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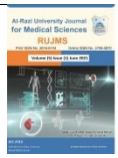

Prevalence and Mortality Predictors of Venous Thromboembolism Among 48 Model Hospital Patients (2016-2020)

Ashwaq Al-Faqih[1], Ahmed Kaid Salem[2], Abdulhafeedh Al-Habeet[3]

[1]Arabian and Yemeni Board in Internal Medicine, 48 Model Hospital, Sana'a City Yemen.
[2]Professor of Internal Medicine and Hematology, Faculty of Medicine, Sana'a University.
[3]Master of Public Health (MPH), Epidemiology and Biostatistics, Supervisor at Dawa Family for Pharmaceutical Industries and Herbal Products, Sana'a City Yemen.

Abstract:

Background: Venous thromboembolism (VTE) is the third most prevalent vascular disease, and it has a substantial impact on morbidity and mortality. Although its effectiveness, evidence-based thromboprophylaxis is still underutilized in many countries including Yemen. **Aims**: We aim to estimate the prevalence and mortality predictors of VTE among 48 model hospital patients during five years (2016-2020), as well as evaluate how often VTE patients in 48 Model Hospital received appropriate thromboprophylaxis. **Patients and Methods:** This study is a retrospective observational registry at a single hospital (48 model hospital, Sana'a City, Yemen). One hundred and fifty-one confirmed VTE cases were enrolled in our study. **Results**: Three quarters of our patients were males 112 (74.2%). Median of age was 30 years with the 25th to 75th percentile interquartile range 23-38 years. More than half of patients were < 30 years with the distribution 82 (54.3%). Most common risk factors were immobilization followed by underwent major surgery and then trauma. The prevalence of VTE during five years was 0.53%. Proximal lower limb deep venous thromboembolism (L.L. DVT), pulmonary embolism (PE) and upper limb DVT were the most common VTE in our patients. Only 40% of VTE patients didn't receive appropriate prophylaxis. The mortality rate was 7.3%. Patients with infection, underutilized of thromboprophylaxis, coagulopathy and bleeding together as barriers to treatment, low platelets (PLAT) at admission, and high serum creatinine (S.Cr) at admission were 5, 8, 1.9, 7.7 9.5 and 13.7 times more likely to mortality among VTE patients in 48 model hospital respectively. **Conclusion**: The findings of our study highlight that thromboprophylaxis therapy was underutilized in 48 Model Hospital patients, indicating a gap between practice and guidelines. Therefore, there was a high prevalence of VTE among 48 model hospital patients. Infection, underutilized of thromboprophylaxis for prophylaxis, coagulopathy and bleeding as barriers to treatment, low PLAT at admission, and high S.Cr at admission were all independent predictors of mortality among VTE patients in 48 model hospital. Strict adherence of health care professionals for The National Institute for Health and Care Excellence guideline to assess risk factors and management of VTE for all patients.

Keywords: Venous Thromboembolism, Deep Venous Thromboembolism, Pulmonary Embolism, Thromboprophylaxis, 48 Model Hospital, Yemen.

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Address for Correspondence:
Abdulhafeedh Al-Habeet: Dawa Family for Pharmaceutical Industries and Herbal Products, Sana'a City Yemen, ***E-mail***: abdulhafeedh86@gmail.com

Introduction

Deep vein thrombosis (DVT) is the symptomatic or asymptomatic formation of a blood clot in a deep vein, most commonly in the legs or pelvis [1]. The risk of a clot detaching and causing pulmonary embolism (PE) is the most common life-threatening concern with DVT, and both PE and DVT are classified to be part of the same overall disease process, which is called venous thromboembolism (VTE) [1].

VTE is a complex disease involving interactions between clinical risk factors and thrombophilias (acquired or inherited) [2, 3]. The third most common vascular disease is VTE [4], which is a dangerous and underdiagnosed medical illness that can lead to impairment and death if not treated. DVT and PE are often serious, however treatable medical disorders. DVT is crucial to understand, because it can affect anyone and can cause disability, serious illness, and even death [5]. In addition to the immense impact of VTE on morbidity and mortality, the economic burden of the disease is considerable (e.g. costing the health care system in USA more than $1.5 billion/year). [6] Although much of the costs of VTE are associated with managing the acute event, there are also significant costs associated with its long-term complications such as recurrent VTE, post-thrombotic syndrome, and pulmonary hypertension [6].

DVT is common health problem in Republic of Yemen [7], and no study have been carried out about this topic in this developing country. In 48 model hospital and during last 5 years, we noticed increased incidence and complications of VTE in all department with longtime admission and readmission of patient due to VTE. It is the most common preventable cause of hospitalization-associated morbidity and mortality [3]. However, no study has so far been conducted in Yemen on VTE patients. Therefore, in this study, we aim to estimate the prevalence and mortality predictors of VTE among 48 model hospital patients during five years (2016-2020), as well as evaluate how often VTE patients in 48 Model Hospital received appropriate thromboprophylaxis.

Patients and Methods

This study is a retrospective observational registry at a single hospital (48 model hospital, Sana'a City, Yemen). Firstly, we identified the patients who were admitted to hospital during the study period. Those patients who hospitalized at least 24 hours, and aged ≥ 15 years with an established diagnosis of VTE were included in our study. There were 28694 patients hospitalized at 48 model hospital during five years. Two hundred cases with clinical diagnosis of VTE were identified. Out of them, 151 were confirmed to be VTE patients.

Data collection

Data was obtained from medical records and the hospital's computerized database to ensure that no patient or file was missed. A preliminary step of collecting data comprised of collecting all patients with clinical diagnosis of VTE and all deaths during the period from 1 January 2016 till 31 December 2020. All patients with confirmed VTE diagnosis at discharge whether dead or alive were identified in the next step.

Diagnosis of VTE was confirmed by Doppler US of the affected site (Doppler US of extremities, Doppler US of jugular vein, Doppler US of portal vein, and Doppler US of IVC), as well as, CT scan angiogram of the affected site (pulmonary, neck vessels, abdominal), and MRV specifically was used for diagnosis of cerebral venous sinus thrombosis) or echocardiography in major PE and hemodynamic instability. Death was considered to be a result of VTE if the patient was diagnosed as VTE. VTE diagnosis was confirmed by the aforementioned investigations and there were no other possible clinical explanations for death.

Statistical analysis

For the analysis, the statistical program for the social sciences (SPSS) version 25.0 was utilized (SPSS, Inc., Chicago, Illinois, USA). The mean and standard deviation (SD) of continuous normally distributed variables were obtained. The median associated with the 25th to 75th percentile interquartile range (IQR) was used to represent non-normal distributions. To compare categorical variables, the Chi-square test was employed; when any of the predicted values were less than 5, Fisher's exact test was used instead. All statistical tests were run at a 5% level of significance, and variables with a p-value of less than 0.2 were included into logistic regression for additional

analysis and confound adjustment. Kaplan Meier survival curves were used to construct the survival curves. The Cox proportional hazards model was used to examine the differences between the curves.

Results

Three-quarters of our patients were males 112 (74.2%). Median age was 30 years (IRQ= 23, 42 years), and more than half of our patients were < 30 years with distribution 82 (54.3%). Regarding cause of admission of patients, more than half were post war trauma patients with distribution 85 (56.3%), followed by patients who complained medical disorder 33 (21.9%), then pregnancy & postpartum patients were 14 (9.3%), and post road traffic accident (RTA) patients and patients who complained from others were 8 (5.3%) and 11 (7.3%) respectively. The distribution of type of case groups, orthopedic, surgical, medical, neurosurgery, and Gyne-obstric was 44 (29.1), 41 (27.2%), 39 (25.8%), 35 (23.2%), and 13 (8.6%) respectively. Most common risk factor was immobilization with distribution 101 (66.8%), followed by major surgery, orthopedic, surgery, or neurosurgery risk factor 96 (64%), trauma/ minor leg injury was 53 (35.3%), then infection 33 (22%), central line 31 (20.7%), inflammatory/ autoimmune 16 (10.7%), previous VTE 14 (9.3%), pregnancy/ postpartum 14 (9.3%) and older age 14 (9.3%). The distributions of risk factors groups APLAS, heart failure, cancer, obesity, chemotherapy, and OCP were 9 (6%), 5 (3.3%), 4 (2.7%), 3 (2%), 1 (0.7%), and 1 (0.7%), respectively.

Table 1: Baseline characteristics of VTE patients

Characteristics	Frequency	Percentage (%)
Age < 30 years	82	54.3
Median age = 30 (IRQ= 23, 42) years		
Males	112	74.2
Cause of admission		
Post war trauma	85	56.3
Medical disorder	33	21.9
Pregnancy & postpartum	14	9.3
Post road traffic accident	8	5.3
Others	11	7.3
Types of case		
Orthopedic	44	29.1
Surgical	41	27.2
Medical	39	25.8
Neurosurgery	35	23.2
Gyne-obstric	13	8.6
Risk factors		
Old age	14	9.3
Immobilization	101	66.8
Major surgery	96	64
Previous VTE	14	9.3
Central Line	31	20.7
Pregnancy/ PostPartum	14	9.3
OCP	1	0.7
Trauma/ minor leg injury	53	35.3
Infection	33	22
Inflammatory/Autoimmune	16	10.7
Active Cancer	4	2.7
Chemotherapy	1	0.7
Heart Failure	5	3.3
APLAS	9	6
Obesity	3	2

Distribution of Well's Score Applicability

From total 151 patients, 18 (11.9%) patients were excluded from analysis, and the distribution of others 133 patients among groups low risk (3%), moderate risk (15%), and high risk (75%) was 3 (2.3%), 7 (5.3%), and 123 (92.4%) respectively. Sixteen (10.6%) patients were excluded, and the distribution of others 135 patients among groups PE likely, and PE unlikely were 115 (85%) and 20 (15%), respectively, (Table 2).

Table 2: Distribution of Well's Score Applicability

Distribution of Well's clinical predication rule for DVT (N=133)	F	%
Low risk (3%)	3	2.3
Moderate risk (15%)	7	5.3
High risk (75%)	123	92.4
Distribution of Wells score for PE (N=135)		
PE likely	115	85
PE unlikely	20	15

Nearly half of patients was admitted to hospital with VTE and they distributed as 79 (52.3%), only 12 (8%) patients developed VTE after ≤ 3 days from their date of admission to hospital, 19 (12.6%) patients after 4-10 days, and 41 (27.1%) patients after >10 days.

The distribution of length of stay in hospital in groups ≤ 14 days, 15-29 days and ≥ 30 days was 57 (37.7%), 27 (17.9%), and 67 (44.4%) respectively, and median of length of stay in hospital = 22 (IRQ= 10, 45 days), males median = 32 (IRQ = 12, 50 days), females median = 12 days (IRQ = 8, 20).

From total 151 patients, 20 patients discharged or died before reaching target INR. The others 131 patients were checked their INR with mean 11.76 ± 11.8 days, and 9 (6.9%) patients reach target INR early (< 3 days, because they had coagulopathy), 59 (45 %) reach target INR during 3-9 days, 51 (38.9%) patients reach target INR during 10-20 days, and 12 (9.2%) reach target INR during > 20 days. Table 3.

Table 3: Distribution of VTE Development period, length of stay in hospital & duration to reach target INR after therapeutic anticoagulant

Variables	Frequency	Percentage (%)
Period of VTE Development (Days)		
On day of admission	79	52.3
≤ 3 days	12	8
4-10 days	19	12.6
>10 days	41	27.1
(Mean = 18.69 ± 17.3) Days		
Length of stay in hospital (Days)		
≤ 14	57	37.7
15-29	27	17.9
≥ 30	67	44.4
Median = 22 (IRQ= 10, 45) days		
Duration to reach target INR after therapeutic anticoagulant (Days)		
< 3 days	9	6.9
3-9 days	59	45
10-20 days	51	38.9
> 20 days	12	9.2
(Mean = 11.76 ± 11.8) days		

During 2016-2020, there were 28694 patients hospitalized in 48 Model Hospital, and out of these, 151 patients were confirmed diagnosis with VTE. Therefore, prevalence of VTE during five years was 0.53%.

In addition, prevalence of VTE in each year 2016, 2017, 2018, 2019, and 2020 was 0.37% (22/5954), 0.6.4% (34/5275), 0.4% (23/5905), 0.47% (28/5938), and 0.78% (44/5266) respectively, (Figure 1).

In respect to distribution of VTE types, 101 (66.9%) were with proximal lower limb DVT (L.L. DVT), 22 (14.5%) were with PE, 10 (6.6%) were with upper limb DVT (U.L. DVT), 7 (4.6%) were with jugular vein thrombosis (JVT), 6 (4%) were with portal vein thrombosis (PVT), 5 (3.3%) were with CVST, 3 (2%) were with superficial vein thrombosis, and 3 (1.3%) were with IVCT (Figure 2).

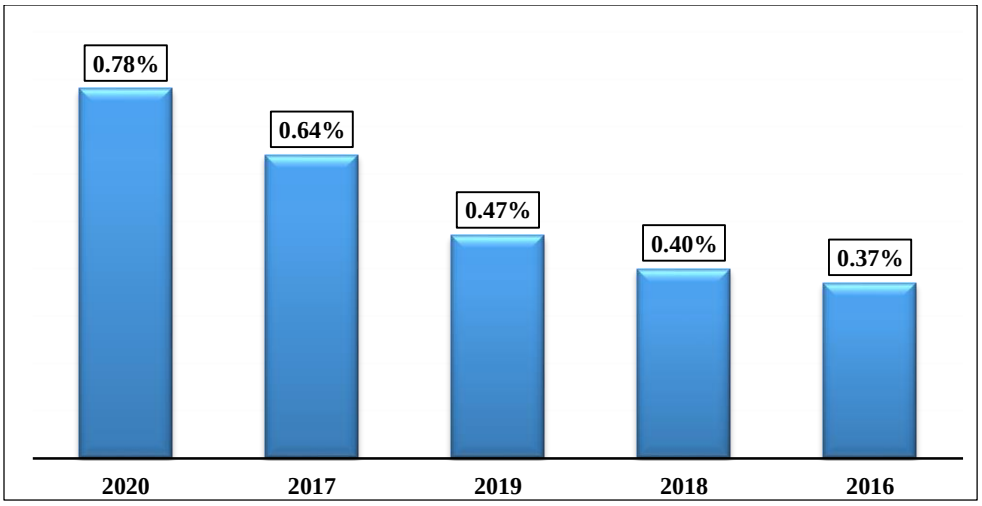

Figure 1: Prevalence of VTE per years

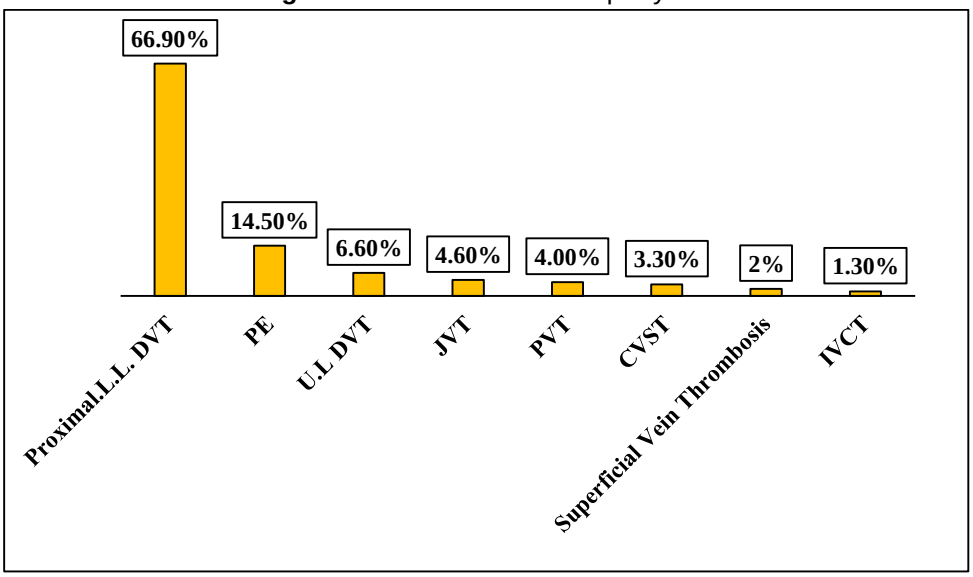

Figure 2: VTE types distribution among patients

Prophylaxis distribution among patients

From total 151 patients, 25 (16.5%) patients not need prophylaxis. The others 126 patients need prophylaxis. Out of these, 45 patients were OPD patients, and all of them didn't receive any prophylaxis. Out of 81 IPD patients, 52 (64%) patients given prophylaxis, and others 29 (36%) didn't give prophylaxis. Figure 3

Distribution of barrier to anticoagulant

As mentioned above, 25 (16.5%) patients not need prophylaxis from total 151 patients. Out of others 126 patients, 76 (60.1%) patients with no barrier, 42 (33.3%) patients with bleeding, 5 (4.2%) patients with both bleeding and coagulopathy, and 3 (2.4%) patients with coagulopathy only.

Majority of patients were with no barriers with frequency and percent 94, and 62.3% respectively. Bleeding was the most common barrier with distribution 35 (23.2%), followed by coagulopathy 12 (7.9%), and then both bleeding and coagulopathy 10 (6.6%). Only 10 (6.6%) patients treated by IVC filter, and others 141 (93.4%) patients didn't treat by IVC filter. Mortality in hospital was 11 (7.3%).

On the other hand, when placing IVC filter was not associated with events (mortalities) (p-value= 0.533), other different predictors associated with it.

From all of risk factors which measured, only infection risk factor had significant association with the event, as patients with infection were 5 times

more likely to event than patients without infection (Crude odd ratio (COR)= 5, confidence interval (C.I.) = 1.426- 17.68). IPD patients without any prophylaxis anticoagulant on time were 8 times more likely to event than patients with prophylaxis anticoagulant on time (COR=8, C.I.= 2.424-19.654).

Patients with bleeding barrier to prophylactic anticoagulant were 7 times more likely to event than patients without any barrier to prophylactic anticoagulant (COR= 7, C.I.= 0.815- 60.1), and no significant association with others groups.

Patients without any prophylactic anticoagulant were 1.9 times more likely to event than patients who used UFH as a prophylactic anticoagulant (COR= 1.9, C.I.= 0.981-6.121).

Patients with barriers of both bleeding and coagulopathy together were 7.7 times more likely to event compared to patients with barriers bleeding to treatment only (COR= 7.7, C.I.= 2.701-22.931).

Similarly, low admission PLAT patients were 9.5 times more likely to event than normal admission PLAT patients (COR= 9.5, C.I = 3.116-30.432). Also, high admission S.Cr patients were nearly 14 times more likely to event compared to normal admission S.Cr patients (COR= 13.75, C.I.= 2.896-65.298).

Table 4: Distribution of barrier to anticoagulant, IVC filter and mortality

Variables	F	%
Barriers to prophylactic anticoagulant (N= 126)		
No barrier	76	60.1
Bleeding barrier	42	33.3
Coagulopathy	3	2.4
Both bleeding and coagulopathy	5	4.2
Barriers to therapeutic anticoagulant (N= 151)		
No barrier	94	62.3
Bleeding barrier	35	23.2
Coagulopathy	12	7.9
Both bleeding and coagulopathy	10	6.6
IVC filter (N= 151)		
Treated by IVC filter	10	6.6
didn't treat by IVC filter	141	93.4
Mortality in hospital	11	7.3

Table 5: Associations between predictors and event

Predictors	Event		95% C.I.	COR	P-value
	Yes	No			
With infection	6	27	(1.426- 17.68)	5	0.012
Without infection	5	113			
Placed IVC Filter	0	10			0.533
Not placed IVC Filter	11	130			
IPD without utilization any prophylaxis anticoagulant	7	22	(2.424-19.654)	8	0.014
IPD with utilization prophylaxis anticoagulant	2	50			
Have bleeding barrier to prophylactic	7	36	(0.815- 60.1)	7	0.043
Without any barrier to prophylactic	2	75			
Without utilization any prophylactic anticoagulant	9	88	(0.981-6.121)	1.9	0.036
Used UFH as prophylactic anticoagulant	2	38			
Have both bleeding and coagulopathy barriers to treatment	5	5	(2.701-22.931)	7.7	0.039
Have bleeding barrier to treatment	4	31			
Low admission PLAT	4	8	(3.116-30.432)	9.5	0.013
Normal admission PLAT	6	114			
High admission S.Cr	5	12	(2.896-65.298)	13.75	0.000
Normal admission S.Cr	6	128			

There were no significant differences in survival between patients who were administered LMWH compared to those administered UFH as treatment (p-value > 0.05). See Table 6, and Figure 4.

Table 6: Overall comparisons between UFH and LMWH

Comparison methods	Chi-Square	P-value
Log Rank (Mantel-Cox)	0.006	0.937
Breslow (Generalized Wilcoxon)	0.152	0.697
Tarone-Ware	0.152	0.859

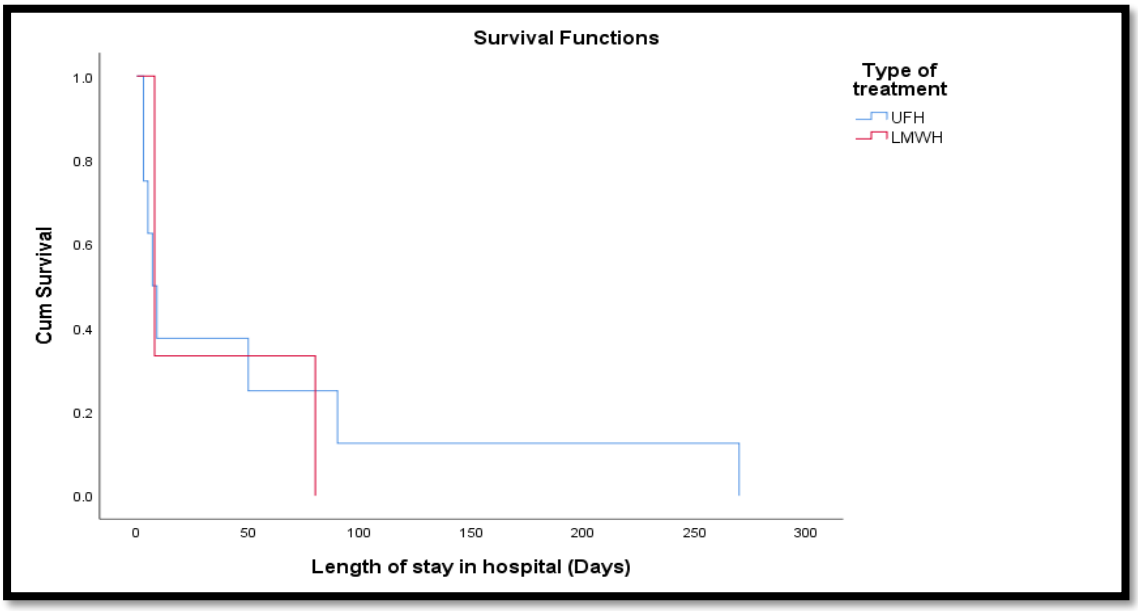

Figure 4: Survival curve of patients with UFH and LMWH

Discussion

As mentioned earlier, no systematic research has so far been conducted in Yemen on VTE patients, therefore, comparisons are difficult at national level.

Our study patients present 24 years younger than their Saudi counterparts [8]. Although Elkhadir *et al.,* reported Saudi females were affected by VTE more than Saudi males [8], we can't say for sure that males were affected more than females according our study results, due to 48 model hospital is a military hospital.

Surgical cases represented 27.2% from total our study patients, and this is higher than Al-Hameed *et al.,* result among Saudi patients, as surgical cases represented 21.4% [9]. Medical cases were 26% from total our study patients, but this is lower than Al-Hameed *et al.,* result, as 78.6% were hospitalized for acute medical illnesses [9]. The war in Yemen and nature of study hospital contributed in increasing of surgical cases, and decreasing medical cases in our study compared with Saudi study.

On the other hand, most common risk factors were immobilization, major surgery, and trauma respectively among our study patients. This result is similar to what reported in India by Bagaria *et al.,* [10], however it is inconsistent with Al-Zahrani *et al.,* result, as age more than 50 years, obesity, vasculitis, malignancy and postpartum were the common factors encountered among Saudi study patients [11]. Also, Elkhadir *et al.,* concluded elderly has been found to be the most common risk factor among Saudi patients [8].

In contrast, because only 40% of high-risk patients not received VTE prophylaxis, VTE prophylaxis was underutilized in the 48 model hospital patients. This finding is higher than in Kuwait (33.5%), and in UAE (33.1%) [12], and nearly equal to 40.9% in Saudi Aribia [9], as well as equal to 40.2% reported in the overall Gulf countries which was estimated by Alsayegh *et al.,* [12], however it is lower than approximately 50% reported in the worldwide utilization of VTE prophylaxis in the ENDORSE study [13].

Prevalence of VTE among 48 model hospital patients during five years was 0.53%. This is lower than what reported among Australian hospitals patients (11.45 per 1000 patients; 1.1%) [14]. The explanation of high prevalence of VTE among Australian patients could be relate to older ages and high comorbidity among Australian study patients compared to our study patients. At the same time, our study VTE prevalence is higher than the incidence of hospital acquired thrombosis (HAT) which was estimated in Ireland 0.4% [15], and also higher than what was estimated in England (0.147%) [16].

Prevalence of DVT among our study patients was slightly higher than what was reported among Saudi patients (67% V.S. 58.3% respectively), but PE was lower than what was reported among Saudi patients in Al-Hameed *et al.,* study [9] (14.5% VS. 21.7% respectively). The explanation of differences could be relate to differences of type of cases between two studies.

According to our study results, 2020 year had higher prevalence of VTE compared with previous 4

years (2016-2019). The explanation might be related to accumulation of immobilized cases from previous years, and/or due to the intensification of fighting in the country in 2020 year.

According to our study data, mortality in hospital was 11 per 151 (7.3%), and this result is lower than reported by Assareh *et al.,* in Australian hospitals, as one in ten (10%) who developed HA-VTE died in hospital [14]. The explanation could be related to older ages and high comorbidity among Australian study patients compared to our study patients. In contrast, our study result was higher than what was reported among Saudi patients by Abo-El-Nazar Essam and Al-Hameed*,* , as case fatality rate was 3.1% [17], also higher than Al-Hameed *et al.,* result (1.6%).

Infection was an independent predictor of event among VTE patients according to our study results, where patients with infection was 5 times more likely to event. This result is coherent with Chadha *et al.,* who concluded patients with infection were 11 times more likely to death [18]. Also, according to a prospective cohort study in Switzerland; Faller *et al.,* found infection was one of the most common causes of death among VTE patients [19].

Although there are guideline recommendations and widespread use of IVC filters worldwide, IVC filter placement was not associated with event according to current study results. This inconsistent with Liu *et al.,* who found IVC filter group was at lower risk of mortality (risk ratio = 0.17) [20]. Secemsky *et al.,* reported IVC filter placement was associated with a lower ratio of mortality, which was unchanged after additional adjustment by a propensity score for IVC filter placement [21]. Similarly, a 2016 study of patients in California without cancer demonstrated decreased mortality for those who received an IVC filter with active bleeding [22]. According to *Stein et al.,* mortality was reduced with IVC filters only if the filters were inserted in the first 4 or 5 days [23]. The differences might be related to lack of sensitivity in our study towards IVC filter placement.

Patients with bleeding barrier to prophylactic anticoagulant were 7 times more likely to event than patients with no any barrier to prophylactic anticoagulant. This result is coherent with Spencer *et al.,* who found the occurrence of bleeding was the strongest predictor of recurrent VTE and was also a predictor of total mortality [24]. In addition, according to Swiss study, Faller *et al.,* concluded bleeding was one of the most common causes of death [19].

Patients with bleeding and coagulopathy together barriers to treatment were 7.7 more likely to event than those patients with bleeding barrier only. This result is coherent with Chung *et al.,* who concluded coagulopathy increased mortality by 5-fold [25].

On the other hand, low admission PLAT patients were 9.5 times more likely to event compared to normal admission PLAT patients. According to a study published in The American Journal of Cardiology, moderate-to-severe thrombocytopenia at baseline is associated with significant risk for major bleeding and all-cause death in patients with VTE [26].

In the same context, high admission S.Cr patients were nearly 14 times more likely to event compared to normal admission S.Cr patients. This result is in coherent with Giannis *et al.,* who found chronic renal disease patients were 2.1 times more likely to mortality [27]. Goto *et al.,* found the presence of concomitant moderate to severe chronic kidney disease was associated with increases in the risk of death, recurrent VTE, and major bleeding compared with mild to no chronic kidney disease [28].

Not far from the topic of mortality, there was no significant differences between patients who were administered LMWH as therapeutic anticoagulant compared to those administered UFH. This result is absolutely the opposite of what concluded by Jacobs *et al.,* as patients administered LMWH had a decreased risk of mortality VTE compared to UFH [29]. These differences need urgent and necessary studies to examine the effectiveness of LMWH in our country, which has recently become circulated through smuggling.

Limitations

Our study has some limitations. It is a single hospital and retrospective study, therefore has an inherent selection bias. A military nature of study hospital not reflect what happens in other hospitals, whether public or private hospitals. In addition, the low in hospital events does not provide enough power to test for other unmeasured confounders.

Conclusion

The findings of our study highlight that thromboprophylaxis therapy was underutilized in 48 Model Hospital patients, indicating a gap between practice and guidelines. Therefore, there was a high prevalence of VTE among 48 model hospital patients. Infection, underutilized of thromboprophylaxis for prophylaxis, coagulopathy and bleeding as barriers to treatment, low PLAT at admission, and high S.Cr at admission were all independent predictors of mortality among VTE patients in 48 model hospital. Strict adherence of health care professionals for The National Institute for Health and Care Excellence guideline to assess risk factors and management of VTE for all patients,

as well as balance the person's individual risk of VTE against their risk of bleeding when deciding whether to offer pharmacological thromboprophylaxis to medical patients are recommended.

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