
Thrombosis Risk Assessment as a Guide to Quality Patient Care

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Background

Venous thromboembolism (VTE) is a serious complication that is frequently encountered in medical and surgical practice. Approximately 2 million people each year will suffer from a deep vein thrombosis (DVT), and approximately 600,000 of these individuals will suffer a pulmonary embolism (PE), which is fatal in about 200,000 patients annually.¹ Pulmonary hypertension can be expected to develop in approximately 30,000 patients who survive their PE. The postthrombotic syndrome (PTS) will be seen in approximately 800,000 patients annually in the United States; 7% of these individuals will have a severe form of the problem and become permanently disabled.² One of the most troubling statistics is the fact that 50% of the 2 million cases of DVT yearly are “silent.” Occasionally, the first sign or symptom of the disease is a fatal PE.³ Furthermore, it has been estimated that approximately 1 of 20 hospitalized medical patients will suffer a fatal PE if they have not received appropriate thrombosis prophylaxis.⁴

Another serious complication of DVT is nonhemorrhagic stroke that may occur in a patient with a patent foramen ovale.⁵ A clot in the deep venous system of the leg can break off and travel to the right atrium, dilating that heart chamber. If the patient is one of the 25 or 30% who have a nonfunctioning patent foramen ovale, this atrial dilatation can open the patent foramen and allow the clot to enter the left side of the heart and proceed to the brain, producing a stroke.⁶ The diagnosis of this problem is difficult because once the right atrium returns to normal size, the patent foramen ovale may be difficult to detect. Often when the clot breaks off from the leg, it does so cleanly without residual damage that can be detected on subsequent duplex examination.⁶

Table 1 shows some of the commonly seen problems that at first glance

TABLE 1. Common manifestations of venous thromboembolism including required investigations to uncover all instances of the disease

| |
|----------------------------------------------------------------------|
| Leg pain |
| Leg tenderness |
| Leg swelling |
| Chest pain |
| Shortness of breath |
| Transient or orthostatic hypotension |
| Transient hypoxemia |
| Unexplained decrease in level of consciousness |
| Suspected narcotic excess |
| Suspected postoperative myocardial infarction |
| Postoperative nonhemorrhagic stroke |
| Postoperative pneumonia |
| Unexplained sudden death |
| Unexplained cardiovascular collapse |
| Postoperative death without autopsy |
| 90-day follow-up for death, readmission, outpatient treatment of VTE |
| 5-year follow-up looking for signs of the postthrombotic syndrome |

may not seem to be associated with a DVT. We recommend keeping a high level of suspicion for patients who exhibit these clinical manifestations. Not all of these problems will result in a fatal or serious outcome. They may predispose the patient to later develop the postthrombotic syndrome or have a higher incidence of DVT if they have a subsequent operative procedure.

The problem of long-term follow-up of patients is not easy to solve and many DVT events occur several weeks or longer after discharge. Readmissions, deaths, and outpatient treatment of DVT using low molecular weight heparin (LMWH) may be very difficult data for the surgeon to obtain. The average busy clinician may not associate a stroke or a variety of other postoperative symptoms as being caused by a postoperative DVT. It is no wonder that many feel that VTE is not a problem in their clinical practice.

Risk Assessment

The process of providing appropriate thrombosis prophylaxis to medical and surgical patients is a complex issue because many times the administration of powerful anticoagulants may carry the risk of side effects, most notably bleeding. The seventh American College of Chest Physicians' Consensus on antithrombotic and thrombolytic therapy has recently published a thorough evaluation of the literature that has been translated into evidence-based guidelines for thrombosis prophylaxis and

TABLE 2. Prophylaxis regimen

| Total Risk Factor Score | Incidence of DVT | Risk Level | Prophylaxis Regimen |
|--------------------------------|-------------------------|-------------------|--------------------------------------------------------------------------------------------|
| 0–1 | <10% | Low | No specific measures; early ambulation |
| 2 | 10–20% | Moderate | ES or IPC or LDUH, or LMWH |
| 3–4 | 20–40% | High | IPC or LDUH, or LMWH alone or in combination with ES or IPC |
| 5 or more | 40–80% 1–5% mortality | Highest | Pharmacological: LDUH, LMWH,* Warfarin,* or Fac Xa* alone or in combination with ES or IPC |

Based on Geerts WH, Pineo GF, Heit JA, et al: Prevention of venous thromboembolism. *Chest* 2001; 119:132S–75S; Nicolaides AN, Breddin HK, Fareed J, et al: 2001 International consensus statement: prevention of venous thromboembolism guidelines according to scientific evidence; Caprini JA, Arcelus JI, et al: State-of-the-art venous thromboembolism prophylaxis. *Scope* 2001;8:228–240; Oger E: incidence of venous thromboembolism: a community-based study in western France. *Thromb Haemost* 2000; 657–660. Turpie AG, Bauer KA, Eriksson BI, et al: Fondaparinux vs. enoxaparin for the prevention of venous thromboembolism in major orthopedic surgery: a meta-analysis of 4 randomized double-blind studies. *Arch Intern Med* 2002;162(16):1833–40. ES, elastic stockings; IPC, intermittent pneumatic compression; LDUH, low-dose unfractionated heparin; LMWH, low molecular weight heparin; Fac Xa, Factor X Inhibitor.

treatment.¹ It is an excellent compilation of relevant medical literature as interpreted by some of the foremost authorities in the field. This document endorses the concept of thrombosis risk assessment, although they point out that individual formal risk assessment models have not been adequately validated, are cumbersome, and are infrequently used by the physician. They recommend a simplification of the process by assigning patients to one of four VTE risk levels based on type of operation, age, and the presence of additional risk factors (Table 2). Some of us feel that this approach leaves certain gaps in the implementation of prophylaxis and calculation of degree of risk. In certain cases the number of risk factors is so great that the patient's decision to have a quality-of-life procedure may be affected.⁷ We feel that all possible risk factors need to be queried to identify the extent of risk for each individual patient. Thrombosis prophylaxis then needs to be individualized on the basis of the results of this analysis. If one misses any of these factors, the patient's thrombosis risk may not be properly estimated. In those with a double-digit point score, the risk may be extremely high and, although this has not been subjected to rigorous clinical trial to determine the degree of increased risk, still needs to be considered. Some patients may want to forgo elective quality-of-life procedures when the point score indicates an extremely high chance of VTE.

Thrombosis Risk Factor Assessment

Patient's Name: _____ Age: ____ Sex: ____ Wgt: ____ lbs

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Choose All That Apply

Each Risk Factor Represents 1 Point

- Age 41-60 years
- Minor surgery planned
- History of prior major surgery (< 1 month)
- Varicose veins
- History of inflammatory bowel disease
- Swollen legs (current)
- Obesity (BMI > 25)
- Acute myocardial infarction
- Congestive heart failure (< 1 month)
- Sepsis (< 1 month)
- Serious lung disease incl. pneumonia (< 1 month)
- Abnormal pulmonary function (COPD)
- Medical patient currently at bed rest
- Other risk factors _____

Each Risk Factor Represents 3 Points

- Age over 75 years
- History of DVT/PE
- Family history of thrombosis***
- Positive Factor V Leiden
- Positive Prothrombin 20210A
- Elevated serum homocysteine
- Positive lupus anticoagulant
- Elevated anticardiolipin antibodies
- Heparin-induced thrombocytopenia (HIT)
- Other congenital or acquired thrombophilia

If yes:
Type _____
*most frequently missed risk factor

Each Risk Factor Represents 2 Points

- Age 60-74 years
- Arthroscopic surgery
- Malignancy (present or previous)
- Major surgery (> 45 minutes)
- Laparoscopic surgery (> 45 minutes)
- Patient confined to bed (> 72 hours)
- Immobilizing plaster cast (< 1 month)
- Central venous access

Each Risk Factor Represents 5 Points

- Elective major lower extremity arthroplasty
- Hip, pelvis or leg fracture (< 1 month)
- Stroke (< 1 month)
- Multiple trauma (< 1 month)
- Acute spinal cord injury (paralysis)(< 1 month)

For Women Only (Each Represents 1 Point)

- Oral contraceptives or hormone replacement therapy
- Pregnancy or postpartum (< 1 month)
- History of unexplained stillborn infant, recurrent spontaneous abortion (≥ 3), premature birth with toxemia or growth-restricted infant

Total Risk Factor Score

Interpretation of Risk Assessment Guidelines

Our group has been performing detailed individual risk assessment on medical and surgical patients since the late 1980s.⁸ The latest version of this model is seen in Table 3. We use a hybrid approach which begins with evidence-based guidelines and consensus statements, combined with logic, emotion, and the experience of the interviewer. This approach was selected because it is the approach used by physicians when dealing with patients and their illnesses. If there is no available level 1 data or if the patient's circumstances would have resulted in them being excluded from

Prophylaxis Regimen

| Total Risk Factor Score | Incidence of DVT | Risk Level | Prophylaxis Regimen | Legend |
|-------------------------|--------------------------|---------------|--------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 0-1 | <10% | Low Risk | No specific measures; early ambulation | ES - Elastic Stockings IPC - Intermittent Pneumatic Compression LDUH - Low Dose Unfractionated Heparin LMWH - Low Molecular Weight Heparin Fac Xa - Factor X Inhibitor |
| 2 | 10-20% | Moderate Risk | ES or IPC or LDUH, or LMWH | |
| 3-4 | 20-40% | High Risk | IPC or LDUH, or LMWH alone or in combination with ES or IPC | |
| 5 or more | 40-80% 1-5% mortality | Highest Risk | Pharmacological: LDUH, LMWH*, Warfarin*, or Fac Xa* alone or in combination with ES or IPC | |

Prophylaxis Safety Considerations: Check box if answer is 'YES'

| Anticoagulants: Factors Associated with Increased Bleeding |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <input type="checkbox"/> Is patient experiencing any active bleeding? |
| <input type="checkbox"/> Does patient have (or has had history of) heparin-induced thrombocytopenia? |
| <input type="checkbox"/> Is patient's platelet count <100,000/mm ³ ? |
| <input type="checkbox"/> Is patient taking oral anticoagulants, platelet inhibitors (e.g. NSAIDS, Clopidigrel, Salicylates)? |
| <input type="checkbox"/> Is patient's creatinine clearance abnormal? If yes, please indicate value _____ |
| If any of the above boxes are checked, the patient may not be a candidate for anticoagulant therapy and should consider alternative prophylactic measures. |
| Intermittent Pneumatic Compression (IPC) |
| <input type="checkbox"/> Does patient have severe peripheral arterial disease? |
| <input type="checkbox"/> Does patient have congestive heart failure? |
| <input type="checkbox"/> Does patient have an acute superficial/deep vein thrombosis? |
| If any of the above boxes are checked, then patient may not be a candidate for intermittent compression therapy and should consider alternative prophylactic measures. |

Based on: Geerts WH et al: Prevention of Venous Thromboembolism. Chest 2001; 119:132S-175S; Nicolaidis AN et al: 2001 International Consensus Statement: Prevention of Venous Thromboembolism. Guidelines According to Scientific Evidence; Caprini JA, Arcelus JI et al: State-of-the-Art Venous Thromboembolism Prophylaxis. Scope 2001; 8: 22S-24J, and Oger E: Incidence of Venous Thromboembolism: A Community-based Study in Western France. Thromb Haemost 2000; 857-869; Turpie AG, Bauer KA, Eriksson BI, et al: Fondaparinux vs. Enoxaparin for the Prevention of Venous Thromboembolism in Major Orthopedic Surgery: A Meta-analysis of 4 Randomized Double-Blind Studies. Arch Intern Med 2002; 162(16):1833-40; Ringley et al: Evaluation of pulmonary...intermittent pneumatic compression boots in congestive heart failure. American Surgeon 2002; 68(3): 286-9; Morris et al: Effects of supine intermittent compression on arterial inflow to the lower limb. Archives of Surgery 2002. 137(11):1269-73. © 2001 Evanston Northwestern Healthcare, all rights reserved.

Examining Physician's Signature: _____ Date: _____

a randomized trial, they still need to be treated in the best manner possible using a combination of science, logic, emotion, and experience.⁹

Case Study

One practical example of this principle would be a 62-year-old morbidly obese male requiring arthroscopic knee surgery on the left leg. The patient has a past history of venous thrombosis after cholecystectomy 20 years ago, and 4 years ago had successful surgical treatment for

prostate cancer. The point score for this patient using our model is 9 and includes 2 each for surgery, cancer, and age over 60 years, and 3 for past history of DVT.¹⁰ There is no specific trial that would address this clinical situation. If one looks at the Chest Guidelines, thrombosis prophylaxis for outpatient arthroscopic surgery is not recommended unless additional risk factors are present. There are no specific guidelines regarding the intensity or duration of prophylaxis. The Consensus Guidelines are based on clinical trial data and many clinical trials would exclude patients with a past history of venous thrombosis, such as the individual in this example. The question is what this patient's risk is and what prophylaxis, if any, should be used. According to our risk scoring system, the patient's point total is 9 and we know, according to Chest Consensus Guidelines, that patients with more than five risk factors are in the very high-risk group and have a 40 to 80% chance of developing a venous thrombosis with up to 5% mortality.¹

Length of Prophylaxis

Furthermore, we know that abdominal surgery cancer patients, who are also in this very high-risk group, when given 30 days of LMWH, have a statistically significantly lower incidence of thrombosis than when 7 days of prophylaxis are used.¹¹ If one were to apply the Caprini score to the average patient in this trial, the following calculations would be done. We would assign 2 points each for abdominal surgery, cancer, and age over 60 years for a total score of 6. Since our hypothetical arthroscopic surgical patient has a score of 9, we could extrapolate that he should receive at least 30 days of LMWH prophylaxis postoperatively. This regime significantly reduced the incidence of DVT in abdominal surgery patients who had an estimated score of 6 as noted above. The all cause fatality rate in this trial for those receiving 30 days of the drug was 0.3%. Quite an improvement compared to the up to 5% fatal PE death rate in those in the highest risk group not receiving prophylaxis as quoted in the Consensus Guidelines.

Personal or Family History of VTE

One of the most frequently missed risk factors is a past history or family history of VTE. In our practice 56% of patients with a past history of thrombosis were found to have a positive marker for thrombophilia, while 42% of patients with a family history of thrombosis were found to have a positive marker.¹² We feel that a history or family history of VTE in combination with patients having

a major operation is sufficient to classify an individual in the very high-risk group.¹³

Obstetrical History

Another important and frequently overlooked risk factor occurs in women with a past history of an obstetrical complication including a stillborn, miscarriage in any trimester, premature birth with toxemia, or growth-restricted infant. These past events may be the clinical manifestation of a serious thrombophilia defect known as anticardiolipin antibodies, which includes the lupus anticoagulant.¹⁴⁻¹⁹ We also are careful to question patients about a history or family history of stroke, since, in some of these individuals, elevated levels of homocysteine have been found and this is easily treated with vitamin prophylaxis.²⁰⁻²²

Long-Term Prophylaxis

The length of prophylaxis in postoperative patients is important. Except for certain orthopedic and general surgical populations, not many studies have been done to show the benefit of long-term prophylaxis. In the above-mentioned groups we know that statistically significant lowering of the venographic incidence of venous thrombosis has been achieved with 4 to 6 weeks of postoperative prophylaxis using various pharmacologic agents.^{23,24} One thing to keep in mind when deciding about long-term prophylaxis is the mobility of the patient. Seriously ill patients are discharged with fistulas, draining wounds, or intravenous catheters for nutritional support or antibiotic treatment. These individuals spend most of the time in a recliner, which is not early ambulation but rather early angulation.

Efficacy versus Safety

One of the most important considerations regarding the choice of thrombosis prophylaxis is to balance efficacy and safety concerns. Many times clinicians use inadequate prophylaxis because of a concern for bleeding despite the fact that some of these patients are already at enormously high risk. It is natural for a surgeon to consider bleeding to be a surgical problem and thrombosis to be an act of God. We would like to suggest a different philosophy. Depending upon the patient's level of risk, one may require a type or intensity of prophylaxis that may increase their chances of bleeding. These increased risks, however, can be justified by the very high incidence of fatal PE or disabling stroke. We feel it is important to have a preoperative discussion with patients and their families regarding the relative risks and benefits of a particular thrombo-

sis prophylaxis strategy. This should include a realistic evaluation of the risk of serious venous thromboembolic complications. One must also remember that if the patient is at very high risk and thrombosis prophylaxis has to be discontinued in the early postoperative period due to bleeding, the chances of a serious event are magnified. Patients undergoing quality-of-life procedures must weigh the risks and benefits of such procedures if they are in this very high-risk group.

Finally, we feel that a careful individual assessment of thrombosis risk must be done in every patient to minimize the morbidity and mortality of venous thromboembolic events. As a part of this analysis, the length of prophylaxis needs to be determined based on the patient's individual circumstances.

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