EM ADVANCES

Clinical outcomes and patient satisfaction of a pharmacist-managed, emergency department–based outpatient treatment program for venous thromboembolic disease

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ABSTRACT

Objective: The purpose of this study was to evaluate the efficacy, safety and patient satisfaction outcomes of our pharmacist-managed, emergency department (ED)–based outpatient treatment program for venous thromboembolism (VTE) disease.

Methods: We conducted a prospective cohort study of all patients who were enrolled in the Vancouver General Hospital (VGH) outpatient VTE treatment program over a 7-year period (1999–2006). Efficacy outcomes include recurrent VTE events at 3 and 6 months following discharge from the program. Safety evaluation included major and minor bleeding complications and the development of thrombocytopenia during the acute phase of therapy. Patient satisfaction was assessed using an 18-question patient satisfaction survey, which was mailed to all patients following discharge from the program.

Results: Overall, 305 patients were included in the study. Of the 260 evaluable patients, 2 patients (0.8%, 95% confidence interval [CI] 0.2–2.7) experienced a recurrent VTE at 3 months and 5 patients (1.9%, 95% CI 0.8–4.4) had a recurrence at 6 months. One patient (0.3%, 95% CI 0.1–1.8) experienced a major bleeding complication. Seven patients (2.3%, 95% CI 1.1–4.7) experienced a minor bleeding complication and no patient developed thrombocytopenia. Overall, 96.1% were comfortable having their condition treated as an outpatient and 85.7% felt it was more convenient to return to hospital daily for medications and assessment than to be admitted to hospital. Finally, 96.9% of respondents were very satisfied or satisfied with the treatment they received in the outpatient program, and 96.1% would enroll again if future treatment was indicated.

Conclusion: Our pharmacist-managed, ED-based outpatient treatment program for VTE disease is safe, effective and achieves a high level of patient satisfaction.

Key words: deep vein thrombosis, pulmonary embolism, anticoagulation, outpatient, pharmacist, emergency department

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RÉSUMÉ

Objectif : Cette étude visait à évaluer l'efficacité, la sécurité et la satisfaction des patients de notre programme de soins ambulatoires pour la thromboembolie veineuse (TEV), programme géré par un pharmacien dans un service d'urgence.

Méthodes : Nous avons réalisé une étude de cohorte prospective de tous les patients qui étaient inscrits au programme de prise en charge ambulatoire de la TEV à l'hôpital général de Vancouver sur une période de 7 ans (de 1999 à 2006). Les principales mesures de l'efficacité comprenaient des épisodes récurrents de TEV trois et six mois après la fin de leur participation au programme. La sécurité a été évaluée en fonction des épisodes d'hémorragie grave et de saignements mineurs ainsi que de la survenue d'une thrombopénie pendant la phase aiguë de traitement. Un sondage de 18 questions envoyé par la poste à tous les patients après la cessation de leur participation au programme a permis d'évaluer la satisfaction des patients.

Résultats : Dans l'ensemble, 305 patients ont été inclus dans l'étude. Parmi les 260 patients évaluables, deux [0,8 %, intervalle de confiance (IC) à 95 %, 0,2 à 2,7] ont eu un épisode récurrent de TEV après trois mois, et cinq patients (1,9 %, IC à 95 %, 0,8 à 4,4) ont subi une récurrence à six mois. Un patient (0,3 %, IC à 95 %, 0,1 à 1,8) a eu une hémorragie grave. Chez sept patients (2,3 %, IC à 95 %, 1,1 à 4,7), des saignements mineurs sont survenus et aucun patient n'a développé de thrombopénie. Au total, 96,1 % ne voyaient pas d'inconvénients à être traités en externe, et 85,7 % des patients préféraient se rendre à l'hôpital quotidiennement pour l'administration de leurs médicaments et une évaluation plutôt que d'être hospitalisés. Enfin, 96,9 % des répondants étaient très satisfaits ou satisfaits du traitement reçu dans le cadre du programme de soins ambulatoires, et 96,1 % s'y inscriraient de nouveau si un traitement futur était indiqué.

Conclusion : Notre programme de soins ambulatoires pour la TEV géré par un pharmacien dans un service d'urgence est sécuritaire, efficace et suscite un degré élevé de satisfaction des patients.

Introduction

Venous thromboembolism (VTE) disease has an estimated annual incidence of 67 per 100 000 among the general population.[1,2] Traditionally, patients diagnosed with deep vein thrombosis (DVT) or pulmonary embolism (PE) required a 5- to 7-day hospitalization to initiate treatment.[3,4] In many cases these patients are otherwise healthy and clinically stable, and are admitted for no other reason than to receive continuous infusion and to monitor intravenous unfractionated heparin and titrate their warfarin dosing. Low molecular–weight heparins (LMWHs), derived from the chemical or enzymatic depolymerization of unfractionated heparin, have a more predictable anticoagulant response and a longer elimination half-life allowing for once daily subcutaneous administration.[5,6] Clinical trials have demonstrated outpatient treatment with LMWH is as safe, as effective and as economically attractive as inpatient treatment using unfractionated heparin for the initial management of DVT or PE.[7–12] As a result, outpatient management of DVT and PE has expanded to various settings and become the standard of care for eligible patients.[13–19]

Many models exist for the provision of outpatient care of patients with DVT or PE.[20] The most common programs involve either teaching patients to self-inject LMWH at home or having patients return to an ambulatory care clinic or hospital for medication administration and monitoring. Both strategies have merits and in most cases the preferred strategy is based on available resources to ensure efficient and safe outpatient care. Pharmacist-managed anticoagulation has been implemented for some outpatient models.[21–25]

In June 1999, the Vancouver General Hospital (VGH) implemented an outpatient DVT treatment program, which was unique in that it was a pharmacist-managed, emergency department (ED)–based program into which most patients were enrolled by emergency physicians without requiring hospitalization. Patients returned to hospital each day for LMWH administration and monitoring and were contacted by telephone by a clinical pharmacist for warfarin titration. Because our program involved a different setting than most outpatient programs, it was important to ensure that both efficacy and safety as well as patient satisfaction were maintained.

The purpose of this study was to evaluate the efficacy, safety and patient satisfaction of our pharmacist-managed, ED-based outpatient treatment program for VTE.

Methods

Setting

VGH is a Canadian, tertiary care, university-affiliated

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teaching hospital and referral centre for the province of British Columbia. The ED treats approximately 63 000 patients annually and is staffed by physicians who are certified in emergency medicine by the Royal College of Physicians and Surgeons of Canada. The VGH outpatient DVT treatment program is a pharmacist-managed, ED-based program that enrolls patients 7 days a week, 24 hours a day.

Design

The study protocol was approved by the Ethics Board at the University of British Columbia and the VGH Research Advisory Committee. We conducted a prospective cohort study of patients enrolled in the VGH outpatient VTE treatment program over a 7-year period (1999–2006).

Study population

All patients accepted into the VGH outpatient VTE treatment program were eligible to participate in our study. A majority of patients were enrolled in the ED by emergency physicians and did not spend any time in the hospital. Patients were deemed eligible for outpatient treatment if they had a radiographically-confirmed DVT by compression ultrasonography or stable PE confirmed by ventilation-perfusion (V/Q) scan or spiral CT. In addition, patients had to agree to return to hospital each day for LMWH injection and laboratory monitoring and to be reachable at home for instructions on warfarin dosing each day. All patients were required to have a primary care provider who could ensure warfarin monitoring after discharge from the outpatient VTE program. Patients were excluded from the program for the following reasons: active bleeding, recent gastrointestinal or genitourinary bleed (1 mo), recent trauma or major surgery (1 mo), recent hemorrhagic stroke or intracranial bleed (3 mo), renal dysfunction (creatinine clearance < 0.5 mL/s), severe uncontrolled hypertension (systolic blood pressure > 180 mm Hg or diastolic blood pressure > 110 mm Hg), platelet count $< 50 \times 10^9$/L, allergy to heparin, history of heparin-induced thrombocytopenia, known thrombophilia or pregnancy.

Once deemed eligible for outpatient therapy, patients received baseline blood work followed by daily subcutaneous administration of either tinzaparin (Innohep, Leo Laboratories, Ajax, Ontario) 175 U/kg (1999–2003) or dalteparin (Fragmin, Pfizer Canada, Kirkland, Quebec) 200 U/kg (2004–2006) administered by a nurse, and warfarin 10 mg orally (PO). Patients who were > 75 years old and either weighed < 50 kg or received medications known to interact with warfarin were given an initial warfarin dose of 7.5 mg. At the time of enrolment, each patient was provided with a written education package that outlined information about DVT and PE and also included information about anticoagulants (LMWH and warfarin). Within 24 hours of enrolment, an education session was conducted by the clinical pharmacist, who outlined information in the package and answered any questions. The duration of warfarin therapy was determined based on current guidelines.[26]

Patients returned to hospital daily for LMWH administration, laboratory monitoring (complete blood count and International Normalized Ratio [INR]) and bleeding assessment. On weekdays, patients returned to the medical daycare centre, and on weekends they returned to the ED. After the first day, subsequent warfarin doses were determined by the clinical pharmacist until the INR was therapeutic. LMWH injections continued daily for a minimum of 5 days and until the INR was within the therapeutic range (2–3) for 2 consecutive days. At the time of discharge from the program, the clinical pharmacist transferred care both verbally and by written discharge letter to the family physician who continued to monitor the patient's anticoagulation and clinical progress for the duration of the treatment. Patients were also informed that they would receive a patient satisfaction survey by mail within 7 days and be contacted by telephone at 3 and 6 months following discharge from the program to determine recurrence.

Study outcomes

The primary efficacy outcome was recurrent VTE at 3 and 6 months following discharge from the program. VTE recurrence was diagnosed if new clinical symptoms developed and were confirmed on compression ultrasonography, V/Q scan or spiral CT as a new thrombus or an extension of a previous thrombus. Safety evaluation included screening for major or minor bleeding, or the development of thrombocytopenia during the period of treatment in the program. Major bleeding was defined as intracranial or retroperitoneal bleeding resulting in a hemoglobin drop of greater than 20 g/L or requiring transfusion of 2 or more units of blood. Thrombocytopenia was defined as a reduction in platelets by 50% from baseline or to less than 50×10^9/L.

The secondary outcome was assessment of patient satisfaction using an 18-question patient satisfaction survey. Patients were provided with a self-addressed stamped envelope and asked to anonymously complete and return the survey. In addition to overall satisfaction with the outpatient program, the survey was designed to evaluate

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specific aspects of the program, which included the comfort and convenience of having the condition treated at home, the knowledge and care provided by hospital staff, the education provided and the efficiency of hospital visits (Appendix 1).

Data management and statistical methods

All data were entered into an Excel (Microsoft Corp., Redmond, Washington) database for analysis. Categorical data are presented as percentages of frequency of occurrence. Continuous data are presented as means with standard deviations (SDs). Binomial 95% confidence intervals (CIs) for proportions were calculated using Stat Version 5.0 Mac (StataCorp LP, College Station, Texas).

Results

Three hundred and five patients were enrolled in the outpatient DVT treatment program and were included in our study. Direct enrolment into the program occurred in 269 (88.2%) patients. Of the study patients, 36 (11.8%) patients received initial inpatient treatment prior to enrolment for localized thrombolysis for upper extremity DVT or ileofemoral DVT (n = 15), stabilization of symptomatic PE (n = 13) or additional diagnostic testing (n = 8). The mean age of subjects was 55.2 (SD 18.9) years and 48% of subjects were female. Two hundred and twenty-three (73.1%) patients experienced lower extremity proximal vein thrombosis, 51 (16.7%) had pulmonary embolism, 16 (5.2%) had upper extremity thrombosis and 15 (4.9%) had isolated calf vein thrombosis. Risk factors for VTE were present in 181 (59.3%) patients and included injury or recent orthopedic surgery (n = 70), previous DVT or PE (n = 39), malignancy (n = 37), immobilization (n = 18), and hormone replacement or oral contraceptive therapy (n = 17). The mean duration of treatment in the outpatient program was 5.6 (SD 1.2) days.

For the efficacy evaluation, follow-up was achieved in 260 of the 305 patients (85.2%). Forty-five patients were lost to follow-up. We were unable to reach 43 by telephone at the follow-up assessment times and 2 patients had died from cancer. Of the evaluable patients, 2 (0.8%, 95% CI 0.2–2.7) experienced a recurrent VTE at 3 months, and 5 patients (1.9%, 95% CI 0.8–4.4) had recurrence at 6 months. In all 5 cases, warfarin therapy had been discontinued after 3 months of therapy.

All 305 patients were included in the safety assessment. One patient (0.3%, 95% CI 0.1–1.8) experienced a major bleeding complication with an INR of 1.89. This patient had a known uterine fibroid and the risk of bleeding was discussed with her and her gynecologist prior to enrolment. Seven patients (2.3%, 95% CI 1.1–4.7) experienced a minor bleeding complication. These included hematuria (n = 3), epistaxis (n = 2), bleeding gums (n = 1) and injection site hematoma (n = 1). None of the patients with minor bleeding complications had a supratherapeutic INR. No patient developed thrombocytopenia.

Patient satisfaction surveys were returned by 231 of 305 patients, resulting in a 75.7% response rate. Complete results are outlined in Table 1. Overall, 96.1% of respondents were comfortable having their condition treated as an outpatient and 85.7% felt it was more convenient to return to hospital daily for medications and assessment than to be admitted to hospital. Most respondents (98.2%) felt that the medical daycare centre nursing staff was courteous and understanding, and they were very satisfied or satisfied (97.4%) with the education provided by the clinical pharmacist. Overall, 96.9% of respondents were very satisfied or satisfied with the treatment they received in the outpatient program, and 96.1% would enroll again if future treatment were indicated. If taught, 51.5% of respondents were willing to self-inject LMWH at home if future treatment were indicated.

Discussion

Outpatient management of VTE disease has become the standard of care for eligible patients in many institutions. Despite the existence of different models for the provision of outpatient care, it is important to ensure that efficacy, safety and patient satisfaction can be maintained in all practice settings. Although outcomes have been reported for outpatient management of VTE disease, to our knowledge this study is the first to demonstrate that a pharmacist-managed, ED-based outpatient program is safe, effective and achieves a high level of patient satisfaction. Initial therapy with LMWH and warfarin resulted in 1 major bleeding complication and no cases of thrombocytopenia. Only 7 minor bleeds were reported, all in patients with subtherapeutic or therapeutic INRs. Two cases (0.8%) of recurrent VTE were identified at 3 months and only 5 (1.9%) at 6 months following discharge from the program. These efficacy and safety outcomes are consistent with reported rates from larger randomized trials and assure us that we are able to provide safe and effective care within the current structure of our program.[7,8,27]

Overall, 1689 admission days were avoided by having patients treated in this program. Although not the purpose of this study, previous groups have evaluated the economic

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Table 1. Patient satisfaction survey results, *n* = 231

Question	Response	% of patients
At the time the blood clot was diagnosed, were you satisfied with the explanation given to you about:		
Why procedures or tests were done?	Yes	96.9
	No	3.1
What was wrong with you?	Yes	93.1
	No	6.9
Your follow-up arrangements in the DVT program?	Yes	95.2
	No	4.8
Do you understand why your condition was treated at home rather than having to stay in hospital?	Yes	96.1
	No	3.9
Do you feel you should have been admitted to hospital?	Yes	12.1
	No	87.9
Were any questions you had regarding your treatment adequately answered by VGH staff?	Yes	91.3
	No	8.7
It was more convenient to return to hospital to get your injections than having to stay in hospital?	Yes	85.7
	No	6.5
	Neutral	7.8
When you returned for treatment on the weekend, how satisfied were you with how long you had to wait to receive treatment in the ED?	Very satisfied	36.4
	Satisfied	36.8
	Neutral	12.1
	Unsatisfied	10.0
	Very unsatisfied	4.8
Were the ED staff courteous and understanding?	Yes	93.9
	No	6.1
When you returned for treatment on the weekdays, how satisfied were you with how long you had to wait to receive treatment in the medical daycare?	Very satisfied	61.9
	Satisfied	29.4
	Neutral	4.3
	Unsatisfied	3.0
	Very unsatisfied	1.3
Were the medical daycare staff courteous and understanding?	Yes	98.2
	No	1.8
Did you have any problems finding the medical daycare?	Yes	15.2
	No	84.8
Was it convenient for you to be called at home to receive information on what dose of warfarin to take?	Yes	97.0
	No	3.0
Were there any days during your treatment with warfarin when you were not sure what dose you were supposed to take?	Yes	3.9
	No	96.1
Were the written instructions and information provided in the DVT package clear, easy to read and understand?	Yes	98.7
	No	2.3
How satisfied were you with the teaching provided by the clinical pharmacist?	Very satisfied	78.8
	Satisfied	18.6
	Neutral	2.2
	Unsatisfied	0.4
	Very unsatisfied	0.0
Were you comfortable having your condition treated as an outpatient?	Yes	96.1
	No	3.9
Overall, how satisfied were you with the treatment you received in the outpatient DVT program?	Very satisfied	72.2
	Satisfied	24.7
	Neutral	2.2
	Unsatisfied	0.9
	Very unsatisfied	0.0
Should you develop another clot, would you want to take part in the same outpatient DVT program?	Yes	96.1
	No	3.9
If taught, would you be willing to give yourself injections at home?	Yes	51.5
	No	48.5

DVT = deep vein thrombosis; VGH = Vancouver General Hospital; ED = emergency department.

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implications of outpatient versus inpatient care for DVT and PE in Canada. Using data from Ontario, Boucher and colleagues performed a cost-minimization analysis and estimated that institutional cost savings associated with outpatient care of VTE disease was $2578 for every patient enrolled.[11] Based on this analysis, we estimate that treating the 305 patients in our outpatient program has resulted in a cost saving to the institution of more than $786 000. In addition to the economic implications, the impact of an ED-based program on overcrowding cannot be quantified. However, the ED-based outpatient program was designed to ensure the continuity of acute care of this patient population and resulted in rapid discharge from the ED thus eliminating the significant length of ED stay these patients would have incurred if hospital admission were required.

Very few studies have attempted to describe patient satisfaction of outpatient care of VTE disease. Harrison and colleagues conducted a patient satisfaction survey on 89 patients treated at home with LMWH for DVT.[28] Results of this survey indicated that 91% were pleased with home treatment and 92% were satisfied with the support and instruction they received with their outpatient treatment. Seventy percent of patients were comfortable with self-injecting LMWH at home. Although our study evaluated care in a different outpatient model, patient satisfaction was also high in our outpatient program.

Limitations

Our study has limitations. First, using clinical features of recurrent VTE to dictate any need for radiographic imaging by which to confirm recurrence may underrepresent the rate of recurrence. A higher recurrent VTE rate may have been seen if all patients were imaged at 3 and 6 months. However, it could be argued that symptom-directed investigations for recurrence most closely reflect clinical practice. Second, the patient satisfaction survey was an unvalidated assessment tool. Unfortunately no validated survey was identified for outpatient DVT treatment thus we had to rely on developing our own. Many of the questions were developed to address many aspects of the program and, although unvalidated, we are confident the results are an accurate reflection of patient satisfaction. Finally, after the first 5 years of the program, the LMWH used in the program changed from tinzaparin to dalteparin. This change was owing to a number of clinical and economic reasons based on overall LMWH use throughout the institution. A recent comparative trial demonstrated no apparent differences in efficacy and safety between tinzaparin and dalteparin for the treatment of VTE disease and we are confident that this switch did not result in any change in clinical outcomes in the program.[29]

Conclusion

Our pharmacist-managed, ED-based outpatient treatment program for VTE disease is safe and effective, and is able to achieve a high level of patient satisfaction.

Competing interests: None declared.

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Appendix 1. Vancouver General Hospital (VGH) Outpatient DVT Treatment Program patient satisfaction survey

Outpatient Deep Vein Thrombosis (DVT) Program Patient Satisfaction Survey

Thank you for taking the time to complete this survey. Your participation will help us improve patient care and the quality of the Outpatient DVT Program. All results are anonymous and will be kept strictly confidential.

Please place a check in the circle of your choice.

1. At the time the blood clot was diagnosed, were you satisfied with the explanations given to you about:	
a) Why procedures or tests were being done?	O Yes O No
b) What was wrong with you (diagnosis)?	O Yes O No
c) Your follow-up arrangements in the outpatient DVT program?	O Yes O No
2. Do you understand why your condition was treated at home rather than having to stay in the hospital?	O Yes O No
3. Do you feel you should have been admitted to the hospital?	O Yes O No
4. Were any questions you had regarding your treatment adequately answered by VGH staff?	O Yes O No
5. It was more convenient to return to the hospital to get your injections than having to stay in the hospital?	O Yes, strongly agree O Yes, agree O Neutral O No, disagree O No, strongly disagree
6. When you returned for treatment on the weekend, how satisfied were you with how long you had to wait to receive treatment in the emergency department?	O Very satisfied O Satisfied O Neutral O Unsatisfied O Very unsatisfied
7. Were the emergency department staff courteous and understanding?	O Yes O No
8. When you returned for treatment on weekdays, how satisfied were you with how long you had to wait to receive treatment in the medical daycare centre?	O Very satisfied O Satisfied O Neutral O Unsatisfied O Very unsatisfied
9. Were the medical daycare staff courteous and understanding?	O Yes O No
10. Did you have any problems finding the medical daycare centre?	O Yes O No
11. Was it convenient to be called at home to receive information on what dose (how many pills) of warfarin to take?	O Yes O No
12. Were there any days during your treatment with warfarin when you were not sure what dose or how many pills you were supposed to be taking?	O Yes O No
13. Were the written instructions and information provided in the DVT package clear and easy to read and understand?	O Yes O No
14. How satisfied were you with the teaching provided by the clinical pharmacist?	O Very satisfied O Satisfied O Neutral O Unsatisfied O Very unsatisfied
15. Were you comfortable having your condition treated as an outpatient?	O Yes O No
16. Overall, how satisfied were you with the treatment you received in the Outpatient DVT program?	O Very satisfied O Satisfied O Neutral O Unsatisfied O Very unsatisfied
17. Should you develop another clot, would you want to take part in the same Outpatient DVT program?	O Yes O No
18. If taught, would you be willing to give yourself injections at home?	O Yes O No
19. Comments (including suggestions for improving our service)	

Thank you for completing this questionnaire.
Please return in the self-addressed envelope at your earliest convenience

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