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VENOUS THROMBOEMBOLISM PROPHYLAXIS IN MEDICAL INPATIENTS AND ADHERENCE TO GUIDELINE RECOMMENDATIONS: A PROSPECTIVE STUDY

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ABSTRACT: Background: Venous thromboembolism (VTE) is a common complication during and after hospitalization for medical patients. Previous studies have shown that only about one third of high risk medical patients receives VTE prophylaxis. Guidelines such as the one produced by the American college of Chest Physicians (ACCP) are aimed at reducing hospital associated VTE. The objective of this study was to determine the appropriateness of VTE prophylaxis in medical inpatients at a large teaching hospital. **Methods:** In a prospective cross-sectional study, VTE prophylaxis were evaluated and the data were recorded during October 2014 to March 2015 in medical wards of “Alzahra” hospital, Isfahan, Iran. A caprini score, a VTE risk factor assessment tool was calculated for each patient based on data collected. Appropriate prophylaxis was determined after examining data, caprini score and prophylaxis regimen according to the ACCP 9th edition guideline. **Results:** A total of 100 patients met the inclusion criteria and were reviewed. According to the risk stratification, 18 patients classified as low risk, 30 as moderate and 47 as high risk. 66% of patients did not receive appropriate prophylaxis in accordance with the guideline. Adherence to VTE prophylaxis for high-risk patients was 100% for pharmacological prophylaxis and 5% for mechanical prophylaxis. **Conclusion:** VTE prophylaxis was underutilized in high-risk medical inpatients in our center, on the other hand it is overused in low-risk patients. There is a need to implement a program to improve VTE awareness and prophylaxis. Also the hospital should develop a formal strategy, including a local guideline for VTE prevention.

INTRODUCTION: Venous thromboembolism (VTE) in the form of deep vein thrombosis (DVT) or pulmonary embolism (PE) is a significant cause of hospital-related morbidity and mortality with an annual incidence of 1-3 per 1000 patients¹⁻³. In the absence of prophylaxis, the risk of VTE in medical patients is about 16%⁴.

A recent Meta-analysis showed that prophylactic doses of unfractionated heparin (UFH) reduced the risk of DVT and PE by 51% and 53%, respectively, in medical patients with no significant increase in hemorrhage⁵. Several other clinical trials and Meta-analysis have shown efficacy and safety of prophylaxis with UFH and Low- molecular weight heparins (LMWH) for preventing VTE⁵⁻⁹.

In addition to this, consensus conferences and guidelines for DVT prophylaxis have been published, which recommend the use of prophylactic heparins in patients at risk of venous thrombosis. Despite this, previous studies have

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shown underuse of prophylaxis¹⁰⁻¹³. A chart review of 446 medical patients shows that only 33% (about one-third) of them received VTE prophylaxis¹⁴. The main problem with most of these studies was low use of prophylaxis in moderate/high risk patients.

Medical patients are classified as low, moderate and high risks for VTE depending upon their underlying medical condition and other combined risk factors. Risk assessment methods have been developed to classify them according to risk factors. Patients with lower limb paralysis (stroke and hemiplegia), major medical illness, thrombophilia and previous VTE are high risk patients for developing thrombosis^{15, 16}. Heart or lung diseases, cancer, inflammatory bowel disease, rheumatological disease, severe infection and advanced age are moderate risk factors and uncomplicated pneumonia or cellulitis are low risk factors for developing VTE. Risk of VTE is less than 10%, 10-30% and more than 30% in patients with low, moderate and high risk factors respectively¹⁷.

The American College of Chest Physicians (ACCP) has provided guidelines to prevent DVT and PE¹⁰. Dr. Joseph Caprini developed a VTE risk assessment tool to help physicians identify patients at risk for VTE with greater efficiency¹⁸. This tool assesses the risk for VTE at the following levels: 0-1 low risk, 2 moderate risk, 3-4 higher risk and ≥ 5 highest risks. Despite the availability of detailed guidelines for the prevention of VTE and a growing awareness of this problem, use of appropriate prophylaxis is neither uniform nor common.

The objective of this study is to determine the frequency of appropriate use of VTE prophylaxis in medical inpatients; and the assessment of the adherence to recommendations of the AACP guideline in the large teaching hospital, in Isfahan, Iran.

METHODS:

This observational, cross-sectional study was conducted from October 2014 to March 2015 in "Alzahra" teaching hospital, Isfahan, Iran. This hospital considered as the major referral hospital in

the region with 850 beds in total which 150 beds belong to medical inpatient wards.

All patients admitted to the medical wards of the hospital and had ≥ 18 years of age were selected for inclusion in the study. Patients from maternity and pediatric area, intensive care unit (ICU), and surgical wards were not included. Patients were excluded from the study if they were on heparin or warfarin before admission and if they had a diagnosis requiring anticoagulation (as treatment) including: acute coronary syndrome, atrial fibrillation, stroke, and DVT or PE.

Quantitative information was gathered on a data collection form that was piloted in September 2014, amended and subjected to peer review amongst medical colleague. The form was designed, so essential characteristics pertaining to the 9th edition of the ACCP guideline for VTE prevention were collated¹⁰. The Caprini score was calculated for each individual using data recorded on the form and a published risk factor assessment form¹⁸.

Patient data were collected during the study period on each medical ward for one month to obtain a snapshot representation of that ward and to follow patients. Data from patient chart, the drug Kardex and laboratory results were recorded. Information about the demographic characteristics of patients, patient's risk factors of VTE, methods of prophylaxis against VTE, contraindication to methods of VTE prophylaxis, the outcome of prophylaxis and outcome of patients was recorded. Since "Alzahra" hospital follows no specific prophylaxis guideline, VTE prophylaxis was determined to be indicated and appropriate based on the ACCP 9th edition guideline and the Caprini score. The major criteria regarding contraindications are as follows: history of gastrointestinal or genitourinary bleeding, active bleeding, and severe thrombocytopenia ($\text{Plt} < 50000 \text{ mm}^3$).

This study aims to assess the level of compliance with VTE prophylaxis guideline at "Alzahra" teaching hospital. The objectives were as follows:

1. Identify risk factors for VTE for medical inpatients.

2. Identify the presence of contraindications for VTE prophylaxis at hospital.
3. Evaluate adherence to the ACCP guidelines within the Alzahra hospital.
4. Calculate Caprini scores for patients.
5. Determine appropriateness for prophylaxis.
6. Ascertain reasons why VTE prophylaxis was inappropriate.

RESULTS: During the study period (October 2014 to March 2015), 100 patients admitted to medical wards of Alzahra hospital enrolled in the study of whom 56 were male. The age range of patients was 20-94 with the mean \pm SD of 58.5 ± 19.5 years old. Table 1 shows the baseline characteristics, reasons for admission and age distribution of patients.

30% of patients received VTE prophylaxis with as appropriate medication, dose and duration; 66% didn't receive prophylaxis in accordance with the guideline; and 4 patients received pharmacological prophylaxis despite contraindication. Adherence rates in high-risk medical patients was: 47% for pharmacological prophylaxis and 4.2% (2/47) for mechanical prophylaxis. All patients with moderate risk (n=30) received appropriate pharmacological prophylaxis; mean while half of these patients advise to ambulate for further VTE prophylaxis.

The result of our risk stratification shows that 30 patients were classified as moderate risk for VTE, 47 of them as high risk and 18 patients as low risk for VTE. The remaining five patients were classified as very low risk which equal to caprini score=0. 26 out of 100 patients had ≥ 7 risk factors. The most frequent risk factors were age >40 years (N=77), immobilization (N=45), Chronic Obstructive Pulmonary Disease (COPD) (N=40), serious lung disease (including pneumonia <1

month) (N=16) and swollen legs (current) (N=24). **Table 2** shows the frequency of risk factors of patients. Common risk factors in very low and low risk category (N=23) were age >40 years (N=9), COPD (N=9), swollen legs (N=4) and obesity (N=3). Among these patients, 17 of them received both pharmacological and non-pharmacological prophylaxis (ambulation), and the remaining (N=6) received pharmacological prophylaxis. Pharmacological prophylaxis with UFH was applied to 61 patients and with LMWHs (just enoxaparin) to 39 patients. The dosing range was 5000 Iu (BID or TDS) for UFH and 40 mg once daily for enoxaparin.

Non pharmacological prophylaxis with elastic bandage was utilized in 3 patients. 37 patients advise to ambulation for VTE prophylaxis. Only 18 patients had contraindication, absolute or relative, concerning the use of heparin (7 active hemorrhage, 10 patients with past medical history of GI bleeding (during the past month) and 1 advanced hepatic disease). Pharmacological prophylaxis were used in all of moderate (N=30) and high risk (N=47) patients. In high risk patients, only two of them received mechanical prophylaxis in addition to pharmacological prophylaxis. Table 3 shows characteristics of patients, according to risk factors and use of VTE prophylaxis in different medical wars; the results varied between different wards.

Four patients developed VTE (1 case of DVT and 3 cases of PE) despite prophylaxis. The mean duration of VTE prophylaxis was 11.2 ± 9.5 days (with a range of 1-67 days). The mean length of hospital stay was 16.7 ± 22.2 days (3-217 days). Eight of our patients died during the study period. In five patients, prophylactic regimen changed to therapeutic and in one patient prophylaxis was stopped because of development of thrombocytopenia.

TABLE 1: BASELINE CHARACTERISTICS OF PATIENTS.

Patient's characteristics	Frequency (N)
Age (Mean \pm SD)	58.5 ± 19.5 (20-94 years)
less than 41years	23
41-60years	21
61-74years	36
more than 75 years	20

Reasons for hospital admission	
Pneumonia	20
Asthma/ COPD	14
Cancer	12
Renal disorders (e.g. ESRD)	10
Metabolic disorders (e.g. diabetes)	5
Meningitis/encephalitis	5
Diabetic food	5
GI bleeding	4
Congestive Heart Failure	4
Rheumatoid arthritis	3
Others	18

COPD: chronic obstructive pulmonary disease, ESRD: end stage renal disease, GI: gastrointestinal.

TABLE 2: FREQUENCY OF RISK FACTORS AMONG THE STUDY POPULATION.

Risk factors	Frequency (N)
Age > 40 years	77
Immobilization	45
COPD	40
Swollen legs	24
Serious lung disease (including pneumonia)	16
Malignancy	15
Obesity	14
Congestive Heart failure	11
Myocardial infarction	6
Minor surgery	5
Prior VTE	4
Multiple trauma	4
Prior history of major surgery	2
Sepsis	2
Others (e.g. pregnancy and lupus)	5

COPD: chronic obstructive pulmonary disease, VTE: venous thromboembolism.

TABLE 3: RISK FACTORS OF PATIENTS AND PROPHYLAXIS OF VTE ACCORDING TO DIFFERENT WARDS.

Ward	Pulmonary	Gastrointestinal	Nephrology/hematology	Cardiac/ endocrine/ dermatology
Number of patients	56	12	17	15
Mean age \pm SD (range)	63 \pm 18.4 (20-94)	53.6 \pm 23.4 (20-90)	59 \pm 17.5 (23-80)	48.2 \pm 19.4 (20-76)
Mean number of risk factors, Mean \pm SD (range)	4.9 \pm 2.3 (0-12)	5.8 \pm 4.6 (1-15)	4.2 \pm 3.6 (0-13)	3 \pm 1.9 (0-6)
High risk	30 (53.5%)	5 (41.6%)	8 (47%)	4 (26.6%)
Moderate risk	17 (30.3%)	5 (41.6%)	4 (23.5%)	4 (26.6%)
Low risk	8 (14.2%)	2 (16.6%)	3 (17.6%)	5 (33.3%)
Very low risk	1 (1.7%)	0	2 (11.7%)	2 (13.3%)
Methods of prophylaxis, N(%)				
Mechanical(ambulation) + pharmacological	20 (35.7)	5 (41.6)	8 (47)	4 (26.6)
Pharmacological	36 (64.3)	7 (58.3)	9 (53)	11 (73.3)

DISCUSSION: The data gathered in this study show that VTE prophylaxis were not appropriately prescribed based on the ACCP 9th edition guidelines. However, our results also suggest that there may be overuse in low-risk patients (17%) and some underuse in moderate and high risk patients (45%). It is interesting to note that most

studies point out, as could be accepted, to underutilization of prophylaxis in high-risk patients^{19, 20}; but there are no studies indicating the problem of overuse. In addition, the adherence was regarding inappropriate use of mechanical prophylaxis.

Our results are consistent with the data published elsewhere. In general, most studies report low levels of appropriate prophylaxis²¹⁻²³. The literature reports quite a range of levels of appropriate prophylaxis, from as low as 14.5%²³ to as high as 77%²⁴. Variation in study population and quality of practice are as contributing factor in level of adherence.

In the ENDORSE trial, investigators enrolled 68183 hospital inpatients; 30827 (45%) were surgical patients and 37356 were medical patients. They found that 52% of enrolled patients were at risk for VTE, including 64% of surgical patients and 42% of medical patients. Among them, 59% of surgical patients and 40% of medical patients received ACCP recommended VTE prophylaxis²⁵. Other studies reported that surgical patients received higher level of appropriate VTE prophylaxis than medical patients^{22,26}. Although in this study, we focused on medical inpatients, but our data about the appropriateness of VTE prophylaxis were consistent with the other studies. This highlights the need for greater VTE risk education among medical teams.

In this study, we used of the Caprini score to help decide the level of prophylaxis needed. This allows for an objective evaluation of each patient based on their risk factors. According to Caprini score and also ACCP recommendation, high risk medical patients advised to receive both modes of prophylaxis (medical and mechanical). All of our high risk patients received appropriate pharmacological prophylaxis, but only two of them received mechanical prophylaxis in combination (in the form of elastic bandage). None of our patients received intermittent pneumatic compression (IPC); because we have limited pneumatic pumps in our center which usually used for critically ill patients.

Our physicians prefer to ambulate patients for VTE prevention. 15/30 of moderate risk patients and 17/30 of low risk patients advise to ambulate; but even all of these patients received pharmacological prophylaxis, in addition to ambulation. So the concepts about the risk stratification of patients and selection of the appropriate level of prophylaxis should be improved and revised in our hospital for

prevention of overuse and underutilization of VTE prophylaxis.

Overuse of pharmacological prophylaxis in low risk patients and underutilization of mechanical prophylaxis in high risk patients were the main reasons why a regimen deemed inappropriate. ACCP guidelines recommend the duration of thromboprophylaxis should be limited to the period of patient immobilization or acute hospital stay. The VTE prophylaxis usually begin within 2-3 days of our patient's admission and continue till their death or discharge.

In one patient, the prophylaxis discontinued because of adverse reaction and in four patients prophylactic regimens changed to the therapeutic regimen because of thrombosis evolution (DVT and PE). Despite the ambulation of many patients (especially low risk patients), pharmacological prophylaxis continued in all of our patients. Not only the medical consequence of overuse of pharmacological prophylaxis (such as development of serious adverse reaction (e.g. thrombocytopenia and bleeding)) is dramatic, but also from the economic standpoint, overuse of drugs will be increased total cost for both patients and health systems. Although many studies reported under usage of VTE prophylaxis in medical wards compared to surgical wards²⁷; but further analysis of our data on risk factors, shows overuse of pharmacological prophylaxis in low-risk patients. These results may reflect a low level of perception of the risk of VTE among some hospital physicians, combined with a lack of awareness about the other modes of prophylaxis.

Despite of active bleeding (gross hematuria), pharmacological prophylaxis continued in four patients in our study. The ACCP guideline recommends mechanical prophylaxis in case of active bleeding. This data also reflect malpractice or misconception among our physicians.

Age > 40 years, chronic and serious lung disease, immobilization, and cancer were among the most common documented risk factors in our study. We couldn't collect exact patient weight. Therefore, obesity was under presented as a risk factor in the study. Also, prior VTE is another most commonly

missed risk factor in our study because of lack of previous medical reports.

Further research that would include surgical, pediatric and maternity patients at Alzahra hospital would broaden our understanding of VTE prophylaxis at this hospital.

Our study highlights the need for strategies that improve VTE prophylaxis. Increasing physician's awareness through training and the implementation of procedures to assess VTE risk during hospitalization, along with the application of evidence-based guidelines for VTE prophylaxis and treatment, are meant to improve VTE prophylaxis coverage. Using of risk assessment scoring systems, adherence to VTE prophylaxis in high-risk patients, the use of mechanical prophylaxis in patients with contraindications to pharmacological prophylaxis and in low-risk patients are major area of practice that requiring improvement.

It should be noted that there is no local guideline for the prevention and treatment of VTE in Iran. Considering that VTE is a serious clinical situation that may lead to patient death, VTE is usually asymptomatic and VTE prevention is more cost-effective than treatment, we do recommend the development of a national guideline and the assessment of VTE risk for all hospitalized patients at admission and during hospitalization. Also for selection of VTE prevention, socioeconomic situation of our country should be taking into consideration.

CONCLUSION: The results of our study reveal that VTE prophylaxis is not properly addressed in medical inpatients in our hospital. We have overuse of pharmacological prophylaxis (especially in low-risk patients) which leads to substantial economic burden on the health care system. Other means of VTE prevention, such as mechanical prophylaxis are under used in our setting. There is room for development of a local guideline or at least implement of international evidenced-based guideline throughout the hospital to reduce variability in daily practice decision making. Appropriate corrective measures to improve prophylaxis of VTE may be continuing medical

education with discussion and consensus with physicians, dissemination of guidelines with relevant information and regular clinical audit as feedback on prescribing patterns for groups of physicians.

There is no conflict of interest to declare.

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