.6)	60 (5.4)
Intracranial hemorrhage	18 (3)	4 (0.8)	22 (2)
Low platelet count (<100,000/ μ l)	6 (1)	16 (3.1)	22 (2)
Known bleeding disorder (congenital or acquired)	2 (0.3)	2 (0.4)	4 (0.4)
Hepatic insufficiency (clinically relevant)	2 (0.3)	12 (2.3)	14 (1.3)
Bleeding at hospital admission	13 (2.2)	10 (1.9)	23 (2.1)
Active gastroduodenal ulcer	5 (0.8)	8 (1.6)	13 (1.2)
Aspirin on admission	19 (3.2)	195 (37.9)	214 (19.3)
NSAIDs on admission (excluding aspirin)	47 (7.9)	31 (6)	78 (7)

Data are shown as number (percentage). Denominators may vary due to missing data.

Skróty: NSAID – non-steroidal anti-inflammatory drugs

TABLE 4 Type of prophylaxis used in at-risk patients

	Surgical risk (n = 597)	Medical risk (n = 514)	All risk (n = 1111)
Any anticoagulant	399 (67.7)	220 (46.5)	60 (5.4)
Intermittent pneumatic compression without anticoagulant	1 (0.2)	0	1 (0.1)
Graduated compression stockings without an anticoagulant or intermittent pneumatic compression	3 (0.7)	0	3 (0.3)
Low-molecular-weight heparin	392 (65.7)	176 (34.2)	568 (51.1)
Unfractionated heparin	12 (2)	6 (1.2)	18 (1.6)
Vitamin K antagonist	2 (0.3)	31 (6.0)	33 (3)
Fondaparinux	0	0 (0.0)	0
Other anticoagulants	9 (1.5)	23 (4.5)	32 (2.9)
Intermittent pneumatic compression	1 (0.2)	0	1 (0.1)
Foot pump	1 (0.2)	0	1 (0.1)
Graduated compression stockings	11 (1.8)	0	11 (1)

Data are shown as number (percentage). Denominators may vary due to missing data.

of medical patients) with substantial variations depending on the geographic region.¹¹

In Poland all 10 hospitals participating in the study were non-academic to better reflect average hospital practice. The percentages of patients at VTE risk receiving recommended prophylaxis were not different from the global data, they were however slightly lower than those in the neighboring Czech Republic and Slovakia, and much lower than in Germany, the leader in antithrombotic prophylaxis among all participating countries.¹¹ Numbers of patients at risk were comparable.

This is the first published report on DVT prophylaxis in medical and surgical hospital patients in Poland. The only other available in Poland data come from the EPID registry.¹² This survey performed in internal medicine wards from 64 hospitals has shown that among medical patients at VTE risk, 44% received antithrombotic prophylaxis. This is in agreement with the findings presented in the discussed study (46.5% of all medical patients at risk receiving any VTE prophylaxis).

Wide differences in everyday practice of VTE prophylaxis in patients deemed as being at risk suggest that in many Polish hospitals, despite availability of original evidence-based consensus guidelines^{1,7} and its national adaptations^{13,14}, the awareness of the risk of VTE in hospitalized patients is still insufficient. Efforts should be made to increase this awareness through vigorous educational actions and in-hospital alert systems.¹⁵

Heparins were by far the most often used type of prophylaxis in Polish medical patients. Mechanical prophylaxis was not used. While heparins were even more often used in surgical patients, a few patients received mechanical prophylaxis, mainly graduated compression stockings. In general, proportions of the type of VTE prophylaxis used in Poland are similar to the global data, but the use of mechanical prophylaxis is lower. Similarly to the other European countries,^{8,16} low-molecular-weight heparins (LMWH) were the most frequent pharmacologic approach (nearly 100% of heparins used) whereas in the USA unfractionated heparin was more prevalent in this setting.^{9,10}

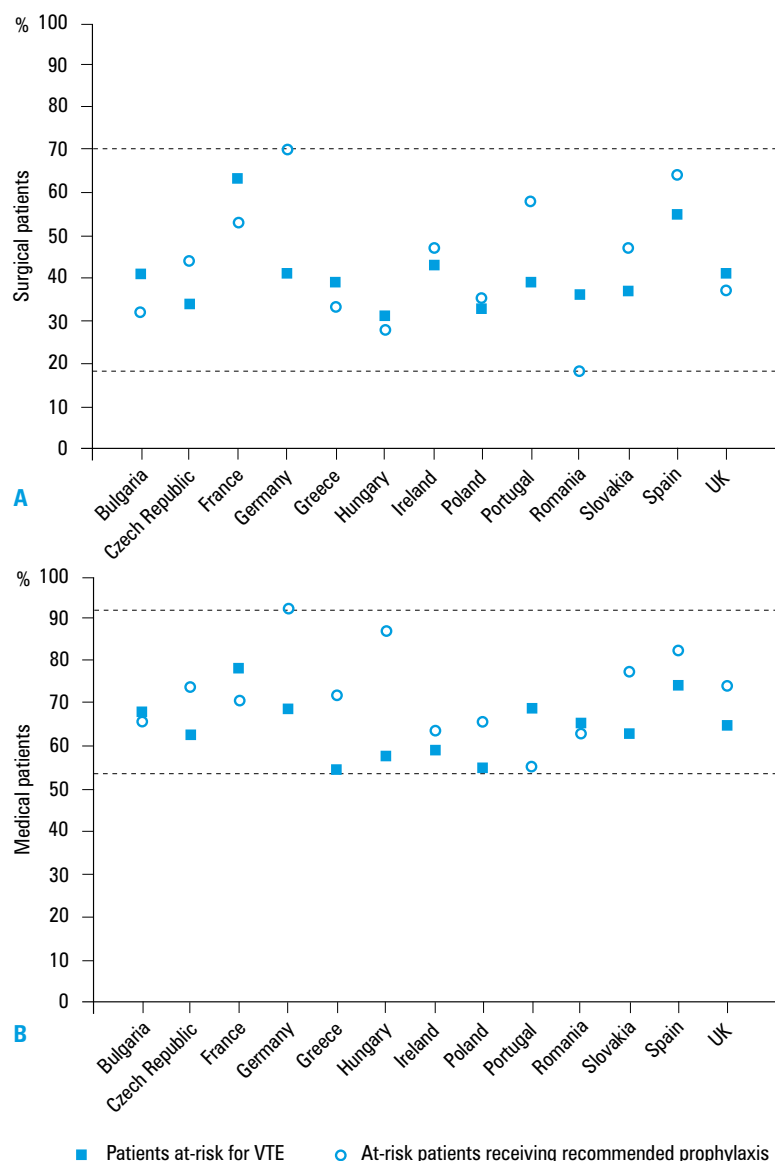


FIGURE 2 Proportion of medical (A) and surgical (B) patients at-risk for VTE and proportion of at-risk patients receiving recommended prophylaxis in the EU countries, including Poland

In Poland, as in other countries, including the European ones, ACCP-recommended prophylaxis was more often used in surgical than in medical patients.¹¹ This is probably, at least in part, related to the clear VTE risk description for different types of surgical procedures included in the 2004 ACCP recommendations.¹ There was no such risk categorization for medical patients in the ACCP guidelines. In the recently published 2008 ACCP guidelines¹⁷ medical patients are categorized into 2 groups. Fully mobile medical patients are considered as being of low (<10%) risk of deep-vein thrombosis (DVT) and do not require specific thromboprophylaxis, in contrast to bedridden or acutely ill medical patients who are considered to be of moderate (10–40%) risk of DVT. Thromboprophylaxis options for the latter group include LMWH, unfractionated heparin or fondaparinux administration. Low rates of VTE prophylaxis in acutely-ill medical patients at high risk of VTE has been described in the past.¹⁸

The ENDORSE study on Polish patients has several limitations. The first, and the most important, is the hospital (and consequently, patients) sample size. In Poland, a country with 40 million

inhabitants and over 700 hospitals, even a random choice of ten hospitals might be too low to be fully representative. However, the wide variation of the everyday practice in implementing VTE prophylaxis with even the highest numbers being far from ideal are a sufficient argument for a “call to action”.¹⁵ Secondly, some inaccuracies might have been introduced during data collection (one-day cross-sectional study), which however should not influence general conclusions. It is quite probable that the VTE risk factor was omitted rather than added in error. Thirdly, VTE prophylaxis could have been withheld due to the personal conviction of the attending physician that the risk of bleeding was high. Finally, survey awareness could have changed physicians’ behavior. Even then, they would probably have increased the use of prophylactic measures rather than withhold them.

In summary, results of the ENDORSE study in Poland show that, like in many other countries all over the world^{3,8-11,19}, VTE prophylaxis is underused in acutely ill medical and surgical inpatients. It seems that especially in medical patients the risk of VTE is substantially underestimated. Every effort should be made to increase awareness of VTE risk and ensure that at-risk patients receive appropriate prophylaxis through obligatory hospital alert systems and implementation of evidence-based guidelines. Widespread educational actions, among other things, could help achieve this aim.

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LIST OF ENDORSE INVESTIGATORS IN POLAND (number of the charts surveyed)

- 1 Wojewódzki Szpital Zespolony, Płock: **Włodzimierz Klonowski** (355)
- 2 ZOZ im. K. S. Wyszyńskiego, Sieradz: **Zdzisław Prajs** (279)
- 3 Regionalny Szpital Chorób Płuc, Szczecin: **Marek Sell** (240)
- 4 Szpital im. J. Dietla, Kraków: **Andrzej Kosiniak-Kamysz** (235)
- 5 Radomski Szpital Specjalistyczny, Radom: **Tadeusz Kalbarczyk** (234)
- 6 Zakład Opieki Zdrowotnej Ministerstwa Spraw Wewnętrznych, Olsztyn: **Bartłomiej Biedziuk** (180)
- 7 Szpital Wojewódzki, Opole: **Józef Wysota** (180)
- 8 Specjalistyczny Szpital im. E. Szczeklika, Tarnów: **Marcin Kuta** (168)
- 9 Wojewódzki Szpital Specjalistyczny, Wrocław: **Wojciech Witkiewicz** (168)
- 10 Szpital Bielański, Warszawa: **Ryszard Gellert** (147)