Venous Thromboembolism Risk Assessment and Prophylaxis in Intensive Care Unit; Clinical Audit and Performance Improvement Project

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ABSTRACT

Venous thromboembolism is a major cause of morbidity and mortality among hospitalized patients, particularly the critically ill. High incidence rates continue to be reported despite the presence of several high quality prophylaxis guidelines. However, several gaps are frequently identified in the practice that may contribute to the incidence and prevalence of this plethora. **Objectives:** To report the findings of a complete audit cycle on VTE risk assessment and prophylaxis in the intensive care unit of a major hospital in Saudi Arabia. As well as the results of a performance improvement project.

Results: The percentage of patients with completed VTE risk assessment in the first cycle was 89%, that increased to 96% in the second (p = 0.1), proper risk categorization was 74.2% and 90.6% in the first and second cycles respectively (p = 0.01), whereas the percentage of patients receiving the recommended prophylaxis dose was 86.4% in the first cycle, and 94.3% in the second (p = 0.2).

Conclusions: VTE risk assessment, proper risk categorization, and providing optimal prophylaxis doses remain below targets, however; all three parameters could be improved by performance improvement projects. As the main causes of sub-standard practices are related to awareness issues, in addition to underestimation of VTE risk in favor of over-estimation of bleeding concerns.

Keywords: Venous thromboembolism, VTE risk assessment and prophylaxis in the intensive care unit, Clinical audit, pulmonary embolism (PE) and deep vein thrombosis (DVT)

INTRODUCTION

Venous thromboembolism (VTE) generally to encompass known both pulmonary embolism (PE) and deep vein (1) thrombosis (DVT) constitutes a healthcare dilemma worldwide (2) for several reasons. First, VTE incidence and prevalence are astonishingly high, in the general population the incidence of VTE is about 1 -2 cases per 1000, ⁽¹⁾ harboring an moderate incidence in patients risk incidence comparable the to of cardiovascular disease, and cerebrovascular strokes. ⁽⁴⁾ In the hospital the absence setting and in of VTE prophylaxis the incidence of DVT and PE

were reported to affect as high as 80% and 10% of post-operative patients respectively. ⁽⁵⁾ patients in the intensive care unit (ICU) are considered to be at high risk of VTE, owing to the nature of the interventions used in their management such as mechanical ventilation. central lines .indwelling catheters and sedation, ⁽⁶⁾ and incidence rates ranging between 5% and 37% were reported depending on the screening method among patients receiving prophylaxis. ⁽⁷⁾ Second, the toll of mortality and morbidity due to VTE is also enormous, it has been reported that about 30% of patients with VTE will suffer death within 30 days, and 30% will have recurrent VTE at follow up,

⁽⁸⁾ in the United Kingdom, VTE was reported to kill 25,000 persons annually, ⁽⁹⁾ while PE may be responsible for 10% of all in-hospital deaths, in addition to further sequel such as post thrombotic syndrome. ⁽⁵⁾ Perhaps not as critical as human lives, a third reason of the dilemma of VTE is the economic burden it imposes on healthcare systems, in terms of resource utilization and expenditure. More than a decade ago Caprini et al ⁽¹⁰⁾ documented this issue beyond doubt, a more recent Australian article ⁽¹¹⁾ estimated the financial burden imposed by VTE on healthcare systems to be about 1.72 Billion \$.

Furthermore, what makes the issue of VTE even more compelling is the fact that VTE is a potentially preventable healthcare problem according to most researchers, (2, 9, 11) that is to say lives could be saved and expenses could be spared if an evidence based approach was used to identify patients at risk, and offer them suitable prophylaxis. There is no shortage of guidelines on VTE risk assessment, or the recommended prophylaxis, such as the guidelines of the American College of Chest Physicians (ACCP) ⁽¹²⁾ or the more recent NICE guidelines, ⁽¹³⁾ so it seems that the main obstacle may be compliance or adherence to such guidelines, especially when we consider the compiling evidence from meta analyses that following such guidelines does reduce VTE incidence. ^(14, 15)

Recently the Ministry of Health in Saudi Arabia included VTE risk assessment and prophylaxis in its clinical audit program, hence this work was conducted as part of the required compliance by the Quality and Patients' Safety division in the ICU of a major hospital.

Objectives:

This was a complete audit cycle to evaluate appropriateness of VTE risk assessment in the ICU of a major hospital, both before and after an intervention. Additionally, this was a report of a performance improvement project (PIP) conducted after the initial audit to bridge the identified gaps.

METHOD

Setting: This work was conducted in the ICU of King Saud Medical City (KSMC), the largest Ministry of Health in Saudi Arabia in the central region, the ICU harbors 127 beds, fully equipped with monitors and capabilities of non-invasive as well as invasive mechanical ventilation. The ICU is divided into 5 units, namely: surgical, medical, trauma, burn, and maternity units. It is a closed ICU operated by intensivists round the clock, with a nurse: patient ratio of 1:1.

Audit design: we followed the classical audit cycle design recommended by the Healthcare Quality Improvement Partnership (HQIP), ⁽¹⁶⁾ of measuring current practice, compare it to standards, identify opportunities of improvement, apply change, and finally re-evaluate the practice.

Inclusion and exclusion criteria: Similar inclusion and exclusion criteria: Similar applied to both audit cycles, we included adult patients (age \geq 18 years), admitted to any of the ICU units for at least 24 hours, with an expected length of stay (LOS) of at least 48 hours. We excluded patients admitted to maternity and burn units (as those two units follow a different protocol of VTE risk assessment and recommended prophylaxis).

Timeframe and sample size: Each cycle was composed of two-point prevalence days a week apart, in which we randomly evaluated 50 patients each day (to a total of 100 patients per cycle), the same patient was not included twice within the same cycle, nor in the second cycle, if he/she was still in the ICU at the time of the second cycle. The first cycle took place on the 2nd and 9th of June 2019. Whereas the second cycle took place on the 1st and 8th of December 2019. Patients were randomly chosen to be included in the audit according to computer generated random number list without replacement.

Current practice: according to the policy of our institute any patient admitted to the ICU and expected to stay for at least 48 hours must be assessed for risk of developing VTE within 24 hours, patients are also to be assessed for risk of VTE upon change of condition (such as but not limited to of mechanical ventilation, initiation insertion of central line, sedation and immobilization, post operatively). VTE risk assessment is based on a checklist, created by a multidisciplinary team of experts in our institute (figure 1), according to evidence based medicine and best current knowledge and published literature, the checklist scores points for each risk factor of VTE, and the sum is taken, then patients are categorized according to their score, into low (score \leq 2), moderate (score 3 - 4), and high risk (score \geq 5). Different choices are offered for VTE prophylaxis in each category (taking in consideration the kidney function), and one of those options should be checked. The checklist also includes a safety section for anticoagulants contraindications, which if any of its questions is answered "Yes" the patient should be offered mechanical alternatives to pharmacological prophylaxis. It is allowed for the clinicians to over-ride the recommendations based on their clinical judgement, as long as they justify their decision.

Audit standards: the standards against which we measured the practice were:

- 1. All patients admitted to ICU with an expected LOS > 48 hours should have a completed checklist of VTE risk assessment.
- 2. All assessed patients should be categorized into low, moderate or high risk based on their score.
- 3. All assessed patients should be offered VTE prophylaxis in concordance with their assessment category.

The audit team trained to use the assessment checklist reviewed the medical records of each included patient for the presence and completion of the VTE risk assessment form, if the form was present the team repeated the assessment to identify improperly categorized patients, and finally compared the VTE prophylaxis being offered to the patient against the recommendations. The team was composed of two physicians and four registered nurses. This clinical audit and PIP were approved by the total quality management department at KSMC, with waiver of consent.

Continuous data were summarized as mean \pm standard deviation (SD), and compared between cycles using student ttest or Mann Whitney test as appropriate, while categorical data were summarized as number and percentage, and compared between cycles by chi² or Fisher's exact test as appropriate.

RESULTS

First audit cycle: (June 2nd and 9th, 2020): 100 randomly chosen patients were reviewed, there were 59 males and 41 females, with an average age of 52 ± 6 years, and average APACHE 4 score of 61.8 \pm 22, 73 patients were mechanically ventilated. Out of the included 100 patients only 89 (89%) had a VTE risk assessment form in their medical record (although the 11 patients with missing forms were receiving some form of VTE prophylaxis), those patients were admitted from the general ward after emergency intubation (which is a criterion for re-assessment), and when assessed by the audit team 9 of them were categorized as high risk, and 2 as moderate risk. Out of 89 assessed patients patients (74.2%)were properly 66 categorized for risk of VTE, 23 patients were improperly categorized, 13 were categorized as moderate risk when actually they were in the high risk category, whereas 10 patients should have been categorized as moderate risk were categorized as low risk.

Out of total 66 patients properly categorized for risk of VTE 57 patients (86.4%) were receiving prophylaxis according to recommendations based on their risk category, whereas 9 patients didn't receive the recommended prophylaxis dose, with only 3 justifications of over-ride. It is

worth mentioning that all of the 6 patients were receiving a suboptimal dose of VTE prophylaxis (table 1, figure 2).

Table 1: Comparison of audit cycles results:								
	Cycle 1 (n=100)	Cycle 2 ($n = 100$)	P value					
Age (mean ± SD)	52 ± 6	52.6 ± 5	0.4					
Males (n, %)	59 (59%)	63 (63%)	0.7					
APACHE 4 (mean \pm SD)	61.8 ± 22	63.4 ± 24	0.6					
Mechanically Ventilated (n, %)	73 (73%)	76 (76%)	0.7					
Assessment completed (n, %)	89 (89%)	96 (96%)	0.1					
Properly categorized / All assessed	66/89 (74.2%)	87/96 (90.6%)	0.01					
Prophylaxis according to category / Correctly categorized	57/66 (86.4%)	82/87 (94.3%)	0.2					

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VTE RISK ASSESSMENT & PROPHYLAXIS								
Complete on Admission to Unit. Check applicable items RISK FACTORS								
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Each Risk Factors <u>1</u> Points Aqe: 41-60 years	Age: 61-74	actors 2 Poin	□ Age: ≥ 75 ye	actors <u>3</u> Points		vis or leg fracture		
\square BMI > 24 Kg/m ²	Arthroscopic Surgery		History of D	History of DVT /PE		t month)		
Minor Surgery	Laparoscopy Surgery		Family histor	Family history of VTE*		Stroke (within past month)		
Swollen legs (current)	(>45 minutes)			Factor V Leiden		Multiple trauma (within past		
Varicose veins Major Surgeos (in the past month)	Major open surgery (>45 minutes)			Prothrombin 20210A		month)		
 Major Surgery (in the past month) Lung Disease (emphysema or COPD) 		rent or previous)		Lupus anticoagulant Anticardiolipin antibodies		 Elective major lower extremity arthroplasty 		
Currently on bed rest or restricted mobility	Immobilizin	Immobilizing plaster cast		Elevated serum homocysteine		Acute spinal cord injury –		
History of inflammatory bowel disease		for more than 72			paralysis (within the past			
 Acute myocardial infarction Congestive heart failure (< 1 month) 	hours			thrombocytopenia (HIT)		month)		
Sepsis / Pneumonia (<1 month)	Li Central ven	Central venous access		Other congenital or acquired thrombophilia				
Abnormal PFTs			Major surger					
History of unexplained or recurrent			hours					
spontaneous abortion (>3)		*Most common missing						
 Pregnant or post-partum (<1 month) Oral contraceptives or hormone 			"Nost common	missing risk				
Replacement therapy								
Total Risk Factors 1x	+ 2x	+3x +	5x =					
PROPHYLAXIS				ox if answer				
FROFHILARIS			h Increase Blee		IS TES			
Is patient experiencing any active bleed		Sociated with	II IIICI ease Diee	ung				
Dose patient have (OR has had history)								
□ Is patient's Platelet count < 100,000 /m								
□ Is patient take oral Anticoagulant OR Platelet inhibitors?								
Is patient's Creatinin Clerance (CrCI) A	bnormal? If <u>YI</u>	ES, please indi	cate value	ml/min				
If any of the above boxes are checked, the	e patient may	not be a candio	late for Anticoagul	ant therapy and y	ou should	use alternative		
prophylactic method.								
Intermittent Pre			C) or Anti-embo	olism stocking	s(AES)			
Does patient have severe peripheral arterial disease?								
 Does patient have CHF? Does patient have an acute superficial /deep vein thrombosis? 								
If any of the above boxes are checked, the patient may not be a for IPC or AES and you should use alternative prophylactic method.								
Contraindication to anticoagulants? UYES UNO If YES, explain:								
	n Total Ris		select one of					
Risk Score = 0 (Very Low Risks)			isk Score = 1-2 (
Early Ambulation			Mechanical prophylaxis IPC or AES					
Risk Score = 3- 4 (Moderate) Risk Score = > 5 (High risk) Pharmacological agent ± IPC or AES Pharmacological agent + IPC or AES								
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Special Populations with Highest Risk:								
Hip OR knee replacement surgery Pharmacological agent + IPC or AES								
Trauma					ut BID			
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□ Obese: BMI ≥ 40 Kg/m ² □ Bariatric surgery	PMI < 50 kall	 Enoxaparin 50 mg SubCut Dialy, OR special order m² Enoxaparin 40 mg SubCut BID, OR special order 						
	1 BMI <u><</u> 50 kg/i 1 BMI > 50 kg/i		Enoxaparin 40 m					
Physician's Name: Signature:								
Physician's Stamp: Date & Time :								

Figure 1: VTE risk assessment and prophylaxis checklist

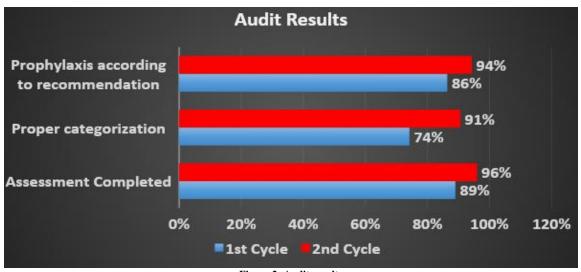


Figure 2: Audit results

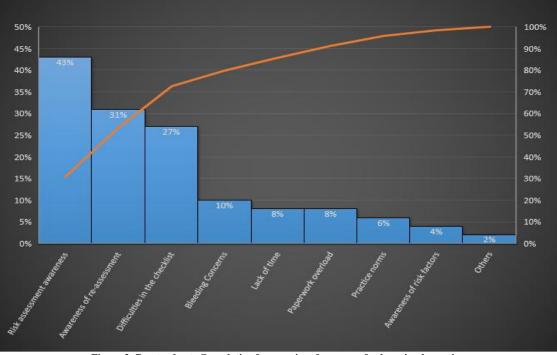


Figure 3: Pareto chart: Cumulative frequencies of reasons of sub-optimal practice.

Performance Improvement Project: The results of the 1st audit cycle prompted the initiation of a PIP to cover the gaps in practice, analysis of data obtained from multiple brain storming sessions with all stake holders revealed several reasons for the suboptimal practice including: Lack of awareness of the VTE risk assessment process, lack of awareness of the need for re-assessment upon change of the patients' condition, improper interpretation of the checklist, practice norm of offering a standard prophylaxis dose to all patients,

fear of bleeding, lack of knowledge of the majority of VTE risk factors, shortage of time, and paperwork overload (figure 3). According to Pareto's principle, 80% of the problems originated from the vital few, which in our case were mainly related to awareness issues, and concerns of bleeding. Our PIP included several activities that took place simultaneously for a period of about 5 months, we provided awareness lectures and presentations during the morning meeting of the department once a week, the lectures covered the scope of VTE, its risk factors,

methods of prophylaxis, and risk assessment checklist clarification.

The team then conducted daily rounds in the ICU on newly admitted patients. we involved the attending physician and nurse in discussions on the proper method of assessing VTE risk, possible available options of prophylaxis, clarifications and answered offered questions by the attending team about the checklist. The PIP also included posters on notice boards in the ICU to remind physicians to perform VTE risk assessment, VTE risk factors, and sequel of VTE. We also organized small competitions between physicians, nurses, and ICU units, with the aim of encouraging compliance, and celebrating success. The most compliant winners were recognized and appreciated monthly in the morning meeting of the ICU. Second audit cycle (December 1st and 8th, 2020): The same method of patients' random selection was used as the 1st cycle, and a total of 100 patients were included. The average age was 52.6 ± 5 years, 63patients (63%) were males, average APACHE 4 score was 63.4 ± 24 , and 76 patients (76%)were mechanically ventilated. There were no demographic differences between patients included in both cycles. In the second cycle of auditing 96 patients (96%) had completed VTE risk assessment documented in their files. VTE risk assessment was missing for four patients three of them admitted from the ward and one post-operatively, the audit team's re-calculation revealed that 87 patients had correct calculation and proper risk categorization (90.6%), similar to the first cycle, the risk of VTE of the improperly categorized 9 patients was underestimated, as 5 of them were categorized as low risk when actually they had moderate risk, while 4 patients of high risk were categorized as moderate. Out of the 87 properly categorized 82 patients (94.3%) were receiving VTE prophylaxis as per recommendations, five patients were not, however, the over-ride was justified for four patients, while only one patient had no justification, and was receiving a suboptimal dose of prophylaxis. Statistically significant difference between cycles was found only between the percentages of patients properly categorized (out of all assessed for VTE risk) with 74.2% in the first cycle, and 90.6% in the second (p =0.01), while the other two standards didn't show significant differences, although both standards improved from the first to the second cycle.

DISCUSSION

This complete audit cycle provided useful insight about several key factors in the process of VTE risk assessment and prophylaxis. To begin with we identified in the first cycle a rate of VTE risk assessment of 89%, a rate which is below our expectations and definitely below our target of 100% assessment, this rate is similar, however; to that reported by others, Cathy Li et al ⁽⁵⁾ reported 82% assessment rate, by (17) 91.7% others. Similar and unsatisfactory rates of proper risk categorization were also reported, in our audit about 25% of those assessed were categorized as a lower risk than they should have, which of course translates into receiving a sub-optimal dose, putting them consequently at higher risk of developing VTE. This is confirmed by the findings of a study that involved 7 major hospitals in Saudi Arabia (including KSMC), ⁽¹⁸⁾ where the majority of VTE patients were not receiving the appropriate prophylaxis dose, while the appropriate dose was associated with 4% absolute risk reduction of VTE. Then the third standard also identified an area for improvement, with 86% of the patients properly categorized receiving the dose they should have, and to complicate things even more, the 14% who didn't receive the proper dose were getting a suboptimal dose of prophylaxis. In published varied significantly studies this rate according to the patients' diagnoses. (5, 17, 18)

The PIP we conducted also revealed several valuable findings, first of all was the identification of the most important reasons

of sub-optimal practice, awareness was a major finding, be it about the need of assessment itself, about the risk factors of VTE, or about the proper way to use the checklist. Another significant finding was the fact that clinicians almost always overestimate the risk of bleeding with VTE prophylaxis, while at the same time underestimate the risk of developing VTE, which seems to be a common finding or remark by similar studies. ⁽⁵⁾ However, we believe that our prize finding is that the practice with regards to VTE risk assessment could be improved by performance improvement projects, targeted awareness and education, repeated reminders, and a little bit of encouragement proved successful in improving all three rates of our audit's three standards. Indeed, there was an increase in the second cycle compared to the first in the percentage of patients with completed risk assessment, proper categorization, and administration of prophylaxis as recommended, although only the improvement of the second standard was statistically significant.

Our audit suffers several limitations including the lack of actual assessment of VTE development, nor its correlation with properly administered prophylaxis dose, however; in our defense, such a correlation may not actually exist, particularly for critically ill patients, Hamad et al ⁽¹⁹⁾ reports that critically ill patients showed high incidence of VTE despite rigorous protocoldriven VTE prophylaxis. The relatively small sample size in our audit may render our results underpowered, and possibly a more informative surveillance method should include all at risk patients, however; this would mandate a much larger task force.

Lessons learnt and conclusions:

- 1. Currently, VTE risk assessment practice is below target.
- 2. Practices could be improved by PIPs using rapid cycles, and utilizing simple methods, such as reminders, awareness

sessions, and celebration of even the slightest success.

- 3. Tools used for VTE risk assessment should be simplified, and made more user friendly.
- 4. More importantly, such tools should address the clinicians' concerns of excessive bleeding as opposed to the risk of developing VTE.
- 5. Policy makers should start looking for ways to involve patients or their families in the process of VTE risk assessment and prophylaxis.

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