

Occurrence of Venous Thromboembolism and Outcomes of Preventive Protocols at the Bangkok Hospital Medical Center: a Retrospective Review of Years 2012-2013



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OBJECTIVE: To determine the occurrence of venous thromboembolism (VTE) of patients at the Bangkok Hospital Medical Center (BMC). To collect data of VTE patients at the BMC about their characteristics, underlying diseases, presenting symptoms and outcomes of diseases. Evaluate the outcome of preventive methods of VTE when using the BMC protocol.

MATERIALS AND METHODS: The retrospective review was conducted from January 1, 2012 to December 31, 2013. The total number of patients diagnosed with VTE is 190 patients. The patients were divided into two groups; in the first group were patients who had been diagnosed in the year 2012, and were not using the preventive protocol, and the second group, were patients who had been diagnosed in the year 2013, and were using the preventive protocol. In both groups, data was collected about their characteristics, underlying diseases, presenting symptoms, and outcomes. Then we further divided patients from both groups into two categories by using BMC protocol criteria; high thrombosis risk and low thrombosis risk. Following this categorisation, we used the Statistical Package for the Social Sciences (SPSS) program to analyze the data collected. We compared populations across both years to verify if there was any difference in any aspect of the baseline characteristics. We evaluated the outcomes of patients who did not develop VTE as a result of using the preventive protocol by comparing high thrombosis risk patients to low thrombosis risk patients across both years to verify if there were any differences in the number of patients who did not receive the protocol (2012), and patients who received the protocol (2013).

RESULTS: There were 190 patients with VTE, 104 patients in 2012 (54.73%) and 86 patients in 2013 (45.27%). Their mean age was 63.52 ± 17.70 years. Ninety two patients (48.42%) are Thai nationals, while 98 patients (52.58%) are non-Thai nationals. There were 76 inpatient department (IPD) patients (40%) and 114 outpatient department (OPD) patients (60%). In IPD patients, there were 71 patients with a high thrombosis risk, 39 patients (37.50%) in 2012 and 32 patients (37.21%) in 2013. There are two statistically significant differences in the populations between both years, first the mean thrombosis risk score (which in 2013 had a higher thrombosis risk score (4.94 vs. 5.86)) and second, the number of patients that died from VTE (with more deaths occurring in year 2012 (10 vs. 1)). Patients who have a high thrombosis risk score in 2012 represent 37.50% of cases, and in 2013 these patients represented 37.21% of cases. The odd ratio (OR) is 1.013 (0.561 - 1.828), relative risk is 1.008 (0.696 - 1.459), relative risk reduction is 0.77 and numbers needed to treat (NNT) is 344.82.

CONCLUSION: From our study we showed a reduction of risk in a number of high thrombosis risk VTE patients when using the risk assessment protocol of BMC with the number need to treat of 344.82. Although it is not statistically significant, due to the limitations of the study, we have seen a trend towards using the protocol to decrease the number of high thrombosis risk VTE patients.

The incidence of venous thromboembolism (VTE, i.e., deep venous thrombosis (DVT) and/or pulmonary embolism (PE)) is now increasing in Thailand because of the recognition of the disease's burden and greater accessibility to diagnostic tools even in rural areas. The delay in the diagnosis of diseases will bring about many complications, such as post-thrombotic syndrome, and that means more morbidities and mortalities. There is literature to indicate that the incidence of VTE in Thailand or Asian countries is no less than in Western countries.¹⁻⁸ Many studies on VTE in multiple countries (including Asian populations) have shown that the benefits of VTE prevention far outweigh the treatment of diseases in every aspect, e.g. less suffering and premature mortality, more quality of life and fewer costs overall.⁹⁻¹³ VTE will occur more often if patients already have risk factors, both modifiable and unmodifiable. According to guidelines from National Institute for Health and Clinical Excellence (NICE) if patients, either medical or surgical, have at least one risk factor or have significant reduction in mobility they are considered to be at an increased risk of VTE and they require further evaluation of risk of bleeding before they are administered preventive interventions. If the patient has at least one risk factor for bleeding, NICE guidelines suggest not giving any pharmacological prophylaxis, unless the risk of VTE outweighs risk of bleeding.¹³

At the Bangkok Medical Hospital Center (BMC) we adapted the NICE guidelines to make a protocol (Appendix 1) to assess the risk of thrombosis and risk of bleeding in our patients, and to guide the prophylaxis interventions. We already knew that some patients are at high risk for VTE without any additional risk factor such as cancer patients, critically ill patients in the Intensive Care Unit (ICU), known cases of thrombophilia and post-operative orthopedic surgery patients, so we used this protocol first in this group of patients, starting from 1 Jan 2013.

Material and Methods

The study was a retrospective study; we collected data from January 1, 2012 to December 31, 2013 by electronic medical records. The populations are the patients who were admitted to the cancer unit, ICU or orthopedic unit which are the units that apply the VTE risk assessment protocol. Both medical and surgical patients were included. In these groups we selected the patients who met all of our inclusion criteria, those who had been diagnosed with VTE at the BMC, who were 15 years

old or older, and have official radiologist reports diagnosis of VTE. Our exclusion criteria are patients aged below 15 years old or with no official radiologist reports.

Once the exclusion criteria were applied, the remaining patients were divided into 2 groups. The first group of patients attended BMC in 2012 and the second group attended in 2013. We applied the protocol only to patients who were hospitalized; therefore we selected IPD patients only. We categorized IPD patients into either high or low thrombosis risk groups using the risk assessment screening for the BMC VTE protocol. We define high thrombosis risk as patients with a thrombosis score ≥ 4 (in medical patients) or score ≥ 3 (in surgical patients). We then used the SPSS program for data analysis. We compared populations from both years to see if there were any differences in baseline characteristics. We evaluated the outcomes when using the preventive protocol by comparing high thrombosis risk patients to low thrombosis risk patients from each year to see if there were any differences in the number of patients before applying the protocol, (in 2012), and after applying the protocol, (in 2013). Then we calculated the odd ratio, relative risk, relative risk reduction and the number needed to treat (NNT).

Results

The total population hospitalized in the cancer unit, ICU or orthopedic unit is 50,027 patients, of whom 26,036 were patients in 2012 and 23,991 were patients in 2013. There were 225 patients with VTE (in 2012 $n = 125$ (55.56%) and in 2013 $n = 100$ (44.46%)). Of these patients, 25 patients were excluded (10 patients with no official radiologist reports and 15 patients with missing demographic and clinical data). Of the remaining total of 190 patients, 104 patients were seen in 2012 (54.73%) and 86 patients were seen in 2013 (45.27%). Of these 190 patients, 95 were men and 95 were women. Their mean age was 63.52 ± 17.70 years. Ninety two patients (48.42%) are Thai nationals, while 98 patients (52.58%) are non-Thai nationals. The top three nationalities are British (13 patients), Qatar (11 patients) and Kuwait (11 patients). Details are shown in Figure 1. There were 76 IPD patients (40%) and 114 OPD patients (60%). Of the IPD patients, 71 patients (93.42%) have high thrombosis risk, 39 patients (37.50%) in 2012 and 32 patients (37.21%) in 2013. A summary of patients' characteristics are shown below in Table 1.

One hundred and fifty patients (78.95%) have underlying diseases. The most common underlying disease that increases the risk of VTE is cancer, found in 56 patients (29.47%). Of these, 19 patients (33.99%) have advanced stage cancer with metastasis. The primary cancers are lung cancer (9 patients (16.07%)), breast cancer (6 patients (10.71%)), colon cancer (6 patient (10.71%)), and rectal cancer (5 patients (8.93%)). Details of primary cancer sites are shown below in Figure 2.

Table 1: Summary of clinical characteristics of enrolled patients (n=190).

Characteristic	n (%)
Patient	190 (100)
Male	95 (50)
Female	95 (50)
Age Mean	63.52 ± 17.7
Nationality	
Thai	92 (48.42)
Foreigner	98 (52.58)
Service	
outpatient department (OPD)	114 (60.00)
inpatient department (IPD)	76 (40.00)
Diagnosis	
Deep venous thrombosis (DVT)	142 (74.74)
Pulmonary embolism (PE)	12 (6.32)
DVT and PE	36 (18.94)
Presenting symptom	
Leg swelling	147 (77.37)
Dyspnea	28 (14.74)
Leg swelling and dyspnea	10 (5.26)
Asymptomatic	3 (1.58)
Arm swelling	2 (1.05)

Other underlying conditions that increase the risk of VTE are stroke (after more than 1 month) 18 patients (9.47%), of whom 13 have been immobilized (72.22%). For each of the following diseases, protein C deficiency and protein S deficiency, there are 6 patients with deficiency (3.16%), 3 patients with antithrombin III deficiency (1.58%) and 1 patient with hyperhomo-cysteinemia (0.53%). A summary of details about underlying diseases is listed below in Table 2.

Their most common presenting symptoms are leg swelling (147 patients, 77.37%). The other symptoms are dyspnea (28 patients, 14.74%), leg swelling with dyspnea (10 patients, 5.26%) and arm swelling (2 patients, 1.05%). There are 3 asymptomatic patients (1.58%) with problems resulting from their cancer, and VTE was revealed in the imaging to define the cancer stage. There were 11 patients (5.79%) who died during our study, and every one of these patients had cancer as comorbidity. The causes of death are cancer (6 patients), massive pulmonary embolism (4 patients) and septic shock (1 patient). In 2012, 10 patients (9.61%) died and in 2013, 1 patient (1.16%) died. All of the deceased patients had a high thrombosis risk score. The VTE sites in our study include superficial femoral vein (115 patients (60.52%)), popliteal vein (99 patients (52.11%)), posterior tibial vein (75 patients (39.47%)), common femoral vein (73 patients (38.42%)), external iliac vein (38 patients (20.00%)), peroneal vein (35 patients

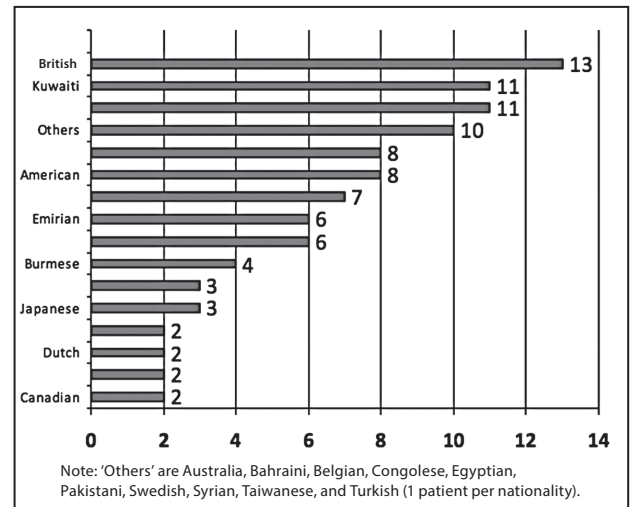


Figure 1: Nationalities of non-Thai population

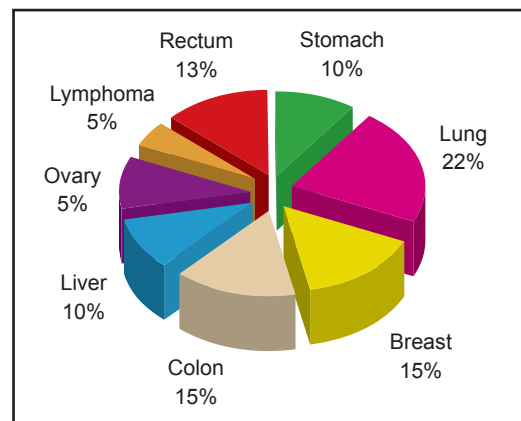


Figure 2: Primary cancer location

(18.42%)) and subclavian vein (2 patients (1.05%)). Of the 2 patients with subclavian vein thrombosis, 1 patient has breast cancer, the other is a Kuwaiti female who has been taking oral contraceptive pills for a long time (> 5 years) without any other risk for thrombosis. The data on thrombosis sites are shown below in Figure 3.

For the statistical SPSS analysis, we used the independent t-test analysis and chi-square to find differences in characteristics between both years. The results found that there are two statistically significant differences in the populations between both years. The first is the mean thrombosis risk score, and the mean difference is -0.918 (-1.589 - -0.248, $p = 0.008$), (mean in 2013 > mean in 2012), the median score in 2012 is 5 and in 2013 it is 6. The second is the number of deceased patients, with more in 2012 than in 2013 ($p = 0.013$). The other non-significant values and summary details are listed below in Table 3. Patients who have a high thrombosis risk score in 2012 are 37.50% and in 2013 are 37.21%. The odd ratio is 1.013 (0.561 - 1.828), the relative risk is 1.008 (0.696 - 1.459), the relative risk reduction is 0.77 and number needed to treat is 344.82.

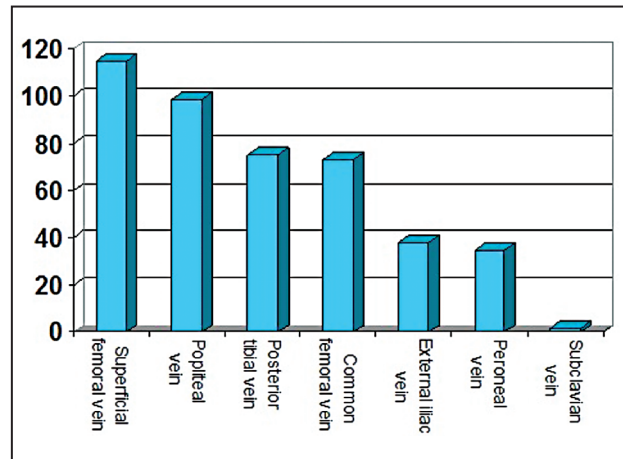
Table 2: Underlying diseases of enrolled patients.

Underlying diseases	n (%)
Hypertension	75 (39.47)
Cancer	56 (29.47)
Diabetes mellitus (DM)	35 (18.42)
Dyslipidemia	21 (11.05)
Stroke (> 1 month)	18 (9.47)
Old myocardial infarction	13 (6.84)
Atrial fibrillation	13 (6.84)
Asthma/COPD	12 (6.32)
Chronic kidney disease	10 (5.26)
Protein C deficiency	6 (3.16)
Protein S deficiency	6 (3.16)
Peripheral arterial disease	5 (2.63)
Varicose vein	4 (2.11)
Liver cirrhosis	3 (1.58)
Antithrombin III deficiency	3 (1.58)
Systolic heart failure	2 (1.05)
Polycythemia vera	1 (0.53)
Essential thrombocytosis	1 (0.53)
Hyperhomocysteinemia	1 (0.53)
Autoimmune hemolytic anemia	1 (0.53)
Chronic hepatitis C infection	1 (0.53)
Spinal cord injury	1 (0.53)
Hypertrophic cardiomyopathy	1 (0.53)

Table 3: Clinical characteristics compared between 2012 and 2013.

Characteristics	Year 2012 n (%)	Year 2013 n (%)	P
Patient (n)	104 (54.73)	86 (45.27)	
Sex			
Male	55 (52.88)	40 (46.51)	0.382
Female	49 (47.12)	46 (53.49)	
Mean age	62.83	64.35	0.557
Nationality			
Thai	48 (46.15)	44 (51.16)	0.492
Non-Thai	56 (53.85)	42 (48.84)	
Service			
OPD	63 (60.58)	51 (59.30)	0.858
IPD	41 (39.42)	35 (40.70)	
Diagnosis			
DVT	72 (69.23)	70 (81.40)	0.126
PE	9 (8.65)	3 (3.48)	
DVT and PE	23 (22.12)	13 (15.12)	
IPD			
High thrombosis risk	39 (37.50)	32 (37.21)	0.967
Low thrombosis risk	65 (62.50)	54 (62.79)	
Mean thrombosis risk score	4.94	5.86	0.008*
Mean bleeding risk score	3.79	3.82	0.941
Number of dead patients	10 (9.62)	1 (1.16)	0.013*

* = significant

**Figure 3:** Site of thrombosis

Discussion

According to the Agency for Health Care Research and Quality, the prevention of VTE is the number one strategy to improve patients' safety in hospitals.²² There is strong evidence from multiple randomized trials and analyses of appropriately employed prophylaxis of VTE that show it is cost effective and has a desirable benefit-to-risk ratio. In Thailand, however, due to many reasons, the VTE prevention strategy is not applied consistently or regularly. Our study of 190 VTE patients showed a trend in reducing the occurrence of VTE in patients, especially in high risk patients; although it's not statistically significant due to many limitations.

In our study the rate of occurrence of VTE was the same across men and women. With regards to nationality we found the rate of occurrence in Thai nationals is roughly the same as in non-Thai nationals. This concurs with the findings of previous studies that the incidence of VTE in Thailand is no less than in Western countries.¹⁻⁸ We used data, however, from a population with VTE, and not from a normal population, so we need to keep in mind that our findings are not necessarily a true rate occurrence of VTE across both Thai and non-Thai nationals. So this data shows that there is a tendency towards an incidence of VTE in Thai nationals that is not low after all, contrary to the old understanding we previously held.

About 60% of patients received OPD services, and the most common presenting symptom was leg swelling (78.5%). There are 3 patients (1.58%) with no symptoms but who do have radiological evidence of VTE. These asymptomatic patients (all cancer patients) incidentally found evidence of VTE from an examination to determine the staging of the cancer with computer tomography (CT). These symptomatic patients were treated for the incidental VTE with a standard treatment if there is no contraindication. Compared to the previous study¹ that found asymptomatic VTE to be about 80%, our study has less asymptomatic patients. This is due to differences in population characteristics, study methods and diagnostic tools for diagnosis.

Hypertension is the underlying disease we found most often in our populations, cancer being the second. We know, however, that hypertension, diabetes mellitus, and dyslipidemia all increase the risk for VTE a little, about 1.1-1.3 times¹⁴⁻¹⁷, so if we look into disease that significantly increases the risk of VTE the first is cancer, which increases the risk 2-3 times.¹⁸⁻²⁰ The most common primary site of cancer is the lung, followed by breast and colon, and 33.99% of cancer patients have advanced stage cancer. A review of previous literature shows that advanced cancer increases the risk of VTE more than early stage cancer.¹⁸ The second most common significant disease that increases the risk of VTE is stroke (after more than 1 month) that confines about 72% of patients to bed. This correlates to previous analysis²¹ that found VTE more often in paralyzed limbs of stroke patients compared to non-paralyzed limbs (60% and 7%). Inherited cases of thrombophilia in our study included antithrombin III deficiency, protein C deficiency, and protein S deficiency (15 cases (7.89%)). This is found in Thai (4 cases), French (1 case), American (3 cases), Swedish (1 case), Bangladesh (3 cases), Kuwaiti (2 cases), and Bahraini (1 case) patients. It can be inferred that most causes of VTE in Thai nationals are acquired, and not so many cases are due to inherited causes. Therefore, the key to preventing VTE is to reduce modifiable risks as much as possible.

From the analysis, we compared the number of high risk thrombosis patients in 2012 to patients in 2013 and we found the odd ratio for high thrombosis risk patients to low thrombosis risk patients is 1.013 and the relative risk is 1.008 with no statistical significance. But from the comparative characteristics data, between both years we found that patients seen in 2013 have a higher mean thrombosis risk score than patients seen in 2012 with statistical significance ($p < 0.05$). It's reflected that although patients in 2013 have a higher mean thrombosis risk score for VTE the occurrence is still lower in 2013. This is interesting data, as we infer that the protocol probably can reduce the number of VTE patients who have a high risk of thrombosis.

There are five limitations to our study. First, our study populations are patients who already have VTE, and are

not drawn from the normal population, so there are some limitations to applying our data to real life practices. Second, the number of patients who have VTE is very low compared to the overall population, so when we use statistical analysis it hardly makes the results significant. We think the reason for this is that most patients are not yet aware of VTE, because most symptoms are not painful. Some patients may feel that VTE is not the main issue when they compare this to their underlying disease (for those who already have one, e.g. cancer.) The other reason may come from a lack of awareness of VTE in physicians because most of them just pay attention to the main diseases their patients have. Third, some patients were hospitalized first in other hospitals with no VTE prevention protocols. Then the patients are referred to BMC when their condition gets worse. Prevention in these cases may be too late, because patients may already have had VTE without symptoms and when the main diseases progress more, the symptoms of VTE appeared later. Fourth, this is a retrospective study; there were no randomization in the population and it cannot have a control confounding factor. Due to ethical considerations, it is not right to randomize patients to either use or not use preventive methods because there are many guidelines that recommend VTE prophylaxis in high risk patients.^{13, 23-28} Fifth, the evidence of VTE using doppler ultrasound has its own limitations, such as in cases of major soft tissue swelling.

Conclusion



These days VTE is a disease that is occurring more frequently than in the past, due in part because today we are more aware of diseases and the technology for diagnosis is more easily accessible. VTE prevention has many benefits, and it is preferable to prevent the disease altogether than cure the disease after it occurs. From our study, we showed a relative reduction in VTE 0.77 when using risk assessment protocol and number needed to treat is 344.82. Although this number may not be statistically significant, due to our study's limitations, nonetheless we saw a trend towards a drop in the number of high thrombosis risk VTE patients when the prevention protocol was applied.

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Appendix 1: Risk assessment for VTE and Flow chart

 <p>ศูนย์การแพทย์โรงพยาบาลกรุงเทพ BANGKOK HOSPITAL MEDICAL CENTER</p>	Name: _____ HN: _____ Visit Date: _____ Birth Date: _____ Allergies (แพ้ยา) : _____	Room: _____ Physician: _____ Department: _____ Age: _____ Sex: _____	
Risk Assessment for Venous Thromboembolism (VTE)		I01-14-011422 Page : [A1]	
Patient screening: <input type="checkbox"/> Surgical patient <input type="checkbox"/> Medical patient			
1. Thrombosis Risk Assessment (Circle on the score of only applicable risk factor)			
Risk Factors	Score	Risk Factors	Score
Patient Related Risk Factors			
Age ≥ 75 years	3	Familial history of thrombosis	3
Age 61 - 74 years	2	History of DVT/ Pulmonary embolism	3
Age 41 - 60 years	1	Known thrombophilia (such as Factor V (Leiden), Prothrombin 20210A, protein C deficiency, protein S deficiency, antithrombin deficiency, antiphospholipid syndrome)	3
Obesity (BMI > 25 kg/m ²)	1	Malignancy (present or previous)	2
Stroke (< 1 month)	4	History of inflammatory bowel disease	1
Acute spinal cord injury (< 1 month)	4	Pregnancy or postpartum (< 1 month)	1
Hip, pelvis or leg fracture (< 1 month)	4	History of unexplained or recurrent spontaneous abortion	1
Multiple trauma (< 1 month)	4	Oral contraceptives or hormone replacement therapy	1
Immobilizing plaster cast (< 1 months)	2	Acute myocardial infarction	1
History of prior major surgery (< 1 month)	1	Congestive heart failure (< 1 month)	1
Sepsis (< 1 month)	1	Central venous access	2
Serious lung disease including pneumonia (< 1 month)	1	Varicose veins	1
Abnormal pulmonary function e.g. COPD	1	Swollen leg (current)	1
Patient Related Risk Factors			
Elective major lower extremity arthroplasty (such as hip or knee replacement)	4	Minor surgery planned	1
Arthroscopic surgery	2	Patient confined to bed (≥ 72 hours)	2
Major surgery (> 45 minutes)	2	Medical patient currently at bed rest	1
Laparoscopic surgery (> 45 minutes)	2	Total Thrombosis Risk Factor Score	
Thrombosis risk assessment: <input type="checkbox"/> High risk (Score ≥ 3, in Surgical Patient or Score ≥ 4, in Medical Patient) <input type="checkbox"/> Low risk (Score < 3, in Surgical Patient or Score < 4, in Medical Patient) [Skip 2. Bleeding Risk Assessment to Plan of the management for thromboprophylaxis]			
Screening by _____ RN Date _____ Time _____ hr.			
2. Bleeding Risk Assessment (Circle on the score of only applicable risk factor)			
Risk Factors	Score	Risk Factors	Score
Patient Related Risk Factors			
Active gastroduodenal ulcer	4.5	Severe renal failure (GFR < 30 ml/min)	2.5
Bleeding in 3 months before admission	4	Moderate renal failure (GFR 30 - 59 ml/min)	1
Platelet count < 50x10 ⁹ cells/L	4	Current cancer	2
Age ≥ 85 years	3.5	Central venous catheter	2
Age 40 - 84 years	1.5	Rheumatic diseases	2
Hepatic failure (INR > 1.5)	2.5	Male	1
ICU or critical care unit admission	2.5	Total Bleeding Risk Score	
Bleeding risk assessment: <input type="checkbox"/> Score ≥ 7; High risk of bleeding (Mechanical thromboprophylaxis is indicated) <input type="checkbox"/> Score < 7			
3. Plan of the management for thromboprophylaxis: <input type="checkbox"/> No thromboprophylaxis <input type="checkbox"/> Pharmacological thromboprophylaxis (please order in the order sheet) <input type="checkbox"/> Mechanical thromboprophylaxis (please order in the order sheet) <input type="checkbox"/> Both pharmacological and mechanical thromboprophylaxis (please order in the order sheet) <input type="checkbox"/> Consult: <input type="radio"/> Hematologist <input type="radio"/> Cardiologist <input type="radio"/> Neurologist <input type="radio"/> Nephrologist <input type="checkbox"/> Other (if any) _____ Comment: _____ _____ _____			
Physician Signature _____ Medical License No. _____ Date _____ Time _____ hr. ()			

Appendix 2: Flow Chart

