Thrombosis in the Emergency Department

Use of a Clinical Diagnosis Model to Safely Avoid the Need for Urgent Radiological Investigation

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Context: The management of patients presenting to hospital emergency departments with suspected deep vein thrombosis (DVT) is problematic because urgent diagnostic imaging capability is sometimes unavailable. Experienced physicians using clinical skills alone can classify patients with suspected DVT into low-, moderate-, and high-probability categories.

Objectives: To determine the accuracy of an explicit clinical model for the diagnosis of DVT when applied by emergency department physicians and to assess the safety and feasibility of a management strategy based on the clinical pretest probability for patients presenting to the emergency department with suspected DVT outside of regular hospital staff work hours.

Methods: A prospective cohort study was performed in the emergency departments of 2 tertiary care institutions involving 344 patients with suspected DVT. Patient conditions were evaluated by an emergency department physician who determined the pretest probability for DVT to be low, moderate, or high using an explicit clinical model. Patients for whom DVT was considered a low pretest probability were discharged from the emergency department and returned the following day for venous compression ultrasound imaging of the affected leg. Patients for whom DVT was considered a moderate pretest probability received a single, weight-adjusted dose of subcutaneous unfractionated heparin sodium (between 12,500 and 20,000 U), were discharged from the emergency department, and returned the next morning to undergo ultrasonography. Patients for whom DVT was considered a high pretest probability were admitted to the hospital, administered intravenous unfractionated heparin, and ultrasonography was arranged within 24 hours. Patients with positive ultrasonographic findings were diagnosed with DVT, except for those with low pretest probability for whom confirmatory venography was performed. Patients with DVT excluded in the initial evaluation period did not receive anticoagulant therapy. All patients were followed up for 90 days to monitor development of thromboembolic or bleeding complications.

Results: Twenty-four (49.0% [95% confidence interval (CI), 34.5%-63.6%]) of 49 patients in the high-probability category, 15 (14.3% [95% CI, 8.3%-22.4%]) of 105 in the moderate-, and 6 (3.2% [95% CI, 1.2%-6.7%]) of 190 in the low-probability category were confirmed to have DVT. Overall, 45 (13.1%) of 344 patients were confirmed to have DVT. No patient developed pulmonary embolism or major bleeding complications within 48 hours of initial evaluation in the emergency department. Of the 301 patients who had DVT excluded during the initial evaluation period, only 2 (0.7% [95% CI, 0.1%-2.3%]) developed venous thromboembolic complications (calf vein thromboses in both) in the 3-month follow-up period.

Conclusions: Using an explicit clinical model, emergency department physicians can accurately classify patients with suspected DVT into high-, moderate-, and low-probability groups. A management plan based on probability for DVT that avoids the need for urgent diagnostic imaging is safe and feasible in the emergency department setting.

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Patients with suspected deep vein thrombosis (DVT) frequently present to hospital emergency departments. Since symptoms and signs of DVT are nonspecific and found in a wide variety of nonthrombotic disorders, timely diagnostic testing must be performed to correctly identify patients with this condition. Compression ultrasound venous imaging is the most accurate noninvasive test for the diagnosis of DVT. Difficult management decisions may arise when patients present to emergency departments with suspected DVT outside of regular hospital work hours because diagnostic imaging capability is usually not immediately available. The emergency department physician is then left with the dilemma of either trying to arrange for urgent imaging.
PATIENTS AND METHODS

A prospective cohort study was performed involving patients presenting with suspected acute DVT to the emergency departments of the QE II Health Sciences Centre, Halifax, Nova Scotia, and the Ottawa Civic Hospital, Ottawa, Ontario, between July 1994 and September 1996. Approval of the Research Review Committees was obtained at both institutions and informed consent was obtained from all participating patients.

PATIENT POPULATION

Patients presenting or referred to the emergency departments outside of regular hospital staff work hours with symptoms of swelling and/or pain in the lower extremity and for whom the emergency department physician could not clinically exclude the presence of acute DVT were potentially eligible for the study. Exclusion criteria were (1) symptoms or signs suggestive of acute pulmonary embolism; (2) previous DVT or pulmonary embolism documented by objective testing; (3) current use of oral anticoagulant therapy; (4) history of bleeding diathesis or other contraindication to the use of anticoagulant therapy; (5) younger than 18 years; (6) pregnancy; (7) life expectancy less than 3 months; (8) geographic inaccessibility to follow-up testing; or (9) refusal to give informed consent.

INTERVENTION

The simplified clinical model used in the study (Table 1) was derived using logistic regression analysis of data collected in a previous study that validated our original clinical criteria for the diagnosis of DVT. The clinical model is a 9-point scale in which 1 point is scored for specific signs and risk factors for DVT and 2 points are deducted if an alternative diagnosis is present that is at least as likely as DVT to account for a patient’s symptoms. For patients with scores of 3 or higher, DVT was considered a high probability; for patients with scores of 1 and 2, DVT was considered a moderate probability, and for those with a score of 0 or less, DVT was considered low probability. Emergency department physicians at both institutions received a 1-hour educational session regarding the application of the clinical model before starting this study.

Eligible patients were evaluated by an emergency department physician who classified pretest probability for DVT into low-, moderate-, and high-probability categories using the clinical model. No diagnostic imaging for DVT was done in the emergency department. Patient management was dependent on the assigned pretest probability for DVT (Figure 1). Patients classified into the low-probability category were discharged from the emergency department without receiving anticoagulant therapy and returned within 24 hours to the radiology department to undergo venous compression ultrasound imaging. If no abnormalities were noted on compression ultrasound, DVT was excluded. However, if patients in the low-probability group had abnormal compression ultrasound results, contrast venography was performed. Patients with abnormal venogram results or those with abnormal results on compression ultrasound in whom venography could not be performed were treated for DVT.

Patients for whom the probability of DVT was moderate received a single, weight-adjusted dose of subcutaneous unfractionated heparin sodium and were discharged from the emergency department with instructions to return within 12 hours to undergo contrast venous ultrasound imaging. The dose of subcutaneous unfractionated heparin sodium was adjusted as follows: (1) patients weighing less than 50 kg received 12 000 U; (2) those weighing 50 to 60 kg, 15 000 U; (3) those from 60 to 80 kg, 17 500 U; and (4) those weighing more than 80 kg, 20 000 U. Patients with abnormal compression ultrasound findings were treated for DVT. Patients with no abnormalities seen on compression ultrasound imaging returned 1 week later for a follow-up ultrasound test. If, again, no abnormalities were seen on compression ultrasound imaging, DVT was excluded. If the follow-up ultrasound results were abnormal, the patient was treated for an acute DVT.

Patients for whom DVT was a high probability were admitted to the hospital to receive treatment with intravenous unfractionated heparin and undergo compression ultrasound imaging within 24 hours. Patients with abnormalities seen on compression ultrasound imaging were continued on heparin therapy, and those with no abnormalities underwent contrast venography testing. If the venogram showed no abnormalities, anticoagulant therapy was discontinued, whereas patients with abnormal venogram results continued heparin therapy.

diagnostic imaging, treating patients for DVT until diagnostic imaging can be performed, or discharging patients. To date, guidelines to assist emergency department physicians in making these difficult decisions are lacking.

We have recently determined that experienced physicians can accurately classify patients with suspected DVT into high-, moderate-, and low-probability categories using explicit clinical criteria. However, these criteria are complex and cumbersome to apply. We reasoned that determination of clinical probability using a simplified clinical model could be used to improve the management of patients presenting to the emergency department with suspected DVT by avoiding the need for immediate diagnostic imaging and restricting the need for hospitalization to patients at high probability for DVT.

The objectives of this study were to determine (1) the accuracy of an explicit clinical model for classifying patients according to pretest probability for DVT when applied by emergency department physicians; and (2) if the application of this clinical model to a patient management strategy that avoided the need for urgent radiographic investigations was safe and feasible for patients with suspected DVT who present to the emergency department outside of regular hospital staff work hours.

STUDY POPULATION

Over the 2-year recruitment period, 447 patients presented to the emergency departments outside of regular hospital staff working hours with suspected DVT. Eighty-seven patients had 1 or more of the exclusion criteria and were ineligible for the study for the following reasons:

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Prior to discharge from the emergency department, all patients were given an information sheet outlining the symptoms of pulmonary embolism and worsening DVT and were asked to return immediately for evaluation if any of these developed. Patients were seen routinely in a follow-up clinic or contacted by telephone 1 week and 3 months after their initial evaluation.

Ultrasound testing was performed using a high-resolution, electronically focused linear array transducer (either 5- or 7.5-MHz probes). The entire proximal deep venous system between the proximal common femoral vein and the trifurcation of the popliteal vein in the calf was evaluated for compressibility at 1-cm intervals. Duplex color Doppler imaging was performed as an adjunct. Ultrasonography results were considered abnormal if a vein or venous segment was not fully compressible. The calf veins were deliberately not examined. Contrast venography was performed using the method of Rabinov and Paulin. Deep vein thrombosis was diagnosed by the presence of a constant intraluminal filling defect present in at least 2 projections.

OUTCOME MEASUREMENTS

A priori, the primary outcome cluster in this study was defined as the development of 1 of the following within 48 hours of evaluation in the emergency department: (1) symptomatic pulmonary embolism confirmed by ventilation perfusion V/Q lung scanning or pulmonary angiography or (2) major bleeding following the institution of anticoagulant therapy for patients who were confirmed not to have DVT. Bleeding complications were classified using previously described criteria.

The secondary outcome was the development of objectively documented proximal DVT or pulmonary embolism in a 3-month follow-up period in patients for whom the diagnosis of DVT was originally considered excluded. Proximal DVT was diagnosed using either ultrasonography or contrast venography as described above. The assessment of patients with suspected DVT or pulmonary embolism was standardized to avoid bias. Patients with suspected DVT underwent ultrasonography of the proximal venous system as previously described. Those whose ultrasound results showed no abnormalities underwent a follow-up ultrasound examination 1 week later. Patients with abnormal ultrasound results were treated for DVT.

58 patients had previous objectively documented DVT or pulmonary embolism; 7 were geographically inaccessible for follow-up testing; 5 had concomitant symptoms of pulmonary embolism; 4 were pregnant; 3 required long-term anticoagulants, and 10 had other reasons. Thus, 360 patients met the eligibility criteria. Of these, 9 refused consent and 4 patients for whom pretest probability was moderate were not enrolled because ultrasonography could not be performed within 12 hours of presentation to the emergency department. A total of 347 patients were entered in the trial, of whom 3 patients were lost to follow-up, leaving 344 evaluable patients (Figure 2). The average age of these patients was 53.8 years, and 154 patients (44.7%) were men (Table 2). The mean duration of symptoms prior to presentation in the emergency department was 6.7 days. Of the 344 evaluable patients, 49 (14.2%) were categorized at high, 105 (30.5%) moderate, and 190 (55.2%) low pretest probability for DVT.

PATIENT OUTCOMES

One hundred eighty-five (97.4%) of the patients for whom pretest probability was low had no abnormalities on ultrasound imaging. The remaining 5 patients for whom probability for DVT was low had abnormal ultrasound findings; DVT was confirmed by venography in 3 of these patients and venography was not performed in the other 2. All 5 patients were treated for proximal DVT. One patient in the low-probability category, who developed worsening symptoms of calf pain, underwent an unscheduled ultrasound examination 1 week following his initial presentation, which again showed no abnormalities. This patient subsequently had contrast venography per-
formed and calf DVT was diagnosed for which the patient was treated.

Of the patients classified with moderate pretest probability, 13 had abnormal compression ultrasound findings and were treated for DVT, and 92 (87.6%) had normal ultrasound findings on the day of initial presentation. One of these latter 92 patients had abnormal ultrasound findings in a test conducted 7 days later. Of the remaining 91 patients, 1, because of persistent severe calf pain, underwent contrast venography following the second ultrasound with no abnormal findings and was diagnosed and treated for calf DVT.

The diagnosis of DVT was given for 20 of 49 patients at high probability on the basis of the findings of the initial ultrasound examination. Four (13.8%) of the 29 patients with normal ultrasound imaging findings were confirmed by venography to have either calf and popliteal DVT (2 patients) or isolated calf vein thrombosis (2 patients). None of the other 25 patients at high probability developed complications of DVT or pulmonary embolism during the 3-month follow-up.

Overall, 49.0% (95% CI, 34.3%-63.6%) of the patients with high, 14.3% (95% CI, 8.3%-22.4%) of those with moderate, and 3.2% (95% CI, 1.2%-6.7%) of those patients with low pretest probability were confirmed to have DVT over the 3-month follow-up period. Overall, 45 (13.1%) of the 344 patients studied were confirmed to have DVT. None of the 344 evaluable patients developed pulmonary embolism or major bleeding within 48 hours of their evaluation in the emergency department (95% CI, 0%-0.9%).

Four of the patients who participated in the study died. Two patients in the high-probability category died subsequent to being given the diagnosis and treated for DVT. Two patients in the low-probability category died who were not considered to have DVT: one from complications of a stroke and the other from complications of lymphoma. These patients died 48 and 71 days following assessment in the emergency department.

We have demonstrated that emergency department physicians can classify patients with suspected DVT into high-, moderate-, and low- pretest probability groups using a simple explicit clinical model. Furthermore, we have shown that by following management algorithms based on clinical pretest probability, urgent diagnostic imaging for DVT in the emergency department can be safely avoided. The short-term safety of our approach was confirmed in that no patient developed pulmonary embolism or major bleeding within 48 hours of their evaluation in the emergency department (95% CI, 0%-0.9%). The long-term safety of our management strategy was demonstrated, since only 2 patients (0.7%) who had DVT excluded in the initial evaluation period were given the diagnosis of DVT or pulmonary embolism in the 3-month follow-up period (95% CI, 0.1%-2.3%). These patients were demonstrated by venography to have DVT isolated to the calf veins after ultrasound imaging showed no abnormalities.

This study confirmed the validity of a simplified 9-point clinical model for the diagnosis of DVT. After a minimal period of instruction, this model was successfully used by emergency department physicians to categorize patients into high-, moderate-, and low-probability groups. The prevalence of DVT in the high-pretest probability category was lower than was observed in our other studies. This, in part, may reflect the lower prevalence of DVT in patients presenting to emergency departments compared with specialized thrombosis clinics. It may also reflect that emergency department physicians were cautious and that, when in doubt, they may have tended to assign a higher score, which resulted in the patient being admitted to the hospital for intravenous heparin therapy. Nevertheless, using our strategy, only 10% of the entire cohort of patients (those considered at high probability for DVT) were admitted to the

### Table 1. Clinical Evaluation Table for Predicting Pretest Probability of Deep Vein Thrombosis*

<table>
<thead>
<tr>
<th>Clinical Characteristic</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Active cancer (treatment ongoing, within</td>
<td>1</td>
</tr>
<tr>
<td>previous 6 mo or palliative)</td>
<td></td>
</tr>
<tr>
<td>Paralysis, paresis, or recent plaster</td>
<td>1</td>
</tr>
<tr>
<td>immobilization of the lower extremities</td>
<td></td>
</tr>
<tr>
<td>Recently bedridden ≥3 d or major surgery</td>
<td>1</td>
</tr>
<tr>
<td>within 12 wk requiring general or regional</td>
<td></td>
</tr>
<tr>
<td>anesthesia</td>
<td></td>
</tr>
<tr>
<td>Localized tenderness along the distribution</td>
<td>1</td>
</tr>
<tr>
<td>of the deep venous system</td>
<td></td>
</tr>
<tr>
<td>Entire leg swollen</td>
<td>1</td>
</tr>
<tr>
<td>Calf swelling 3 cm larger than asymptomatic</td>
<td>1</td>
</tr>
<tr>
<td>side (measured 10 cm below tibial tuberosity)</td>
<td></td>
</tr>
<tr>
<td>Pitting edema confined to the symptomatic</td>
<td>1</td>
</tr>
<tr>
<td>leg</td>
<td></td>
</tr>
<tr>
<td>Collateral superficial veins (nonvaricose)</td>
<td>1</td>
</tr>
<tr>
<td>Alternative diagnosis as least as likely</td>
<td>-2</td>
</tr>
<tr>
<td>deep vein thrombosis</td>
<td></td>
</tr>
</tbody>
</table>

* A score of 3 or higher indicates a high probability of deep vein thrombosis; 1 or 2, a moderate probability; and 0 or lower, a low probability. In patients with symptoms in both legs, the more symptomatic leg is used.

### Figure 1. Management flowchart for patients with suspected deep vein thrombosis (DVT). ED indicates emergency department; PTP, pretest probability; and US, compression ultrasound imaging.
hospital through the emergency department, and 49% of these patients were confirmed to have DVT on subsequent diagnostic testing.

In only 4 of 34 patients scheduled to undergo venography because of discordance between the clinical pretest probability assessment and the ultrasonography results did the diagnosis made by compression ultrasound imaging prove to be incorrect. In each case, thrombi involving the calf and/or distal popliteal veins were diagnosed by venography in patients at high probability with normal ultrasound findings. Since the veins of the calf were deliberately not examined in this study because of the limited accuracy of ultrasonography in this region,1,2 these results should not be regarded as an indication of failure of ultrasonography.

The development of safe and feasible algorithms for the management of patients with suspected DVT that avoids the need for emergency diagnostic imaging has several practical advantages. First, for centers that do not have the capacity for routine diagnostic imaging, these algorithms provide an alternative to admitting patients to the hospital for empiric anticoagulation until diagnostic imaging can be performed. Second, these algorithms allow for the effective triage of patients in the emergency department and thus avoid unnecessary delays. Third, cost savings can be achieved by avoiding the callback of staff to perform urgent ultrasonography.

The results of this study suggest that using management algorithms based on pretest probability for patients presenting to the emergency department with suspected DVT is safe and feasible. However, there were several limitations to our algorithms that could potentially be improved. First, the management of the high-probability subgroup was suboptimal in that more than 50% of these patients were confirmed not to have DVT on radiographic imaging and were thus unnecessarily admitted to the hospital. Second, owing to the short half-life of unfractionated heparin, patients in the moderate-probability group had to return for ultrasound imaging within 12 hours of their evaluation in the emergency department. Management of high- and moderate-probability patients may be improved by substituting low-molecular-weight heparin for unfractionated heparin in the respective algorithms. Two studies have demonstrated that subcutaneously administered low-molecular-weight heparin is safe and effective for the outpatient treatment of DVT.13,14 Owing to its longer half-life, low-molecular-weight heparin preparations may be administered once daily for the treatment of DVT.15,16 Therefore, the use of low-molecular-weight heparin would reduce the need to empirically admit patients at high clinical suspicion for DVT to the hospital. Such patients would then have up to 24 hours before diagnostic ultrasonographic imaging would need to be arranged. Patients subsequently confirmed to have DVT could potentially be entered into an outpatient DVT treatment program, reducing the cost of managing this condition.15

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**Table 2. Demographic and Clinical Characteristics of Patients Based on the Confirmation of a Diagnosis of DVT**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>With DVT</th>
<th>Without DVT</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of patients</td>
<td>45</td>
<td>299</td>
<td>344</td>
</tr>
<tr>
<td>Mean age, y</td>
<td>57.1</td>
<td>53.4</td>
<td>53.8</td>
</tr>
<tr>
<td>Sex, No. M/F</td>
<td>20/25</td>
<td>134/165</td>
<td>154/190</td>
</tr>
<tr>
<td>Mean duration of symptoms, d</td>
<td>5.7</td>
<td>6.9</td>
<td>6.7</td>
</tr>
<tr>
<td>No. (%) of patients with</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cancer</td>
<td>5 (11.1)</td>
<td>12 (4.0)</td>
<td>17 (4.9)</td>
</tr>
<tr>
<td>Recent surgery</td>
<td>6 (13.3)</td>
<td>11 (3.7)</td>
<td>17 (4.9)</td>
</tr>
<tr>
<td>Immobilization</td>
<td>14 (31.1)</td>
<td>36 (12.0)</td>
<td>50 (14.5)</td>
</tr>
</tbody>
</table>

*DVT indicates deep vein thrombosis.*

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**Figure 2. Allocation of patients potentially eligible for the study. DVT indicates deep vein thrombosis; PTP, pretest probability.**
Finally, the D-dimer test has been assessed as a surrogate marker for DVT. Several D-dimer assays have been demonstrated to be highly sensitive but nonspecific for the diagnosis of DVT. The high negative predictive value of D-dimer may be useful in reducing the need for diagnostic testing, especially in patients at low clinical probability presenting to the emergency department with suspected DVT. However, the safety of this approach requires confirmation in large prospective clinical trials in the emergency department.

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