Assessment of Outpatient Treatment of Deep-Vein Thrombosis With Low-Molecular-Weight Heparin

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Background: Low-molecular-weight (LMW) heparins are safe and effective for out-of-hospital treatment of acute deep-vein thrombosis (DVT) in a clinical trial setting. We examined the efficacy, safety, and feasibility of home treatment with LMW heparin of consecutive eligible patients with acute DVT in a routine care setting. In addition, we report our experience with patient compliance, acceptance, and satisfaction.

Methods: We performed a prospective cohort study of consecutive patients presenting to 2 thromboembolism clinics in a large Ontario city. Eligible patients were treated with LMW heparin for a minimum of 5 days and with long-term warfarin sodium. Outcomes included the incidences of bleeding and recurrence of DVT and pulmonary embolism and patient satisfaction as determined by a questionnaire.

Results: One hundred thirteen patients with objectively confirmed DVT underwent screening; 89 patients were treated at home with LMW heparin. During the study, 1 patient died of a combination of pulmonary embolism and major bleeding, another patient required admission to the hospital for bleeding, and 5 patients with active malignant disease had recurrent DVT. Of the patients who completed the satisfaction questionnaire, 75 (91%) of 82 were pleased with home treatment; 44 (70%) of 63 felt comfortable self-injecting the LMW heparin; and 71 (92%) of 77 were satisfied with the support and instruction they received during the outpatient treatment.

Conclusions: Outpatient treatment of DVT with LMW heparin is safe, effective, and feasible for most patients and is associated with a high degree of patient satisfaction.
SUBJECTS AND METHODS

STUDY DESIGN

We conducted a prospective cohort study of consecutive outpatients referred to 2 thrombosis clinics at the Hamilton Health Sciences Corporation, Hamilton (McMaster Division and Henderson Division), from June 1, 1996, to June 1, 1997.

POPULATION

Patients who were referred to the clinics with suspected DVT and had the diagnosis confirmed by results of compression ultrasonography or venography were eligible. Patients were routinely treated as outpatients if they were not considered to have a high risk for bleeding, did not have additional medical conditions requiring hospital admission, and were considered capable of self-treatment at home. Because the outpatient clinics operate only between 9 AM and 5 PM on weekdays, 3 patients were initially admitted to the hospital for intravenous heparin therapy and then treated as outpatients. These patients were considered outpatients if they were hospitalized for less than 24 hours.

Whenever possible, the first dose of LMW heparin (dalteparin sodium [Fragmin, Pharmacia and Upjohn, Toronto, Ontario], 100 IU/kg every 12 hours; or tinzaparin sodium [Innohep, Leo Laboratories, Ajax, Ontario], 175 IU/kg per day) was given by the patient or family member in the thrombosis unit. Subcutaneous injections of LMW heparin were continued for a minimum of 5 days and until the international normalized ratio (INR) was within the therapeutic range (2.0-3.0) for 2 consecutive days. Warfarin sodium therapy was commenced in a dose of 5 or 7.5 mg on the day of diagnosis or on the following day. Dosage adjustments were then made to maintain an INR of 2.0 to 3.0, and treatment was continued for a minimum of 3 months.

RESULTS

During the 12-month study, 113 outpatients received a diagnosis of DVT at 1 of the 2 participating hospitals. Of the 113 patients, 11 required admission to the hospital. Reasons for admission included high risk for bleeding (brain metastases [n = 2], and neurosurgery within 3 weeks [n = 1]), pain control (n = 1), underlying medical problems requiring hospital treatment (n = 4), weekend admission (n = 2), and inability to cope at home (n = 1). One 19-year-old patient with DVT of the calf refused subcutaneous injections and admission to the hospital. Another 4 patients returned to their referring hospitals following diagnostic testing and consultation and were not followed up for the 3 months. Of the remaining 97 patients, 8 were treated at home with UF heparin due to cost considerations (unable to pay for LMW heparin, which is covered by insurance if the patient is admitted to the hospital) or inability to obtain LMW heparin. These patients were not included in our analysis.

The remaining 89 patients were treated at home with LMW heparin. Of these, 69 (78%) had proximal vein thrombosis (which extended into the iliac veins in 2 patients), 11 (12%) had isolated calf vein thrombosis, 7 (8%) had upper-extremity thrombi (superior vena cava thrombosis in 1 patient), and 2 (2%) had confirmed pulmonary embolism in addition to DVT.

Patients ranged in age from 18 to 92 years (average, 61.4 years), and 58 (65%) were female. Sixty-four patients (72%) received dalteparin, and 25 (28%) received tinzaparin.

Risk factors for thromboembolic disease included underlying malignant neoplasms (n = 41), recent sur-
therapy (6%) referred to 2 tertiary care centers could be treated at home. Most of our patients had proximal DVT. The event rates were similar to those reported in other contemporary studies. Thus, the rate of fatal embolism was 1%, and the rate of proven recurrent DVT or pulmonary embolism was no higher than 6%. All of the recurrences occurred during oral anticoagulant therapy in patients with active malignant disease. The incidence of major bleeding was low at 1%.

Our questionnaire shows that most patients with DVT prefer out-of-hospital treatment and are comfortable giving their own injections. We had no reason to doubt that patients took their medications as prescribed.

The organization of an outpatient treatment program requires an efficient diagnostic service to confirm or refute the diagnosis of DVT in a timely manner and a commitment from the institution and certain members of the medical staff. We use dedicated, experienced nurse clinicians to educate the patients about DVT and its complications, to teach the patients how to administer LMW heparin subcutaneously, and, if necessary, to help them procure the LMW heparin. This educational process takes an average of 30 minutes. Experienced medical staff must be available on a 24-hour basis to provide support (usually by telephone) to patients who have concerns about self-injection or symptoms compatible with recurrence or side effects of treatment.

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REFERENCES