

Outpatient-Based Treatment Protocols in the Management of Venous Thromboembolic Disease

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Presentation Summary

Clinical trial data are demonstrating that the safety and efficacy of treating deep vein thrombosis (DVT) on an outpatient basis with low-molecular weight heparin (LMWH) are equal to inpatient care with unfractionated heparin (UFH). Moreover, LMWH therapy offers multiple advantages, including improved bioavailability at lower doses, reduced heparin resistance, a longer half-life, and potentially, less bleeding. Although these potential advantages are acknowledged, patient selection and risk stratification criteria for patients being considered for LMWH therapy are discussed less frequently; nonetheless, they deserve careful consideration. The protocol utilized by Lovelace Health Systems, a staff model health maintenance organization, features an outpa-

tient-based DVT treatment program that includes exclusionary risk factors for outpatient treatment of venous thromboembolic disease (VTE). Evidence from clinical findings at Lovelace suggests that patients without absolute exclusionary risk factors can successfully be treated with LMWH as outpatients. Specific study results show that 61% of patients were eligible for outpatient therapy and had fewer recurrences of VTE (1.9%) than those comorbid matched patients who were hospitalized with traditional UFH therapy the previous year (4.1%). These findings suggest that LMWH is both safe and efficacious in the home treatment of VTE in a managed care setting when established patient selection criteria and risk stratification strategies are carefully maintained.

The prevalence of venous thromboembolic disease (VTE) is estimated to be more than 500,000 cases annually, with serious consequences. The sequelae of VTE include pulmonary embolism (PE), which results in approximately 100,000 to 200,000 fatalities per year. The acute morbidity of VTE has staggering economic repercussions as a result of treatment costs and possible side effects, as well as the cost of hos-

pitalization. Moreover, survivors are at increased risk for recurrent VTE, as well as postphlebotic syndrome, creating a spiral of continuous health and economic consequences. Therefore, goals for treatment of acute deep vein thrombosis (DVT) are both therapeutic and economic.

From a therapeutic standpoint, short-term objectives are to prevent the extension of thrombus, fatal PE, and early recurrence of disease,

whereas long-term objectives are to prevent delayed recurrences and sequelae such as the postphlebotic syndrome and pulmonary hypertension. Economic goals are to safely and effectively treat appropriate patients at home where the costs are substantially less than those of inpatient care. Although the clinical trial data are demonstrating that the safety and efficacy of DVT treatment with low-molecular weight heparin (LMWH) on an outpatient basis are equal to inpatient care with unfractionated heparin (UFH), appropriateness, patient selection, and risk stratification criteria deserve careful consideration.

UFH Versus LMWH

Traditional DVT therapy uses UFH administered by continuous intravenous infusion with concurrent oral warfarin. Because of the variable anticoagulant response of heparin, the drug must be administered in the hospital, where the dosage can be closely monitored by measuring the activated partial-thromboplastin time (aPTT). Five to 7 days of inpatient heparin therapy are usually required before the patient has reached a therapeutic international normalization ratio (INR) on warfarin and is able to be discharged.

The pharmacodynamic advantages of LMWH therapy are many, including less nonspecific protein binding compared to UFH and improved bioavailability at lower doses with reduced heparin resistance. LMWH has a longer half-life, allowing for once- or twice-daily subcutaneous injection, and the dose response is more predictable, minimizing the need for patient monitoring. There are reduced effects on endothelial cells, generally less bleeding, and possibly decreased heparin-induced thrombocytopenia (3.5% versus 0.6% in one study).¹

A Dramatically Altered Therapeutic Approach to DVT

The results of 2 landmark level-I

randomized, multicenter trials—Levine et al² and Koopman et al³—have dramatically altered the therapeutic management of DVT in the United States. In the Levine et al study, approximately 250 patients were enrolled in each of 2 treatment arms, one using intravenous UFH, the standard of care, and the other using a 1-mg/kg twice-daily subcutaneous dosage of the LMWH enoxaparin with reduced or no hospitalization. Warfarin was administered to both groups for 3 months beginning on treatment day 2. Short-term clinical outcomes indices were compared between the 2 study arms.

The Koopman et al trial was constructed similarly, with approximately 200 patients with proven proximal DVT randomized to each of the 2 study arms: intravenous heparin given in a 5000-IU bolus, then 1250 IU/per hour with monitoring of aPTT; and a weight-adjusted dose of the LMWH nandroparin administered subcutaneously twice daily. Both groups were administered warfarin beginning on treatment day 1.

In both of these studies, the 2 study groups did not demonstrate any statistically significant difference in clinical endpoints such as recurrent thromboembolic disease, major bleeding, or death. Both of these studies showed equal staging efficacy, when comparing home-based subcutaneous LMWH treatment of DVT with standard hospital-based therapy using intravenous UFH, in terms of clinical outcomes such as PE, recurrence of thrombus, major bleeding episodes, or death. Using validated quality-of-life (QOL) instruments, the Koopman et al study showed greater patient satisfaction with the home-based therapy, while both studies demonstrated the potential in lowering overall cost by reduced hospital length of stay.

Because of the predominance of the clinical trial data, enoxaparin is

the only LMWH approved by the Food and Drug Administration (FDA) for inpatient treatment of DVT with and without PE at a treatment dose of 1.5 mg subcutaneous once daily or 1 mg subcutaneous twice daily when administered in conjunction with oral warfarin. The FDA has also approved enoxaparin for the outpatient treatment of acute DVT without PE when administered in conjunction with warfarin sodium at a subcutaneous twice-daily dose of 1 mg.

Outpatient Therapies

Review of clinical trial results and outcomes analyses for outpatient treatment of uncomplicated proximal DVT suggests 3 treatment options:

- Complete outpatient DVT program using LMWH
- Standard full inpatient course using UFH intravenously or LMWH
- LMWH initiated in hospital followed by completion of therapy in the outpatient setting

Outpatient Determinations

There are 4 major determinants in the implementation of outpatient-based DVT treatment strategies.

Patient Selection and Risk Stratification Criteria. Clinical exclusionary risk factors for outpatient treatment of DVT are shown in Table 1 and are based upon a published meta-analysis⁴ and our own experience at Lovelace.⁵ Although the itemized exclusionary risk factors do not represent an exhaustive list, they are nonetheless very important in maintaining a sense of which patients are ideal candidates for outpatient DVT treatment.

Patients not well suited to outpatient management are those with relative thrombocytopenia or active hemorrhage. A very conservative exclusionary factor is a gastrointestinal bleed within 6 months; some clinical trial data suggest that exclusion could very well be 90 days.⁶ Patients with any of the following conditions are not good candidates for outpatient care: a history of heparin sensitivity; underlying liver disorder, with synthetic dysfunction in particular; a history of familial bleeding disorder; catheter-associated DVT; hypertensive urgencies or emergencies; or iliofemoral thrombosis. Patients with renal insufficiency, especially with a creatinine clearance rate of less than 30 cc/minute, or dialysis-dependent patients are not good outpatient candidates because of bleeding risk.

Table 1. Exclusionary Risk Factors for Outpatient Treatment of DVT

<p>Absolute Exclusionary Risk Factors</p> <ul style="list-style-type: none"> ■ Platelet count < 100K ■ Active hemorrhage ■ GI bleed within 6 months ■ Heparin sensitivity ■ Underlying liver disorder ■ Familial bleeding disorder ■ Hypertensive: SBP > 220 and DBP > 120 mmHg ■ Catheter-associated DVT ■ Recent surgery ■ Morbid obesity > 30% ideal body weight ■ Congenital/acquired hypercoagulable state ■ Iliofemoral thrombosis ■ Comorbid illness <p>Relative Exclusionary Risk Factors</p> <ul style="list-style-type: none"> ■ Age > 75 years ■ Pregnancy ■ PE (clinically unstable or massive PE is absolute exclusionary criterion) ■ Renal insufficiency (CrCl < 30 cc/min or dialysis-dependent patient is absolute exclusionary criterion) ■ Other factors increasing risk of home treatment (eg, comorbidity, insurance compliance) ■ History of noncompliance with medicines ■ History of substance abuse ■ Language barrier ■ Inability to pay for LMWH ■ Inaccessibility to clinic or telephone ■ Unstable home environment ■ Incompetence to assume responsibility of self-care or inability of family/friend/nurse to administer care

CrCl = creatinine clearance; DBP = diastolic blood pressure; DVT = deep vein thrombosis; GI = gastrointestinal; LMWH = low-molecular weight heparin; PE = pulmonary embolism; SBP = systolic blood pressure.
 Source: References 4, 5.

There are a number of relative risk factors that require individual clinical assessment. For example, although in theory PE patients are not good outpatient candidates, some of the newer clinical trials and outcomes data in the literature suggest that those with clinically stable or submassive PE may indeed be good treatment candidates in the outpatient setting.^{7,9} Although most of the original clinical trial data excluded pregnancy, at Lovelace this has more frequently become a relative exclusionary criterion. Clinical data are still limited, however, thought leaders in the field believe that pregnant women are in fact very good candidates for long-term LMWH use because the drug affects a potential for a greater reduction in incidence of osteoporosis than does UFH, is easier to administer than subcutaneous UFH, with virtually no monitoring indicated, and confers less heparin-induced thrombocytopenia risk.¹⁰ Morbid obesity is another exclusionary risk factor.

Psychosocial and/or socioeconomic barriers to outpatient DVT treatment include:

- History of noncompliance with medicines
- History of substance abuse
- Language barrier
- Inability to pay
- Inaccessibility to clinic or telephone
- Unstable home environment
- Incompetence to administer self-care

Risk stratification criteria in place at Lovelace are detailed in Table 2. To summarize, patients with 1 absolute or 2 or more relative exclusionary factors (clinical or psychosocial) are designated as being at high risk for outpatient DVT therapy. Patients at moderate risk are those with 1 relative clinical exclusionary risk factor in addition to a home health or third-party payer issue. Such patients are in general best admitted for inpatient

care before being further risk stratified. Patients identified as having no exclusionary risk factors, clinical or otherwise, would in theory make excellent outpatient candidates from day zero.

In terms of putting these factors in the context of a relative initial assessment strategy, Beounameaux's rule generally applies: If the patient can walk in, the patient can walk out. Those patients who present via ambulance, wheelchair, or crutches are a probable admit to the hospital.

Estimates vary for the percentage of patients believed to be eligible for outpatient DVT management, with numbers very much dependent on the stringency of explicit exclusionary risk factors (Figure 1). Wells et al treated 83% of total patients with VTE in the outpatient setting, of whom 95% were treated completely as outpatients.¹¹ The Koopman et al study showed that 75% of patients in the LMWH arm were treated in the outpatient setting, of whom 36% represented complete outpatient treatment.³

Table 2. Risk Stratification Criteria

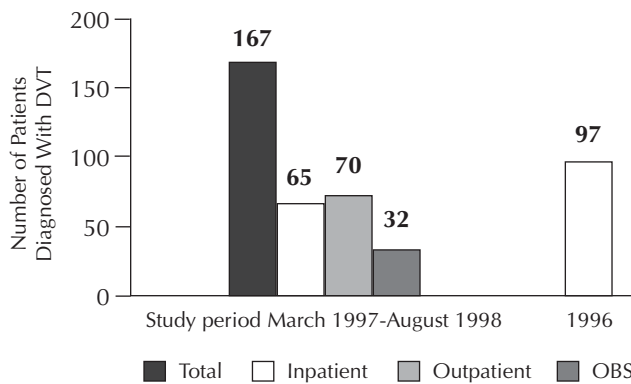
<p>High Risk One absolute or 2 or more relative exclusionary risk factors (inpatient intravenous UFH)</p> <p>Moderate Risk One relative exclusionary risk factor +/- home health issues +/- third-party payer issues</p> <p>Treated in hospital short term with LMWH then re-stratified. If risk stratified as high, converted to IV UFH; if low, discharged to outpatient care with LMWH</p> <p>Low Risk No exclusionary risk factors (outpatient LMWH; no hospitalization)</p>

UFH = unfractionated heparin; IV = intravenous; LMWH = low-molecular weight heparin.

Harrison et al reported that in their hospital's experience, 75% of all DVT patients were treated in the outpatient setting.¹² Levine et al reports that 33% of all screened patients met criteria as outpatient candidates or candidates for early hospital discharge.² Lastly,

the meta-analysis by Yusen et al showed that when utilizing very stringent, explicit exclusionary risk criteria, only 18% of total patients screened would be eligible for outpatient therapy.⁴ These results demonstrate a very wide range of eligibility depending on the investigator or protocol.

Figure 1. Utilization Demographics in Outpatient DVT Management*



DVT = deep vein thrombosis; OBS = observation status (reduced hospital length of stay). *Includes patients with clinically stable pulmonary embolism (1 outpatient, 5 OBS) and upper extremity DVT (1 outpatient, 2 OBS), average patient age 61.7 years. Source: Reference 5.

Dedicated Anticoagulation Service With Home Health Support. The medical literature suggests that anticoagulation management services demonstrate an improvement in clinical endpoints of major hemorrhage and thromboembolic events (Table 3).¹³⁻¹⁶ In one study, an improvement in morbidity outcome is demonstrated as well. Cost savings associated with outpatient management range from \$861 to \$4703 per patient per year. Other analyses suggest that carefully designed and implemented outpatient treatment programs for VTE disease have the potential to demonstrate an annual US savings of \$250 million.¹⁷ These findings demonstrate that when compared to traditional medical management, anticoagulation management services are associated with improved clinical outcomes as well as cost efficiency.

Table 3. Impact of Anticoagulation Management Services

Source Model	Patient Years	Major Hemorrhage*	TE*	Death*	Est. Savings
UMC ¹²	64	12.4	6.2	NA	
AMS	42	2.4	0.0	NA	\$861
UMC ¹³	677	4.7	6.6	NA	
AMS	669	1.0	0.6	NA	
UMC ¹⁴	28	17.8	42.8	NA	
AMS	60	0.0	0.0	NA	\$2300-\$4703
AMS ¹⁵	199	1.5	3.5	NA	
UMC	102	3.9	11.8	3	
AMS	123	1.5	3.3	0	\$1620

*percent/patient-year. TE = thromboembolism; UMC = usual medical care; AMS = anticoagulation management services.

Single or Small Group of Physicians Who Have Developed Expertise in Anticoagulation Management. Carefully selected champions of an outpatient approach to DVT management are essential to the success of such programs. Ideally, the champion will have won widespread respect among peers and be awarded sufficient time and resources for an initially labor-intensive undertaking. The responsibilities of the designated medical director of an anticoagulation service include development of a mission statement, service policy, and operating procedure and institution-specific anticoagulation guidelines.

Support System. Medical assistants, medical records personnel, data

managers, and other support staff constitute the infrastructure for outpatient anticoagulation management services. Such support staff ensure appropriate communication with other clinicians, perform quality assurance and continuous quality improvement, track clinical and pharmacoeconomic outcome indicators, and facilitate research.

Outpatient-Based Treatment Protocol for VTE Disease

A typical protocol for outpatient treatment of VTE is outlined in Table 4. The physician must begin with a very careful and thorough screening physical examination. If after careful consideration by the treating physician the patient is deemed a good outpatient candidate, a series of baseline lab tests are ordered (see Table 4) to detect evidence of microscopic hematuria, liver synthetic dysfunction, renal insufficiency, anemia, or thrombocytopenia. A minimum 5-day overlap with LMWH and warfarin is generally recommended, as is the discontinuation of LMWH when the INR is therapeutic for 2 consecutive days.

Warfarin management is crucial to the overall outcome, regardless of the specific heparin strategy (Table 5). Warfarin administration at a maintenance dose of 5 to 10 mg is initiated on day 0 or 1 of heparin therapy. Crowther et al demonstrated that 88% of patients who were initiated on a maintenance dose of 5 mg of warfarin achieved a therapeutic INR on day 5 of therapy compared with 53% of patients who received a loading dose of 10 mg of warfarin.¹⁸ Subsequent dosing is based on protime results, checked daily by the anticoagulation service until INR is greater than 2.0 for 48 hours, and the patient has received 5 days of heparin therapy. At that point, heparin is discontinued.

Physicians must carefully evaluate the feasibility of self-management of dosing, a practice that will continue to expand in the United States in the

21st century. Sawicki¹⁹ reports that during a 6-month follow-up period only 33% of patients who self-monitored and self-dosed achieved a subtherapeutic INR compared with 50% of patients who received traditional anticoagulant management.

Follow up consists of daily protime assessments, warfarin dose adjustments, compliance checks, and physician notifications of patient status. Generally by day 7, patient care is transferred to the primary care physician for the mainte-

Table 4. Outpatient Treatment Protocol for VTE Disease

<ul style="list-style-type: none"> ■ Objective confirmatory test (duplex ultrasonography) ■ Careful screening physical exam ■ Screening laboratory studies (CBC, PT/aPTT, CHEM panel, UA) day 0 ■ Minimum 5-day overlap with LMWH and warfarin ■ Discontinuation of LMWH when INR is therapeutic (2.0-3.0) for 2 consecutive days
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CBC = complete blood count; INR = international normalization ratio; LMWH = low-molecular weight heparin; PT= prothrombin time; aPTT = activated partial-thromboplastin time; CHEM = chemistry panel; UA = urinalysis.

Table 5. Warfarin Management

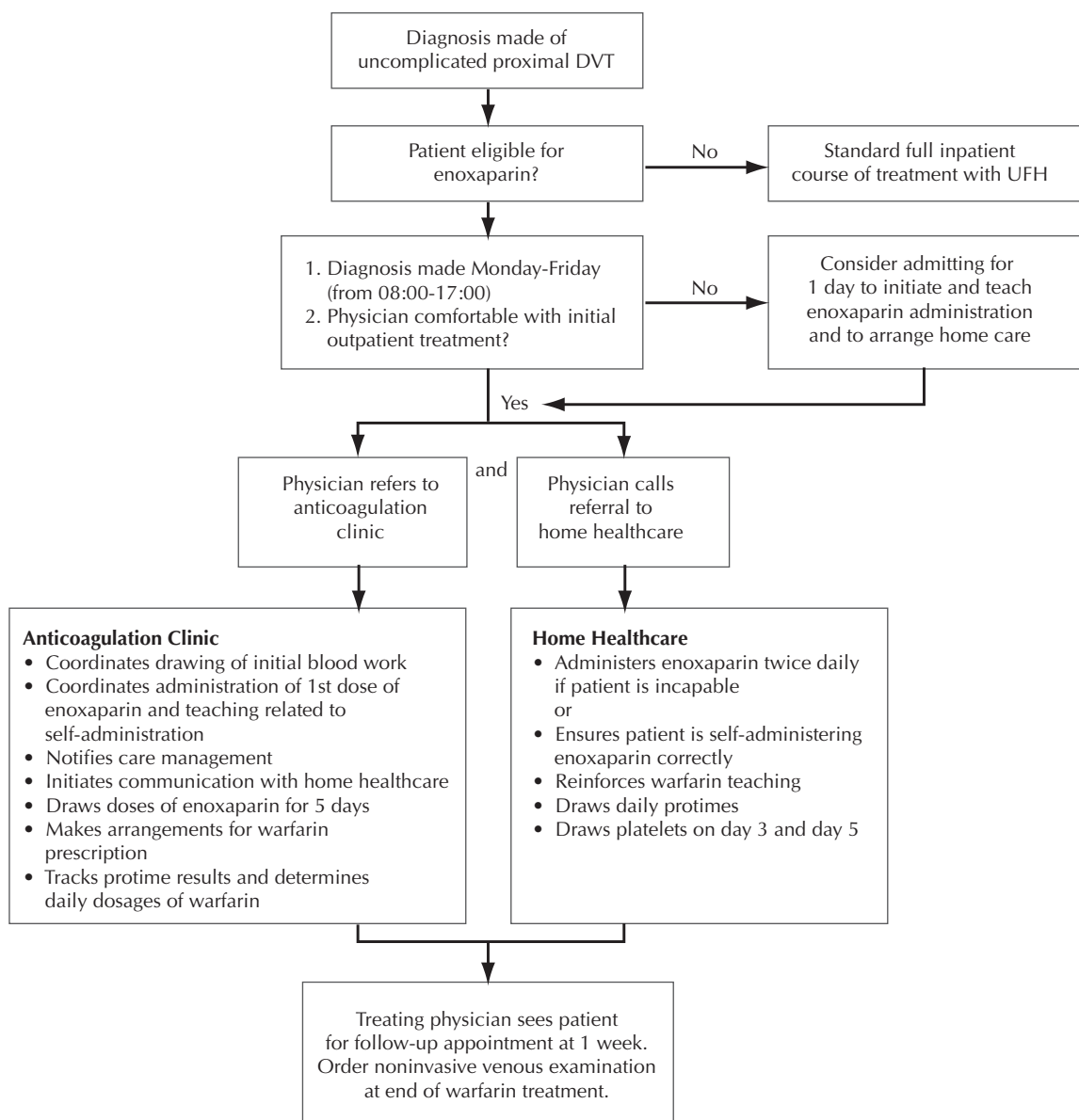
<ul style="list-style-type: none"> ■ Crucial to overall outcome, regardless of specific heparin strategy <ul style="list-style-type: none"> - Start day 0 or day 1 ■ Initiate 5-mg rather than 10-mg warfarin <ul style="list-style-type: none"> - 88% versus 53% therapeutic on day 5 ■ Consider self-management of dosing <ul style="list-style-type: none"> - 33% versus 50% with subtherapeutic INR ■ Duration 3 to 6 months <ul style="list-style-type: none"> - Consider prolonged period (6 months) for idiopathic DVT versus 6 to 8 weeks for DVT 2° reversible RF (ie, surgery)
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DVT = deep vein thrombosis; INR = international normalization ratio; RF = risk factor.

nance phase of anticoagulant therapy. Duration of therapy is usually 3 to 6 months. A prolonged period of 6 months for idiopathic DVT should be considered because some evidence supports increased recurrence rates in

that subgroup. On the other side of the spectrum, a decrease in duration of 6 to 8 weeks should be considered for those patients who have had a reversible risk factor, such as surgery, with no additional comorbidities.

Figure 2. Lovelace Health Systems Protocol for Outpatient DVT Treatment



DVT = deep vein thrombosis, UFH = unfractionated heparin.

**Case Study:
The Lovelace Experience**

The Lovelace program represents a case study for outpatient-based VTE treatment strategies using enoxaparin in an integrated healthcare delivery system. Based in New Mexico, Lovelace Health Systems is a staff model health management organization with approximately 240,000 members and a 235-bed hospital. From its inception, the outpatient DVT program has relied on a clinical protocol to manage VTE events in patients.

The Lovelace protocol for DVT treatment bears similarity to others now in use across the United States (Figure 2). Following diagnosis of uncomplicated proximal DVT by a confirmatory test, the physician will determine whether the patient is eligible for enoxaparin treatment. If the patient meets any of the absolute exclusionary risk factors, the answer is no and the patient receives full inpatient treatment with intravenous UFH. If the answer is yes and the patient is diagnosed during clinic hours, a determination is made as to the physician's comfort level with initial outpatient treatment. Relative exclusionary risk factors discussed previously come into play with physician comfort, as well as psychosocial and insurance factors. If any of these issues are of concern, a patient is admitted for the first day of therapy to initiate LMWH teaching and to further elucidate barriers to outpatient care.

However, if the physician feels without reservation that the patient does not exhibit any extraordinary risk factors, he or she will refer the patient to the anticoagulation clinic. At the anticoagulation clinic, protocol calls for drawing initial laboratory studies, coordinating administration of the first dose of enoxaparin, and providing patient education regarding self-administration. Appropriate patients are referred to case management, including home healthcare. Enoxaparin doses for 5 days

are drawn, warfarin prescriptions arranged, and protime results tracked. Platelet counts are obtained on days 3 and 5.

Patients referred to home health services are administered enoxaparin twice daily by a home health nurse if the patient is incapable of self-administration. If the nurse determines that the patient is self-administering enoxaparin correctly, the nurse reinforces warfarin instruction, draws daily profiles, and obtains platelet counts on days 3 and 5. The treating physician sees the patient for a follow up 1 week after the initiation of therapy.

**Expansion of Protocols to
Emergency Department or
After-Hours Care**

Often the diagnosis of proximal DVT is made after the Lovelace Anticoagulation Clinic has closed. In these situations, it may be possible to treat the patient with enoxaparin, 1 mg/kg subcutaneous and then send the patient home to return in the morning for follow-up care at the anticoagulation clinic. Patients with uncomplicated proximal DVT occurring up to and including the level of the superficial femoral vein are candidates. These patients first need to be evaluated and cleared for discharge from the emergency department (ED) by a physician. If the patient is seen and then released by the ED physician, then the primary treating physician must be contacted directly before the patient leaves (see Table 1 for a complete list of exclusion criteria). To assess a patient's suitability to outpatient care, the protocol outlined in Table 6 is followed.

**Expansion of Outpatient-Based
Protocols to Include
Clinically Stable PE and
Upper-Extremity DVT**

As previously cited, clinical trial and outcomes data suggest no major differences in terms of safety and effi-

cacy between home treatment of patients with clinically stable or submassive PE using LMWH or inpatient therapy with UFH. Based on these findings, physicians with experience in outpatient VTE treatment using LMWH may further risk-stratify patients with PE to determine their suitability for outpatient care.

Clinically stable PE patients can be defined as those with no evidence of hemodynamic instability or severe hypoxia, a ventilation/perfusion mismatch of < 30% on lung scan, no evidence of right ventricle strain by echocardiogram or electrocardiogram, and minimal symptomology, especially in terms of pleurisy (Table 7).

Other patients determined to be good candidates for outpatient care

were those with upper extremity DVT that was idiopathic or exertion related (Paget-Schroetter syndrome) and without evidence of a hypercoagulable state or secondary risk factors.

Prospective Study Findings

After the treatment protocol was well established and varied DVT manifestations were captured within the DVT treatment program, we evaluated specific outcome indicators established during the 18-month start-up period:

- Utilization demographics—determining what percentage of patients were good outpatient candidates

Table 6. Emergency Department Treatment of DVT

Patient history to contain information regarding:	The physical exam must include:
<ul style="list-style-type: none"> ■ Major illness ■ Recent precipitating factors possibly causing DVT ■ Evidence for recent bleeding ■ History of coagulation disorder ■ Recent surgery ■ Age ■ Allergies ■ Medications 	<ul style="list-style-type: none"> ■ Lungs ■ Heart ■ Extremities ■ Rectum/hemocult <p>Labs:</p> <ul style="list-style-type: none"> ■ CBC, UA, PT/aPTT, SMA-12
<p>When patients are evaluated and discharged from the emergency department by a physician, the primary treating physician is contacted before patients can leave.</p> <ul style="list-style-type: none"> ■ Patients need to be informed that the anticoagulation clinic will call them and the treating physician by 10 AM. However, if contact has not been made, then patients must call the anticoagulation clinic directly. The anticoagulation clinic must receive by telephone the following patient information: <ul style="list-style-type: none"> – Name – Medical record number – Telephone number – Diagnosis – Birth date ■ The anticoagulation clinic will verify that they have received the referral from the physician. ■ If the examining emergency department physician is uncertain whether this patient will require admission, the physician may place the patient in the emergency holding area until the patient is evaluated by the hospital or primary physician. 	

DVT = deep vein thrombosis; CBC = complete blood count; UA = urinalysis; PT = prothrombin time; aPTT = activated partial-thromboplastin time; SMA-12 = routine serum chemistry.

- Outcome data, in particular evidence of VTE recurrence or major bleeding
- QOL indices
- Pharmacoeconomic data

During the course of this prospective study from March 1997 to August 1998, which assessed the feasibility of the outpatient-based DVT treatment protocol, it was found that among 167 patients, 61% (n = 102) received some form of outpatient therapy despite very stringent exclusionary risk factors.⁵ Of these 102 outpatients, 70 received complete outpatient therapy, while the remaining 32 had a reduced hospital length of stay.⁵ The other 65 patients were treated in the hospital with intravenous UFH or received LMWH off-protocol (n = 15).

A retrospective analysis in 1996 of 97 hospitalized patients with acute proximal DVT and similar comorbidities formed the foundation for a comparative analysis with more recent findings. Endpoints included primary clinical adverse outcomes, which included recurrent venous thromboembolic events, such as PE, or death from thromboembolism. Secondary clinical adverse outcomes analysis included major bleeding events.

Results in the 1997 to 1998 outpatient group showed 1.9% of patients had a recurrence compared to 4.1% of patients hospitalized in 1996. No major bleeding events occurred in any of the study groups, although minor bleeding and increased symptomology was seen in 2.9% (3/102) of patients treated as outpatients compared to 1.0% (1/97) who were treated as inpatients.

Monitoring in terms of patient satisfaction showed 84% (41/49) of patients rated their overall experience with outpatient care as very good or excellent because of the avoidance of hospital stay, less disruption in routine, and quick return to work. Surprisingly, patients did not take issue with self-injections because they had

support from home healthcare providers. Approximately 67% of providers surveyed (38/58) indicated that the outpatient services resulted in a significant improvement in quality of care.

From a pharmacoeconomic standpoint, hospital length of stay was reduced from 594 days in 1996 to 81 days in 1997 to 1998, with an average length of stay of 5.3 days compared to 0.79 days, respectively. The number of home care visits was about the same between the 2 groups. Overall costs were halved, dropping from \$484,288 in 1996 to \$229,270 in 1997 to 1998. Cost savings per patient were approximately \$2500 with prefilled enoxaparin syringes.

Conclusion

Experience at the Lovelace Anticoagulation Clinic suggests that LMWH (enoxaparin) is both safe and efficacious in the home treatment of VTE in a managed care setting when patient selection criteria and risk stratification strategies are carefully maintained. Moreover, outpatient management is associated with both high patient and provider satisfaction indices while achieving substantial cost savings. The Lovelace outpatient DVT protocol allows successful, step-

Table 7. Expansion of Outpatient-Based Protocols with LMWH to Include Clinically Stable PE and UE DVT

<ul style="list-style-type: none"> ■ Clinically Stable PE Without: <ul style="list-style-type: none"> - Hemodynamic instability - Hypoxia - Ventilation/perfusion mismatch of > 30% on lung scan - Evidence of RV strain by echocardiogram or electrocardiogram - Significant symptomology (ie, pleurisy) ■ UE DVT that is exertion related <ul style="list-style-type: none"> - Paget-Schroetter syndrome

LMWH = low-molecular weight heparin; PE = pulmonary embolism; UE = upper extremity; DVT = deep vein thrombosis; RV = right ventricle.

wise expansion to include after-hours treatment in the ED. In addition, the Lovelace protocol has been successfully extended to include the viable use of outpatient care for other manifestations of VTE such as PE and upper extremity DVT. Future considerations in the management of VTE include the use of once-daily LMWH in the outpatient management of uncomplicated proximal DVT, the routine outpatient management of clinically stable PE, and the use of LMWH in perioperative "bridging" protocols in patients under chronic anticoagulation requiring a nonemergent surgical procedure.

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