Criteria for Outpatient Management of Proximal Lower Extremity Deep Venous Thrombosis*

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Study objectives: To develop and to evaluate selection criteria for outpatient management of deep venous thrombosis (DVT).

Design: We developed outpatient treatment eligibility criteria that incorporated demographic and clinical data. We aimed to exclude patients at high risk for bleeding or recurrent clotting, as well as those with pulmonary embolism, limited cardiopulmonary reserve, or need for hospitalization due to another illness. Then, we retrospectively applied the criteria to hospitalized patients with newly diagnosed proximal lower extremity DVT to determine the fraction of patients eligible for outpatient therapy; patients were classified as eligible, possibly eligible, or ineligible for home treatment based on the selection criteria.

Setting: University hospital.

Patients: One hundred ninety-five hospitalized patients diagnosed as having proximal lower extremity DVT by duplex ultrasound over a 1-year period.

Measurements: Frequency of complications during initial DVT therapy, including major bleeding, symptomatic thromboembolism, and death.

Results: Eighteen (9%) patients were classified as eligible, and 18 (9%) were classified as possibly eligible for outpatient therapy. None of these patients developed complications. Of the 159 (82%) patients classified as ineligible, 13 (8%; 95% confidence interval [CI], 4 to 12%) died or developed serious complications. Therefore, the eligibility criteria had a sensitivity of 100% (95% CI, 92 to 100%) and a negative predictive value of 100% (95% CI, 92 to 100%) for predicting serious complications.

Conclusions: Specific eligibility criteria may identify a subset of patients with acute DVT who can be treated safely at home.

(CHEST 1999; 115:972–979)

Key words: deep venous thrombosis; low-molecular-weight heparin; thrombophlebitis

Abbreviations: CI = confidence interval; DVT = deep venous thrombosis; LMWH = low-molecular-weight heparin; PE = pulmonary embolism

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Supported in part by National Research Service Award F32 HS000124-01 from the Agency for Health Care Policy and Research (Dr. Yusen), and the Norman P. Knowlton, Jr., MD, Incentive for Excellence Fund of Barnes-Jewish Hospital (Dr. Yusen).

Manuscript received August 21, 1998; revision accepted November 4, 1998.

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Unfractionated IV heparin has been used traditionally for the treatment of hospitalized patients who have a newly diagnosed proximal lower extremity deep venous thrombosis (DVT). However, subcutaneously administered low-molecular-weight heparin (LMWH) has been demonstrated to be as safe and effective as therapy with continuous IV unfractionated heparin. The advantages of LMWH over unfractionated heparin include infrequent and subcutaneous dosing and safety without activated partial thromboplastin time monitoring. Given these advantages and their potential for cost savings, LMWHs provide an excellent opportunity for outpatient treatment of patients with uncomplicated proximal lower extremity DVT.

Three recently published randomized studies...
demonstrated that outpatient LMWH is as safe and effective as inpatient unfractionated heparin therapy in carefully selected patients. The studies showed that at least one third of patients with acute proximal lower extremity DVT may be eligible for outpatient therapy. However, patients at high risk for adverse events were likely to have been underrepresented in these studies because the studies contained outpatient treatment arms. Since the selection criteria used in these studies were heterogeneous, we decided to further study selection criteria for outpatient therapy of acute DVT.

Our study aimed to develop and test criteria that would identify patients with acute proximal lower extremity DVT who could be treated safely outside of the hospital. We developed a set of explicit outpatient selection criteria based on the following: risk factors for complications from anticoagulation, and venous thromboembolic disease, symptoms or signs suggestive of pulmonary embolism (PE) or limited cardiopulmonary reserve, the need for hospitalization due to other illness, and objective criteria and readily available data. After development, we validated these a priori criteria by comparing the frequency of complications of hospitalized patients considered eligible for outpatient therapy with those of patients considered ineligible for outpatient therapy during initial DVT therapy.

**Materials and Methods**

**Study Setting and Patients**

Using a computerized registry, we identified all patients who underwent lower extremity duplex ultrasound scanning between July 1, 1993, and June 30, 1994, in the vascular laboratory at Jewish Hospital at the Washington University Medical Center in St. Louis, MO. Patients were selected for chart review if they had been hospitalized and had a new proximal lower extremity DVT diagnosed by duplex examination. During duplex evaluation, proximal lower extremity DVT was defined as a constant and incompressible intraluminal deep venous defect at or above the popliteal vein. Although all study patients were ultimately hospitalized, the timing of the duplex examination in relationship to hospital admission was used to classify each patient’s presentation as an outpatient or inpatient event. Duplex examinations performed in the emergency department prior to hospital admission were considered as part of an outpatient presentation (Fig 1).

**Development of Eligibility Criteria for Outpatient Therapy**

We developed eligibility criteria for outpatient treatment of acute proximal lower extremity DVT to identify patients with a low likelihood of developing complications. The criteria were developed to identify and exclude patients with known risk factors for complications from anticoagulation and from venous thromboembolic disease. We also excluded patients with the need for hospitalization due to other illness or symptoms or signs suggestive of PE or limited cardiopulmonary reserve. We used criteria that were objective and readily available. The criteria (detailed in Table 1) considered patient age, other medical problems, presenting symptoms and signs including vital signs at time of DVT diagnosis, and perceived ability to undergo outpatient therapy. Patients without contraindications to home therapy were labeled as eligible candidates for outpatient treatment. Those patients who had only one relative contraindication (barely falling outside of the eligibility guidelines) were labeled as possibly eligible for outpatient treatment. These relative contraindications included the following: hospital admission for medical problems that could be potentially treated at home; age > 75 years but < 80 years; minimally abnormal vital signs; marked renal dysfunction; pregnancy; and home location > 50 miles from the medical center. We labeled patients as ineligible candidates for outpatient treatment if they were considered to have a higher risk of developing complications from anticoagulants or thromboembolism or a need for hospitalization unrelated to venous thromboembolic disease.

**Application of Eligibility Criteria and Determination of Complication Rates**

By retrospectively applying the a priori eligibility criteria to the study cohort, we classified patients as eligible, possibly eligible, or ineligible for outpatient therapy (Fig 1). Hospital and laboratory records, ventilation-perfusion and pulmonary angiography reports, and autopsy documents were reviewed to see which patients had complications during their hospitalization for initial proximal lower extremity DVT therapy. For the purposes of this study, the relevant hospitalization began when the DVT was first diagnosed. We defined initial therapy as the period that began when patients received IV unfractionated heparin and ended when patients were converted to oral warfarin therapy for treatment of the newly diagnosed DVT.

We used chart review to document the following complications: major bleeding, recurrent symptomatic thromboembolic disease (new DVT or PE), and death. Major bleeding was defined as any hemorrhage that required discontinuation of heparin therapy or that caused death. DVT was considered recurrent if relevant new symptoms occurred in the setting of new or extended clot diagnosed by duplex scan, venography (deep venous intraluminal defect seen in two views), or autopsy. PE was considered present if relevant new symptoms occurred and a lung ventilation-perfusion scan was interpreted as high probability. A pulmonary angiogram showed a constant intraluminal filling defect or autopsy revealed evidence of premortem pulmonary thromboembolic disease. PE was considered absent if lung ventilation-perfusion scanning was normal but possibly present if the scan was given a rating other than normal or high probability. We also documented the occurrence of heparin-induced thrombocytopenia, but this complication was not considered a major complication.

**Statistics**

Frequencies and 95% confidence intervals (95% CI) of complications were determined for the eligible, possibly eligible, and ineligible groups using the normal approximation of the binomial theorem. A two-tailed unpaired t test for means was used to compare the age of different groups of patients. Statistical significance was considered present if p < 0.05.

**Results**

**Patients**

Twelve hundred patients underwent lower extremity duplex ultrasound scanning during the 1-year period (Fig 1). Of these patients, 203 (17%) were
diagnosed as having proximal lower extremity DVT. Of the 199 who had inpatient therapy, 195 had charts available for review, constituting our main study cohort. The mean (± SD) age of the study cohort was 70 (± 16) years with a range of 81 years. Fifty-nine percent of patients were women.

Eligibility for Outpatient Therapy

Thirty percent of patients had the diagnosis of proximal lower extremity DVT made in the outpatient setting, including the emergency department, whereas 70% of patients had the diagnosis made while already hospitalized (Fig 1). Nine percent of the study cohort were eligible for outpatient DVT therapy. Another 9% of the study cohort were possibly eligible. The remaining 82% of patients were ineligible for outpatient therapy.

Complications in Patients Deemed Ineligible for Outpatient Therapy

During the initial treatment period after diagnosis of proximal lower-extremity DVT, thirteen of the
159 patients ineligible for outpatient therapy (8.2%; 95% CI, 3.9 to 12.5%) suffered complications related to DVT/PE or its therapy: 10 patients died, 1 had a nonfatal major bleed, and 2 had nonfatal symptomatic pulmonary emboli (Table 2 and Fig 2).

Ten of 159 patients in the ineligible group died of hemorrhage, stroke, or undetermined causes. One patient with a coagulopathy died of hemorrhage as a complication of a central venous catheter placement. The patient had previously discontinued heparin therapy. Two other patients died of complications of stroke not thought to be related to paradoxical embolization or anticoagulation. Although there were no other clinical suspicions of PE or major hemorrhage documented in their charts, seven patients died with pulseless electrical activity or hypotension. One of these seven patients had a recurrent DVT diagnosed prior to death. Autopsies were not performed on these seven patients.

Nonfatal major bleeding occurred in one of the ineligible patients. The patient developed bleeding at a recent hip surgery wound site. The activated partial thromboplastin time was not supratherapeutic at the time of bleeding.

Two patients in the ineligible group had nonfatal symptomatic PE diagnosed by either high-probability ventilation-perfusion scan (one patient) or pulmonary angiogram (one patient) while being treated for the previously diagnosed proximal

Table 1—Eligibility Criteria in Present Study for Outpatient Treatment of Acute Proximal Lower Extremity DVT

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
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<tbody>
<tr>
<td><strong>Inclusion criteria</strong></td>
<td>Documented acute proximal lower extremity DVT</td>
<td>Hospital admission for reasons other than DVT†</td>
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<tr>
<td>Adult age (age ≥ 18 yr)*†</td>
<td></td>
<td>Pregnancy‡</td>
</tr>
<tr>
<td><strong>Exclusion criteria</strong></td>
<td></td>
<td>Allergy to heparin</td>
</tr>
<tr>
<td><strong>Potential high complication risk</strong></td>
<td>Related to recurrent cloting or bleeding</td>
<td>Related to bleeding</td>
</tr>
<tr>
<td>Adults &gt; 75† years old</td>
<td>Active bleeding/high risk of hemorrhage</td>
<td>Hemoglobin &lt; 7 g/dL at time of diagnosis of DVT</td>
</tr>
<tr>
<td>History of heparin-induced thrombocytopenia</td>
<td>Active bleeding including guaiac-positive stool</td>
<td>History of stroke in past 6 weeks</td>
</tr>
<tr>
<td>High risk of noncompliance or inaccessibility for follow-up‡</td>
<td>Noncutaneous surgery in past 2 weeks</td>
<td>Platelet count &lt; 75,000/mm³</td>
</tr>
<tr>
<td><strong>Related to bleeding</strong></td>
<td>History of stroke in past 6 weeks</td>
<td>Hemodialysis dependency‡</td>
</tr>
<tr>
<td>Hemoglobin &lt; 7 g/dL at time of diagnosis of DVT</td>
<td>Any other medical conditions with high incidence of hemorrhage</td>
<td>Signs or symptoms of PE or of limited cardiopulmonary reserve</td>
</tr>
<tr>
<td>Active bleeding/high risk of hemorrhage</td>
<td>Confirmed or suspected (without confirmatory test) symptomatic PE</td>
<td>Confirmed or suspected (without confirmatory test) PE</td>
</tr>
<tr>
<td>Active bleeding including guaiac-positive stool</td>
<td>Presenting symptom of dyspnea or nonmusculoskeletal chest pain</td>
<td>Abnormal vital signs</td>
</tr>
<tr>
<td>History of stroke in past 6 weeks</td>
<td>Abnormal respiratory rate &gt; 20 or ≤ 8 inches/min</td>
<td>Respiratory rate &gt; 20 or ≤ 8 breaths/min</td>
</tr>
<tr>
<td>Noncutaneous surgery in past 2 weeks</td>
<td>Heart rate &gt; 100 or ≤ 60 beats/min§</td>
<td>Heart rate &gt; 100 or ≤ 60 beats/min§</td>
</tr>
<tr>
<td>Platelet count &lt; 75,000/mm³</td>
<td>Temperature &gt; 38.3°C</td>
<td>Temperature &gt; 38.3°C</td>
</tr>
<tr>
<td>Hemodialysis dependency‡</td>
<td>Systolic BP &lt; 100 mm Hg</td>
<td>Systolic BP &lt; 100 mm Hg</td>
</tr>
<tr>
<td>Any other medical conditions with high incidence of hemorrhage</td>
<td>PaO₂ less than normal for age</td>
<td>PaO₂ less than normal for age</td>
</tr>
<tr>
<td>Signs or symptoms of PE or of limited cardiopulmonary reserve</td>
<td>Evidence of ischemia or new arrhythmia on ECG</td>
<td>Evidence of ischemia or new arrhythmia on ECG</td>
</tr>
</tbody>
</table>

*A 16-year-old patient was admitted to the hospital as an adult and included in the study.
†Age ≥ 75 but < 80 yr.
‡Relative and not absolute exclusion criterion.
§Inaccessible because home is > 50 miles from hospital.
||Vital signs abnormal due only to respiratory rate within 25% of guidelines.
¶Vital signs abnormal due only to heart rate within 10% of guidelines.

159 patients ineligible for outpatient therapy (8.2%; 95% CI, 3.9 to 12.5%) suffered complications related to DVT/PE or its therapy: 10 patients died, 1 had a nonfatal major bleed, and 2 had nonfatal symptomatic pulmonary emboli (Table 2 and Fig 2).

Ten of 159 patients in the ineligible group died of hemorrhage, stroke, or undetermined causes. One patient with a coagulopathy died of hemorrhage as a complication of a central venous catheter placement. The patient had previously discontinued heparin therapy. Two other patients died of complications of stroke not thought to be related to paradoxical embolization or anticoagulation. Although there were no other clinical suspicions of PE or major hemorrhage documented in their charts, seven patients died with pulseless electrical activity or hypotension. One of these seven patients had a recurrent DVT diagnosed prior to death. Autopsies were not performed on these seven patients.

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Two patients in the ineligible group had nonfatal symptomatic PE diagnosed by either high-probability ventilation-perfusion scan (one patient) or pulmonary angiogram (one patient) while being treated for the previously diagnosed proximal

Table 2—Frequency of Complications

<table>
<thead>
<tr>
<th>Classification Group for Outpatient Therapy</th>
<th>Ineligible* (n = 159)</th>
<th>Eligible (n = 18)</th>
<th>Possibly Eligible (n = 18)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complication</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td>10</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Nonfatal major bleeding</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Nonfatal symptomatic PE</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Symptomatic recurrent DVT</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>13†</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

*In the ineligible group, 1 patient who died from a major bleed, 1 patient with a recurrent DVT who died of supposedly unrelated causes, and 1 patient with a suspected PE that was not confirmed are counted only as deaths. 15 total confirmed complications occurred in 13 patients in the ineligible group.
†Significantly different (p < 0.05) from the separate or combined eligible and possibly eligible groups.

FIGURE 2. Frequency of complications in patients categorized by eligibility criteria.
lower extremity DVT. Both of these patients had adequate anticoagulation at the time of their PE with an activated partial thromboplastin time of > 1.5 times the control. Another patient in the ineligible group may have had a PE based on clinical suspicion, but a ventilation-perfusion scan was interpreted as intermediate probability and an angiogram was not performed.

Complications in Patients Deemed Eligible or Possibly Eligible for Outpatient Therapy

The 18 eligible and 18 possibly eligible patients had no serious complications, although the possibly eligible group did include a pregnant patient who developed thrombocytopenia that resolved after the discontinuation of heparin therapy. Therefore, the criteria that defined patients as eligible or possibly eligible had a sensitivity of 100% (95% CI, 92 to 100%) and a negative predictive value of 100% (95% CI, 92 to 100%) for predicting serious complications. The specificity (20%) and the positive predictive value (8%) for predicting complications based on the criteria were quite low, but the goal of the criteria was to maximize sensitivity and negative predictive value so that eligible and possibly eligible patients would be safe to treat at home.

Though post hoc subgroup analyses were limited due to sample size and frequency of complications, we evaluated our choice of 75 years as the lower age limit for the ineligible group. Seventy (44%) of 159 patients in the ineligible group were > 75 years of age and accounted for 85% of the patients with complications in the ineligible group. The elderly group experienced eight deaths, one nonfatal major hemorrhage, and two nonfatal symptomatic PE. The high frequency (12%) of complications in patients with age > 75 years significantly differed from the frequency of complications (2%) in the younger group (p < 0.05). A similar frequency (12%) of complications was seen in patients > 80 years.

Discussion

This study suggests that objective criteria may be used to select patients for proximal lower extremity DVT home therapy. We showed that complications of bleeding, venous thromboembolism, and death were greater in those patients considered ineligible than in those patients considered eligible for home therapy. The ability of the criteria to identify patients safe for home therapy was demonstrated with the 100% sensitivity and the 100% negative predictive value of the criteria for predicting complications; none of the patients in the eligible or possibly eligible groups suffered any major complications.

Although the specificity and positive predictive value of the criteria were low, safety was the focus of this study. The criteria were intended to identify patients who would not have serious complications, and who therefore could be safely treated at home.

Selection Criteria

Our estimate of the fraction of patients eligible or possibly eligible for outpatient therapy, 9 to 18%, is much lower than the fractions proposed by others,9−11 likely due to differences in patient cohorts and our conservative eligibility criteria. Our study included patients with proximal lower extremity DVT and excluded patients with lone distal lower extremity DVT, as well as patients with symptomatic confirmed or suspected PE. Recent studies by Levine et al10 Koopman et al,9 and the Columbus Investigators11 included a much greater proportion of patients presenting as outpatients for DVT evaluation compared with our study. In addition, these other studies evaluated a younger group of patients.

The Koopman et al,9 Levine et al,10 and Columbus Investigators11 showed that outpatient therapy with LMWH was as efficacious as inpatient treatment with IV unfractionated heparin therapy. However, the studies used heterogeneous selection criteria, and their primary objective was not to identify patients who would be “safe” or at a lower risk for complications during outpatient therapy (Table 3). The concept of safe outpatient therapy makes sense and is gaining acceptance, but an acceptable threshold of risk needs to be determined.

Our study’s possibly eligible group, whose members each had one relative contraindication to outpatient therapy, had no in-hospital complications. When developing the a priori criteria, we decided to keep the possibly eligible group separate from the eligible group based on a lack of data related to potential outpatient and LMWH therapy in patients with certain characteristics. For example, there have been limited data published regarding use of LMWH in pregnant patients.26 Also, dialysis therapy is considered a relative contraindication because LMWH is cleared primarily via the kidneys, and appropriate dosing may be difficult.29 In addition, there is an increased risk of hemorrhage in patients with renal failure.16 The geographic criterion was developed because of potential difficulties with follow-up in remote areas. As LMWH use and outpatient treatment of DVTs becomes more routine in the medical community, these contraindications should be reevaluated.

Age > 75 years, seen in almost half of our study cohort, was created as an exclusion criteria based
on studies suggesting an increased incidence of hemorrhage in elderly patients receiving anticoagulation.\textsuperscript{14,16,30} In addition, elderly patients have an increased incidence of venous thromboembolism and death.\textsuperscript{31} Our results confirmed a higher risk of adverse events in the elderly compared with the younger patients, including death, major bleeding, and recurrent venous thromboembolism.

Limitations

The determination of complication rates was based on a retrospective analysis of events during inpatient hospitalization for initial DVT therapy. Retrospective data collection has inherent biases and potential limitations. First, lack of documentation or confirmatory tests by the patients’ health-care providers may have limited our ability to determine accurate complication rates. However, the study’s outcomes (complications) were clearly defined and objective. Second, complications after hospital discharge were not determined. However, complications occurring after the completion of heparin administration have little relevance to the choice of the initial treatment setting.

We applied our criteria to patients based on data known at the time of the DVT diagnosis. All patients received unfractionated heparin as initial DVT treatment. We assumed that the type and frequency of serious complications would be similar if patients would have received LMWH treatment instead. Our study design allowed us to assess the usefulness of the criteria in all patients presenting with proximal DVT and not only those thought to be potentially eligible for outpatient therapy with LMWH therapy.

Although any criteria should undergo validation

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Present Study</th>
<th>Koopman et al\textsuperscript{9}</th>
<th>Levine et al\textsuperscript{10}</th>
<th>Columbus Investigators\textsuperscript{11}</th>
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<tbody>
<tr>
<td>Inclusion criteria</td>
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<tr>
<td>Adult age</td>
<td>C</td>
<td>C</td>
<td>C\dagger</td>
<td>C</td>
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<tr>
<td>Acute proximal lower extremity DVT documented by ultrasonography or venogram</td>
<td>C</td>
<td>C</td>
<td>C</td>
<td>C\dagger</td>
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<tr>
<td>Exclusion criteria</td>
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<tr>
<td>General</td>
<td></td>
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<tr>
<td>Hospital admission for illness other than DVT</td>
<td>C</td>
<td>—</td>
<td>C\dagger</td>
<td>—</td>
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<tr>
<td>Pregnancy</td>
<td>C</td>
<td>C</td>
<td>C</td>
<td>C</td>
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<tr>
<td>Known allergy to heparin</td>
<td>C</td>
<td>C\dagger</td>
<td>C</td>
<td>C</td>
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<tr>
<td>Potential high complication risk</td>
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<tr>
<td>Related to recurrent clotting or bleeding</td>
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<tr>
<td>Advanced age</td>
<td>C</td>
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<tr>
<td>Obesity</td>
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<td>C\dagger</td>
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<tr>
<td>High risk of noncompliance or inaccessibility that would affect follow-up</td>
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<td>C\dagger</td>
<td>C</td>
<td>C\dagger</td>
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<tr>
<td>Related to recurrent clotting</td>
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<tr>
<td>Ongoing risk factors for venous thromboembolism; previous clot history; hereditary clot disorder</td>
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<td>C\dagger</td>
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<tr>
<td>Related to bleeding</td>
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<tr>
<td>History of heparin-induced thrombocytopenia</td>
<td>C</td>
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<td>C\dagger</td>
<td>C\dagger</td>
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<tr>
<td>Marked anemia</td>
<td>C</td>
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<td>—</td>
<td>C\dagger</td>
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<tr>
<td>Active bleeding/high risk of hemorrhage¶</td>
<td>C</td>
<td>C\dagger</td>
<td>C</td>
<td>C</td>
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<tr>
<td>Hemodialysis</td>
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<td>Signs or symptoms of PE or of limited cardiopulmonary reserve</td>
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<td>Confirmed or suspected symptomatic PE</td>
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<td>C</td>
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<tr>
<td>Abnormal vital signs</td>
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<td>C\dagger</td>
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<tr>
<td>Other</td>
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<tr>
<td>Overt postthrombotic syndrome</td>
<td>—</td>
<td>C</td>
<td>—</td>
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</table>

*Other protocol-specific criteria from the published studies not used for reasons related to patient care have been excluded from this chart, such as exclusion of patients using heparin for \(24\) to \(48\) h prior to study enrollment, life expectancy \(>6\) months, thrombolytic therapy planned; C represents a criterion or criteria that was/were used in the cited study. See Table 1 for eligibility criteria used in present study.
†Criteria not explicitly stated in the same manner in the cited publication were confirmed by phone conversation with author.
‡Used as criteria for a subset of patients in the study.
§Only geographic factors taken into account—other factors related to feasibility of home therapy were not used as exclusion criteria.
¶Active/high risk of hemorrhage refers to patients who have had recent surgery, stroke, trauma, peptic ulcer disease, angiodysplasia of the colon, thrombocytopenia, etc.
in centers with different referral patterns and in different populations, the patients in our study were heterogeneous. For example, the presence and degree of comorbid conditions, including those of obesity and ongoing risk factors for thrombosis, may lead to different decision making about outpatient therapy. We did not specifically evaluate the frequency of underlying conditions or the extent of risk factors for thrombosis. However, patients in this study were referred for duplex ultrasound testing by a broad range of health-care providers, including primary care practitioners and medical and surgical subspecialty physicians. In addition, the patients in this study had a wide range of ages. Although the average age in our study cohort was higher than some published cohorts, the incidences of recurrent DVT or PE, major bleeding, and death in our study were consistent with those found in the literature.6–11,30 Also, a study including patients with clots in different anatomic locations other than the proximal lower extremity would allow the eligibility criteria to be evaluated in a broader population.

Selection criteria are needed to identify patients with proximal lower extremity DVT who can be safely treated at home. We aimed to identify patients who (1) did not require hospitalization for other reasons, (2) were not at high risk for bleeding, (3) were not at high risk for recurrent cloting, (4) had no signs or symptoms suggestive of PE, and (5) had adequate cardiopulmonary reserve if a major hemorrhage or another clot were to occur. We validated our a priori selection criteria by retrospective application to a cohort of 195 patients. No patient considered eligible for outpatient therapy had a serious complication. Cautious relaxation of these conservative eligibility criteria may expand the safe and efficacious use of home therapy. However, prospective validation of the proposed criteria is necessary before they are applied indiscriminately.

ACKNOWLEDGMENTS: The authors thank the members of the Division of General Medical Sciences writer’s workshop for their critical appraisal of the article, Kim Tinsley for secretarial assistance, and the Washington University Vascular Laboratory for assistance with data collection.

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