

An observational study for venous thromboembolism risk assessment among hospitalized patients in general surgery clinics across Turkey

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Abstract

Objective: Venous thromboembolism (VTE) still remains a significant public health problem due to gaps between recommendations and clinical practice in VTE prophylaxis. This is the first clinical study designed to evaluate the applicability of a standard 'VTE prophylaxis and risk factor assessment form (VTE-PRAF)' and prescription of VTE prophylaxis among hospitalized patients in the daily practice of general surgeons in Turkey.

Method: A total of 1472 patients (mean age: 52.4 ± 16.9 years; 50.6% were men) were included in cross-sectional ($n = 537$), first longitudinal ($n = 452$) or the second longitudinal ($n = 483$) phases. Data on demographics, hospitalization, surgical intervention and prophylaxis were collected during the cross-sectional phase, whereas utilization of form was evaluated during longitudinal phases.

Results: While 62.1% of patients were identified to be at 'high + highest' risk, prophylaxis was evident only for 65.9%. Utilization of the form was higher in the second longitudinal phase ($P < 0.001$) but there was no relation between implementation of the form and prophylaxis use. VTE-PRAF was completed for 70.6% and 84.8% of patient who received prophylaxis while it was completed for 50.8% and 50.4% of patients with no prophylaxis, in the first and second longitudinal phases, respectively. Prophylaxis was administered in 58.6% and 62.6% of patients with completed VTE-PRAF in the first and second longitudinal phases, respectively. 'Suggested' and 'used' prophylaxis regimens were significantly more consistent for the cases evaluated with VTE-PRAF ($P < 0.001$).

Conclusion: Based on the use of prophylaxis only for 65.9% of general surgery inpatients at high risk for VTE, low use of prophylaxis is assumed to remain a significant threat to public health across Turkey. Inclusion of a standard VTE-PRAF in the hospital protocol seems to raise clinical awareness of VTE risk assessment and appropriate management in VTE which otherwise well-known to be associated with significant mortality and morbidity. Impact of e-VTE-PRAF is worth investigating.

Keywords: venous thromboembolism (VTE); thrombosis prophylaxis; surgery; hospital acquired venous thromboembolic disease

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Introduction

Venous thromboembolism (VTE) is the most common preventable cause of hospital-related mortality¹ resulting from immobilization or surgical intervention itself.^{2,3} As many as 145 in 100,000 may develop symptomatic deep venous thrombosis (DVT) once in their lifetime, and 69 in every 100,000 experience pulmonary embolism. Untreated VTE may lead to long-term morbidity because of post-thrombotic

syndrome and recurrent VTE. In a recent report from six European countries, the estimated numbers of cases of DVT-, PTE (pulmonary thromboembolism)- and VTE-related deaths per year were reported to be 465,715, 295,982 and 370,012 respectively.⁴

Owing to high prevalence of VTE with clinically silent course and significant morbidity and mortality rates documented in the absence of appropriate prophylaxis,⁵ prophylactic therapy is strongly suggested for those determined to be at increased risk for VTE.^{2,3} However, only about a third of patients at risk were reported to receive appropriate VTE prophylaxis⁶ despite overwhelming clinical and economic evidence as well as guidelines based on randomized clinical trials for the efficacy of VTE prophylaxis in patients at risk.¹ Therefore, VTE remains a significant threat to public health due to gaps between recommendations and clinical practice⁷ with significant inadequacies in the international administration of appropriate VTE prophylaxis.⁸⁻¹⁰

Recently, the ENDORSE (Epidemiologic International Day for the Evaluation of Patients at Risk for Venous Thromboembolism in the Acute Hospital Care Setting) study demonstrated that 52% of enrolled hospital inpatients were judged to be at risk for VTE (64% from surgical wards and 42% from medical wards) and 59% of surgical and 40% of medical patients received recommended VTE prophylaxis in Turkey according to the American College of Chest Physicians (ACCP).¹⁰

Indicating high prevalence of patients at risk for VTE and the low rate of prophylaxis use in the contrary, data of ENDORSE study reinforced the rationale for implementing strategies for systematically assessing patients at VTE risk and for providing appropriate prophylaxis.¹⁰ Similar results were also obtained in the literature concerning underuse of VTE prophylaxis among patients at risk of thromboembolism.¹¹

The Turkey arm of the ENDORSE study also showed that not all high-risk patients were considered as candidates for VTE prophylaxis by physicians and only a portion of these patients had a chance to receive prophylaxis with percentage of prophylaxis use identified to be 36.8% across surgery clinics.

Since the major limiting factor for thromboprophylaxis in acutely ill patients was reported to be the lack of documentation of risk assessment for VTE on admission,¹² inclusion of standard 'VTE Risk Assessment Form' in the hospital protocols seems to raise the awareness of VTE and prevent this handicap during routine evaluation of patients on admission. *Per contra* it is apparent that guidelines are of value as long as they are recognized and appreciated by physicians.¹³

In this context, based on the lack of appropriate VTE prophylaxis established among surgical patients despite higher success of identification of at risk population than medical patients documented in Turkey arm of the global ENDORSE study, the present study was designed to evaluate the applicability of Turkish version of a standard 'VTE prophylaxis and risk factor assessment form' (VTE-PRAF) developed for patients hospitalized for surgery and to determine the prescription of VTE prophylaxis among hospitalized patients, in the daily practice of general surgeons across Turkey in relation to cross-sectional (before the training of physicians for the application of the form) and subsequent longitudinal phases (after the training) of the study.

Methods

Determination of sample size

To determine any qualitative parameter at a rate of 5 with an error of 0.02, and alpha set at 0.05 and with a power of 80%, a minimum 931 patients are expected to be registered to the study. As a 15% dropout rate is expected, the overall number of patients to be registered was decided to be 1170 with a minimum of 1144 patients to be included in the longitudinal phases based on alpha set at 0.05, power set at 90% and dropout coverage at 15%.

Study population

Study population of this national observational study was composed of 1472 patients of both sexes hospitalized in 20 different general surgery clinics across Turkey for any type of surgical intervention (according to VII.ACCP guidelines risk classification) who were evaluated at three different time points including cross-sectional ($n = 537$), first longitudinal ($n = 452$) or the second longitudinal phases ($n = 483$) over 11 consecutive months. Pregnant or lactating women were not included in the study.

Written informed consent was obtained from each subject following a detailed explanation of the objectives and protocol of the study, which was approved by the institutional ethics committee and conducted in accordance with the ethical principles stated in the 'Declaration of Helsinki' and ICH/GCP.

Study procedures and flow

Before the initiation of the study, an investigators' meeting, including a training presentation on 'VTE Risk Assessment', was performed. VTE Risk

Assessment Forms were available in each centre and the training sessions on VTE prophylaxis held for surgeons were believed to be sufficient for encouraging the use of the form. After the training presentation, the cross-sectional phase of the study was carried-out during which 537 patients hospitalized for any surgical interventions in the surgery clinics on that day were recorded by using hospital records and asked for informed consent to be included in the cross-sectional phase of the study.

According to the flow chart of the study given in Table 1, three months after the cross-sectional phase, first longitudinal phase registration was carried out and second longitudinal phase was performed six months after this registration. Data on patient demographics, hospitalization, details of surgical intervention and prophylactic measures were collected during cross-sectional phase, whereas additional data on utilization of VTE-PRAF were collected during the following two longitudinal phases based on case report forms, hospital records and VTE-PRAFs in the patient dossiers.

No treatment was required according to the protocol, whereas the VTE-PRAF included recommendations for prophylaxis of VTE according to the ACCP Guidelines (elastic stockings, intermittent pneumatic compression and low molecular weight heparin [LMWH]).

The 'VTE-PRAF' was attached to each case report form and included risk factors revealing total risk factor score and associated risk level and suggested prophylaxis to be filled out by the surgeon/investigator participated in the study.

Thrombosis risk factor assessment was performed based on modified Caprini model classifying risk factors with scores ranging from 1 to 5.¹⁴ Patients with total risk factor score of 0–1, 2, 3–4

or ≥ 5 were considered to be at low risk, moderate risk, high risk or highest risk, respectively.

The second page of the form included brief information on the specific situations for VTE prophylaxis and suggested prophylaxis regimens for each risk group. This form was modified after Caprini's VTE Assessment Form and based on ACCP guidelines.

Statistical analysis

Demographical and clinical characteristics of enrolled patients were evaluated by using descriptive statistical methods (mean, median, percentage, standard deviation and confidence intervals). All changes in main VTE prophylaxis parameters as well as subgroup analysis were performed by parametric and/or non-parametric tests (Spearman's correlation tests). Occurrence frequencies as well as relationship with the prophylaxis applications were evaluated by using descriptive statistical methods. The significance level was set at $P < 0.05$.

Results

Data collection in this study was carried out at three different time points including one cross-sectional registry ($n = 537$) and two longitudinal registries ($n = 452$ and 483).

Of 1441 patients (mean age: 52.36 ± 16.9), 729 (50.6%) were men, whilst abdominal surgery was the leading type of operation listed both in reasons for hospitalization (42.8%) and in surgical operations specific to current hospitalization (25.1%; Table 2).

When surgical operation performed at the current hospitalization was unknown, most frequent reasons for hospitalization in cross-sectional, first and second phases of the study were abdominal surgery (39%, 37.2% and 44.1%; respectively) and abdominal malignancy (23%, 23.2% and 25.7%; respectively).

Analysis of available data revealed that 1227 of 1472 patients (83%) with or without a risk assessment form were evaluated for VTE risk and 763 of 1227 patients (62.1%) were patients at high risk (high + highest risk group) with use of prophylaxis in 51.2% of the overall population (49% in the cross-sectional, 50.4% in the first longitudinal and 54.7% in the second longitudinal phases of the study; Table 3). The data collected indicates that 62.1% of the hospitalized patients in surgery clinics are at high risk for VTE whereas prophylaxis was administered only in 65.9% of them.

Table 1 Study flow chart

Data recorded*		
Cross-sectional phase		
Demographic characteristics	X	
Reason for hospitalization and surgery applied	X	
Prophylaxis usage	X	
Longitudinal phase		
	Visit 1	Visit 2
Inclusion/exclusion criteria	X	X
Informed consent	X	X
Demographic data	X	X
Reason for hospitalization and surgery applied	X	X
Prophylaxis usage (harmoniousness to ACCP criteria)	X	X
Utilization of VTE risk assessment form	X	X

*Patients' data are recorded from hospital records during the hospitalization period

Table 2 Patient demographics and basic features of medical history

	Phases of the study					
	Cross-sectional (n = 537)		1st longitudinal (n = 452)		2nd longitudinal (n = 483)	
	n	%	n	%	n	%
Age (mean ± SD)	51.7 ± 16.8		52.5 ± 17.4		52.9 ± 16.5	
Gender						
Male	263	50.3	222	49.8	244	51.7
Female	260	49.7	224	50.2	228	48.3
Missing	14	–	6	–	11	–
Reasons for hospitalization						
Malignancy						
Abdominal	94	17.50	79	17.48	102	21.12
Breast	37	6.89	33	7.30	8	1.66
Other types	7	1.30	1	0.22	16	3.31
Surgery						
Abdominal	224	41.71	195	43.14	211	43.69
Cardiovascular	15	2.79	20	4.42	31	6.42
Thyroid	32	5.96	32	7.08	38	7.87
Hernia repair	31	5.77	25	5.53	25	5.18
Amputation	3	0.56	5	1.11	6	1.24
Wound repair	25	4.66	25	5.53	14	2.90
Other	69	12.85	35	7.74	29	6.00
Surgical operations specific to current hospitalization						
Follow up without operation	239	44.51	207	45.80	206	42.65
Malignancy						
Abdominal	39	7.26	31	6.86	49	10.14
Breast	25	4.66	20	4.42	0	0.0
Other types	1	0.19	1	0.22	16	3.31
Surgery						
Abdominal	131	24.39	118	26.11	120	24.84
Cardiovascular	6	1.12	5	1.11	10	2.07
Thyroid	24	4.47	21	4.65	26	5.38
Hernia repair	18	3.35	17	3.76	18	3.73
Amputation	3	0.56	4	0.88	6	1.24
Wound repair	7	1.30	7	1.55	14	2.90
Other	44	8.19	21	4.65	18	3.73

Utilization of the VTE-PRAFs was significantly higher in the second longitudinal phase compared with first longitudinal phase of the study (74.1 versus 60.6%; $P < 0.001$; Figure 1).

Evaluation of the relationship between prophylaxis use and the utilization of the VTE-PRAF in patients with VTE-PRAFs during longitudinal phases of the study revealed that VTE-PRAFs were applied to 161 of 228 patients (70.6%) and 224 of 264 patients (84.8%) who received prophylaxis in the first and second longitudinal phases, respectively. VTE-PRAF completion was significantly lower in patients with no prophylaxis (50.9% in the first longitudinal phase and 50.5% in the second longitudinal phase) when compared patients with prophylaxis administration ($P < 0.001$ for each; Table 3).

Among the patients with completed VTE-PRAFs, 58.7% in the first longitudinal phase and 62.6% in the second longitudinal phase were determined to receive prophylaxis. Among the patients lacking

VTE-PRAFs, 37.6% in the first longitudinal phase and 32.0% in the second longitudinal phase were determined to receive prophylaxis. 'LMWH twice a day' was the most frequently used prophylaxis regimen in patients with or without VTE-PRAF. Patients lacking both VTE-PRAFs and prophylaxis composed 68% of the population (Table 3).

In the longitudinal phases of the study, 'suggested' and 'used' prophylaxis regimens were significantly more consistent for the cases with the application of VTE-PRAFs when compared with patients without forms (0.365 versus 0.127 and 0.48 versus 0.278; $P < 0.001$; Figure 2).

When consistency of 'suggested' and 'used' prophylaxis with respect to the risk levels in the three phases of the study is evaluated, the 'suggested' and 'used' prophylaxis was determined to be more consistent in patients with risk score of IV in the cross-sectional phase, risk scores of III and IV in the first longitudinal phase and risk score of II

Table 3 General risk assessment and the relation between utilization of venous thromboembolism prophylaxis and risk factor assessment form (VTR-PRAF) and prophylaxis use among patients

	Phases of the study					
	Cross-sectional (n = 537)		1st longitudinal (n = 452)		2nd longitudinal (n = 483)	
	n	%	n	%	n	%
General risk assessment						
Low (total risk factor score 0–1)	89	22.8	85	21.3	108	24.6
Moderate (total risk factor score 2)	64	16.5	57	14.3	61	14
High (total risk factor score 3–4)	127	32.7	124	31.1	139	31.6
Highest (total risk factor score ≥5)	109	28	133	33.3	131	29.8
Total	389	100	399	100	439	100
Patients who received prophylaxis						
Overall (n = 755)	263	49	228	50.4	264	54.7
Among 'high + highest' risk group (n = 504/763)	158/236	66.9	165/257	64.2	180/270	66.1
Use of VTE-Form with respect to prophylaxis						
VTE-PRAF (+)	N/A		274	60.6	358	74.1
With prophylaxis administration			161	58.7	224	62.6
Early ambulation			4	1.5	16	4.5
LMWH (2 ×, 7–10 days)			140	51.1	179	50.0
LMWH > 7–10 days			–	–	4	1.1
MWH + elastic stockings			15	5.5	25	7.0
Early ambulation + elastic stockings			1	0.4	–	–
Without prophylaxis administration			113	41.2	134	37.4
VTE-PRAF (–)			178	39.4	125	25.9
With prophylaxis administration			67	37.6	40	32.0
LMWH (2 ×, 7–10 days)			67	37.6	37	29.6
Early ambulation			–	–	1	0.8
LMWH + elastic stockings			–	–	2	1.6
Without prophylaxis administration			111	62.4	85	68
Prophylaxis administration with respect to use of VTE-Form						
Prophylaxis (+)			228	50.4	264	54.7
With VTE-PRAF			161	70.6*	224	84.8*
Without VTE-PRAF			67	29.4	40	15.2
Prophylaxis (–)	N/A		224	49.6	224	46.3
With VTE-PRAF			114	50.9	113	50.5
Without VTE-PRAF			110	49.1	111	49.5

NA, not applicable

* $P < 0.001$; compared with the absence of prophylaxis in patients with VTE-PRAF

in the second longitudinal phase of the study ($P < 0.001$; Figure 3).

Consistency of 'suggested' and 'used' prophylaxis with respect to VTE-PRAF application and risk levels is summarized in Figure 4. In the first longitudinal phase the consistency was better in Risk Level 4 with VTE-PRAF application whereas the consistency was better in Risk Level 3 for those patients without VTE-PRAF. In the second longitudinal phase the consistency was better in risk score of II with VTE-PRAF application whereas the consistency was better in risk score of III for patients without VTE-PRAF ($P < 0.001$).

Discussion

Much of the morbidity and mortality associated with VTE, a multifactorial disease involving both

genetic and acquired risks in all age groups, has been considered to be preventable with early and accurate diagnosis and management.¹⁵ However, translation of evidence supporting VTE prevention for the surgical population into real clinical practice has been challenging despite availability of evidence-based guidelines as well as several randomized trials justifying the screening of hospitalized patients for VTE risk and administration of appropriate prophylaxis to those at risk.^{16–19}

According to our findings, neither overall rate of prophylaxis (51.2%) nor the prophylaxis for the patients at high-highest risk (65.9%) differed with respect to consecutive phases of the study. The data collected indicates that 62.1% of the hospitalized patients in surgery clinics are at high risk for VTE whereas prophylaxis was administered only in 65.9% of them. These findings are consistent with multiple recent studies demonstrating the

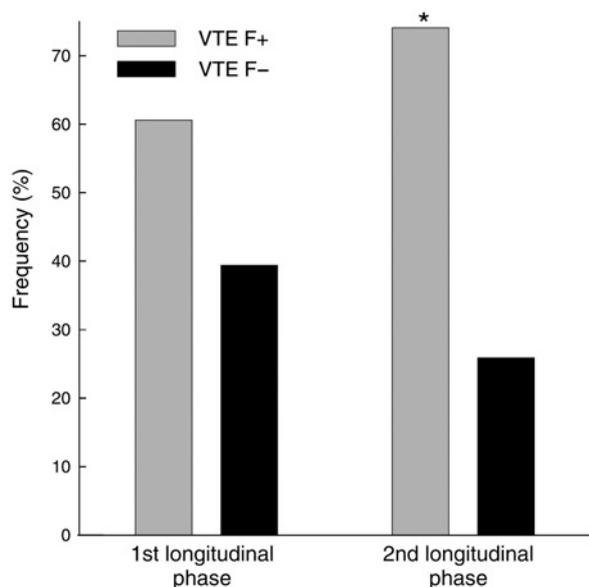


Figure 1 Utilization of venous thromboembolism (VTE) risk assessment form during longitudinal phases of the study. * $P < 0.001$; compared with VTE-PRAF (prophylaxis and risk factor assessment form) utilization in the first longitudinal phase of the study

underuse of VTE prophylaxis as an international public health crisis.²⁰

Indicating the influence of raised awareness among our physicians, utilization of the VTE-PRAFs was significantly higher in the second longitudinal phase compared with first one (74.1 versus 60.6%). While lacking expected crescendo related to gradual increase in the use of form during con-

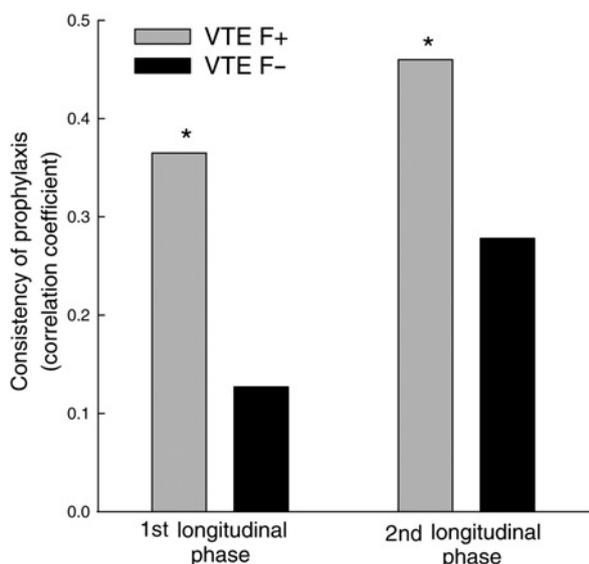


Figure 2 Consistency of ‘suggested’ and ‘used’ prophylaxis in the longitudinal phases with respect to application of venous thromboembolism prophylaxis and risk factor assessment form (VTE-PRAF). * $P < 0.001$; compared with consistency between suggested and used prophylaxis in patients lacking VTE-PRAF

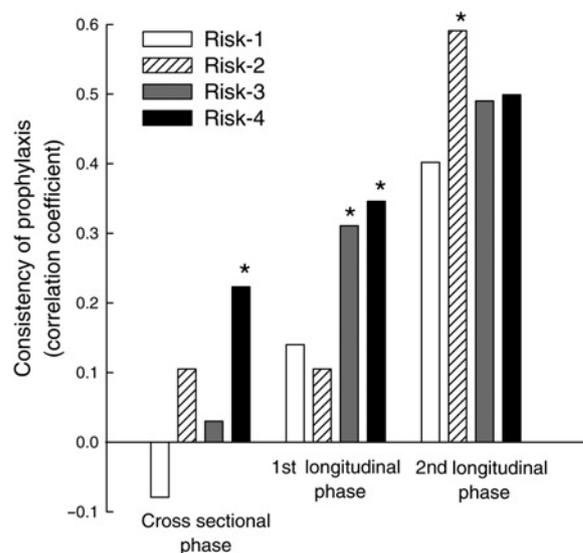


Figure 3 Consistency of ‘suggested’ and ‘used’ prophylaxis in cross-sectional and longitudinal phases with respect to risk scores. * $P < 0.001$; compared with other risk levels in the same group

secutive phases of the present study, the likelihood of prophylaxis administration was determined to be higher in the case of VTE-PRAF completion.

In this context, the training sessions on VTE prophylaxis held for surgeons seem to be sufficient for encouraging the use of the form but not the administration of the prophylaxis, which has been disregarded despite the established risk in almost 40%

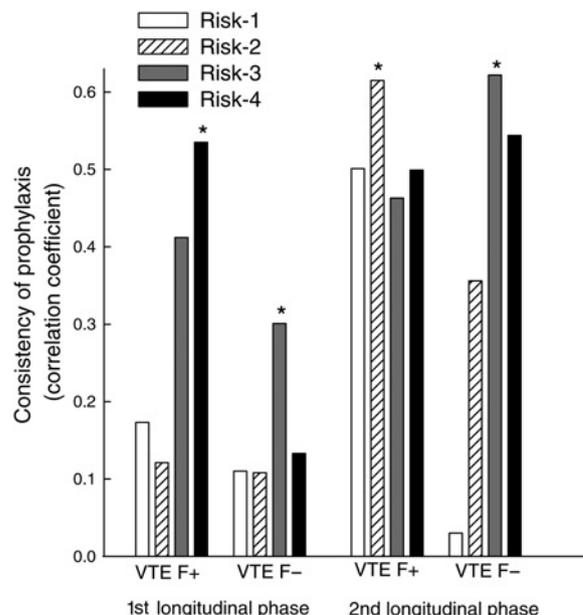


Figure 4 Consistency of ‘suggested’ and ‘used’ prophylaxis in longitudinal phases with respect to venous thromboembolism prophylaxis and risk factor assessment form (VTE-PRAF) application and the risk scores. * $P < 0.001$; compared with other risk levels in the same group

of the population. Likewise, no increase in use of prophylaxis following the guidelines developed by the hospital committee based on available clinical evidence was reported in a recent study despite the great concern with VTE both by the medical and nursing staff.¹⁸

Indeed, VTE risk determined for surgical patients in our study (62.1%) was quite similar to that obtained in the Turkey arm (64.9%) as well as global results (64.4%) of the ENDORSE study, a multinational cross-sectional survey including 68,183 inpatients from 358 hospitals in 32 countries.¹⁰ While surgical patients were reported to have higher VTE risk and more successful screening for risk assessment than medical patients, this success was not reflected in appropriate VTE prophylaxis rates, since VTE prophylaxis was evident only in one-third of the surgical population at risk according to the ENDORSE-Turkey data.¹⁰ Besides, administration of appropriate prophylaxis in 65.9% of our patients at high risk for VTE may indicate the benefit of VTE-PRAF use in achievement of higher rates of VTE prophylaxis in our study sample compared with frequently reported neglect reaching 60% in the past studies.^{1,10,21}

Low probability of physicians to reconsider the wellbeing of patients who discharged without prophylaxis, especially at hospitals with insufficient follow-up routine has been documented to participate in neglecting prophylaxis for patients at VTE risk.²² Hence, besides VTE-PRAF encouragement; nature of the present study enclosing data collection during three consecutive phases may also have a role in higher rates for VTE prophylaxis among our patients.

Indicating the insufficiency of publication of evidence-based guidelines *per se* to ensure compliance with current recommendations, preventive therapy in the high-risk surgical population still has been underused.^{1,19,21,23} Lack of consensus on implementation of guidelines in the past decade has been suggested to play a role in low adherence to evidence-based VTE prophylaxis since initiatives by quality care organizations to improve the implementation of safety measures to prevent VTE within the health-care system have been developed following the Institute of Medicine's landmark report in 1999 on medical errors which brought to public attention failure to provide prophylactic therapy when indicated is a hospital error.¹⁹ Nevertheless, in addition to the increased likelihood of prophylaxis, VTE-PRAF application was also associated with higher consistency of 'suggested' and 'used' prophylaxis regimens in the longitudinal phases of the study. Besides there was a gradual

improvement in the consistency of 'suggested' and 'used' prophylaxis for patients with lower risk scores. In this vein, several quality improvement activities, such as electronic or human alerts,²⁴ continuing medical education,²⁵ hospital prophylaxis guidelines or VTE risk assessment models have been developed to improve prophylaxis in patients at high risk for VTE.

Based on lack of appropriate VTE prophylaxis established among surgical patients despite higher success of identification of at risk population than medical patients documented in the Turkey arm of global ENDORSE study, human alert system via training sessions on VTE prophylaxis was held for surgeons in the present study to encourage the use of the VTE-PRAFs. Unfortunately, while enabled gradual increase in use of VTE-PRAFs, awareness raise activities performed via training sessions in our study failed to achieve corresponding increase in rate of prophylaxis in successive phases of the study. In this context, the training sessions on VTE prophylaxis held for surgeons seem to be sufficient for encouraging the use of the form but not the administration of the prophylaxis leading a substantial underuse of VTE prophylaxis among patients at high-highest risk who were primary candidates for VTE and pulmonary embolus development pertinent to risk scores.

Indeed, use of a computer alert programme instead of personal touch of direct staff communication was reported to be more encouraging for physicians based on the documented benefits of electronic warning on better identification of hospitalized patients at increased risk for VTE and the rate of orders for prophylaxis leading to significant reduction in clinically diagnosed and objectively confirmed VTE, mainly due to a decreased frequency of pulmonary embolism and proximal leg deep vein thrombosis.^{20,24}

Nevertheless, owing to a certain degree of resistance reported to exist among physicians concerning manipulations to their personal clinical management of patients,¹⁸ the encouragement process has been suggested to be more concerned about awareness related to need of prophylaxis rather than suggesting behaviours to be followed after risk classifications assessed by other members of the health-care staff.¹⁸

Physician awareness, availability of guidelines, education factors, reimbursement and national health-care resources were the main factors accused for the variation between countries in terms of ACCP-recommended prophylaxis rates despite the similar proportion of patients at risk for VTE in these countries.^{10,26} Therefore

development of national guidelines seem to give rise to VTE prophylaxis rates better than those documented in ENDORSE study.

In conclusion, owing to use of prophylaxis only for 65.9% of hospitalized patients at high risk for VTE in general surgery clinics across Turkey, low use of prophylaxis is assumed to remain a significant threat to public health despite the availability of effective and safe prophylactic measures and treatments. While consistency of 'suggested' and 'used' prophylactic measures and treatments were determined to be increased with the application of VTE-PRAF, treatment options which are not based on the guidelines are still common in daily practice in surgery clinics. Inclusion of a standard VTE-PRAF in the hospital protocol as well as increasing resources for computer-based decision-support strategies and medical informatics to raise clinical awareness of VTE risk assessment may enhance effectiveness of VTE prevention measures.

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