

Still unmet problems with low molecular weight heparin prophylaxis of venous thromboembolism. An Italian survey

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ABSTRACT

Background: a survey was launched to assess the challenges that Italian patients and physicians face with home prophylaxis using low-molecular-weight heparin (LMWH), promoted by the «Arianna Anticoagulazione» Foundation, Bologna, Italy.

Methods: conducted between March and October 2024, the survey targeted readers of the «anticoagulazione.it» website, distributed through a newsletter and social media. There were two different surveys, one addressed to patients\caregivers and the other to physicians.

Results: the professional survey revealed significant uncertainties about managing chronic patients, with over half of physicians identifying them as a «gray area.» A third of clinicians were unsure about the duration and necessity of home prophylaxis for acute patients. Arbitrary suspension of treatment was reported by a significantly lower proportion of patients\caregivers than professionals (4% vs 38%; $p < 0.0001$).

Conclusions: home prophylaxis presents challenges, especially for chronic patients, acute patients treated at home, and those with specific conditions (e.g., renal insufficiency or extreme body weight). The lack of clear guidelines and the widespread use of LMWH outside standard recommendations highlights the need for large-scale clinical trials to address these issues. Discrepancy in compliance reported by patients\caregivers and clinicians underline the need for improved professional-patient communication.

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Key words: thromboprophylaxis; heparin; venous thromboembolism.

Contributions: all the authors contributed equally, read and approved the final version of the manuscript and agreed to be accountable for all aspects of the work.

Conflict of interest: the authors declare no competing interests.

Availability of data and materials: the datasets used and/or analysed during the current study are available upon reasonable request from the corresponding author.

Funding: funded by Arianna Anticoagulazione Foundation which received an unrestricted grant from Sanofi to conduct the online survey.

Acknowledgments: the authors thank Emilia Antonucci for reviewing the manuscript, Silvia Malosio and Marta Bottagisio for technical support in developing and spreading the survey through the portal anticoagulazione.it and retrieving the data.

Ethics approval: not applicable.

Received: 28 February 2025.

Accepted: 25 August 2025.

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Bleeding, Thrombosis and Vascular Biology 2025; 4:177

doi:10.4081/btvb.2025.177

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Introduction

Deep vein thrombosis (DVT) and pulmonary embolism (PE), collectively referred to as venous thromboembolism (VTE), are common, serious, and potentially life-threatening diseases. The incidence of VTE in the general population in Europe and North America ranges from 1.0 to 1.83 per 1,000 population in population-based studies.^{1,2} VTE is predominantly a disease of the elderly, as its incidence increases significantly with age.³ In many cases, the occurrence of VTE is due to hospitalization. In a population-based study, 37% of VTE occurred during hospitalization; however, 16% of those VTE occurred at home had been hospitalized within three months.² In an analysis of California patients hospitalized with first-time VTE, 23% had surgery within 2 months, 15% had VTE during hospitalization for medical illness, 2% had major trauma, 18% had cancer, and 41% were idiopathic.⁴

In fact, hospitalization is the most important risk factor for the development of thromboembolic complications, and the risk continues beyond hospitalization, especially within the first six weeks after discharge.⁵ It is estimated that at least 50% of VTE episodes are diagnosed after discharge from hospital and this can occur up to three months after discharge.^{6,7}

Thromboprophylaxis is the most effective strategy for reducing VTE complications. It is important to ensure that all individuals at risk receive effective and safe VTE prophylaxis not only during hospital stay but also at home, especially in an era when patients are being discharged from hospital as early as possible to reduce the risks associated with prolonged hospitalization. While in-hospital VTE prophylaxis is currently well established

according to the specific needs of different departments, there are still more uncertainties and problems in the real-life practice of home VTE prophylaxis. The link between hospital and home VTE prophylaxis is a critical moment for correct prophylaxis and patient safety.

In this article, we would like to address some of the issues that may affect this link and hinder effective and safe VTE prophylaxis at home.

In-hospital prophylaxis

Antithrombotic prophylaxis is a critically important medical intervention to reduce VTE morbidity and mortality in patients during and after hospitalization for surgery or medical illness. Antithrombotic prophylaxis significantly reduces VTE risk but does not eliminate it completely. A recent study by the American College of Surgeons showed a 42% reduction in the odds of a 30-day postoperative VTE events in high-risk general surgery patients who received prophylaxis.⁸ Less favourable appear to be the results of prophylaxis in hospitalized medical patients. A systematic review of randomized trials supported by the National Institute for Health Research (NIHR), reported an approximately 30% reduction in symptomatic VTE with intermediate dose low-molecular weight heparin (LMWH) prophylaxis, but with an increased incidence of major bleeding. No difference was found in all-cause mortality.⁹

Risk stratification for VTE prevention is essential, and validated tools are available for physicians. Specific clinical variables and demographics, such as increasing age, BMI, family or personal history of VTE, type, and duration of surgery, and need for postoperative transfusion are included in the scores for stratification of VTE risk. Among the validated tools available, the Caprini score is widely used for assessing VTE risk in surgical patients,¹⁰ for hospitalized medical patients Padua Prediction¹¹ and IM-PROVE¹² scores are commonly used.

Despite clear recommendations on the type, dose, and even duration, the prophylaxis remains underused, as shown by many studies. It has been reported that approximately 50% of at-risk patients receive no (or suboptimal) pharmacologic prophylaxis.¹³ A recent study found that over one-third of high-risk patients (36%) received inappropriate or no prophylaxis.¹⁴ An international survey in 2008 showed that only 39.5% of hospitalized high-risk patients received prophylaxis.¹⁵ Over the years, efforts have been made to improve prophylaxis in hospitalized patients, including clinical decision support systems with electronic alerts. These electronic systems that automatically remind physicians of the need for VTE prophylaxis, along with continuing medical education on VTE prevention, have proven useful.¹⁶ These systems can help but may suffer from «alert fatigue» and do not guarantee a culture of prevention.¹⁷

It should be recognized that ordering appropriate therapy does not ensure its administration and missed doses are common. A study in hospitalized patients found that approximately 10% of ordered doses of pharmacologic VTE prophylaxis were not administered, 44% due to patients' refusal.¹⁸ Several studies have shown that missed doses of inpatient chemoprophylaxis are common and associated with VTE occurrence.¹⁹⁻²¹ Recently, a concept of «defect-free» VTE prophylaxis has been proposed,²² which includes several important aspects: clinicians must assess patients' risk for VTE and prescribe the appropriate therapy in relation to

each patient's risk; patients must understand the role and importance of prophylaxis and accept the prescribed therapy; and nurses must administer the therapy as prescribed. However, these steps are not always well-coordinated. For example, the American College of Surgeons study showed that only 32% of over 4,200 high-risk surgical patients had a «perfect» in hospital VTE prophylaxis order, and missing orders were associated to higher VTE rates.⁸

Post-discharge prophylaxis

A significant number of VTE events occur after hospital discharge, especially following major orthopedic surgeries like total hip arthroplasty, where 75% of VTEs occur post-hospitalization.^{23,24} In turn, a short course of prophylaxis in hospitalized medical patients may be insufficient to prevent late symptomatic VTE events.²⁵ The transition from hospital to home care is certainly a vulnerable period for patients requiring careful coordination.²⁶ Discharge instructions are often incomplete or missing.²⁷ Clear and complete information should include the type, dose, and duration of any chemoprophylaxis to be continued at home, but they are frequently omitted. An analysis of thromboprophylaxis rates in a US medical centre showed that 66.1% of discharged patients received inadequate prophylaxis: 38.4% received no prophylaxis at all, 16.7% had an inappropriate duration of prophylaxis according to current guidelines, and 6.3% received an inappropriate dosage.²⁸

The problem of non-optimal patient compliance with post-discharge VTE prophylaxis is well known and has been studied especially in patients after high-risk orthopedic surgery.^{29,30} The reasons include problems related to purchase, patient education, information on the importance of continuing prophylaxis at home, and patient training to self-administer LMWH injections, which is the most commonly used type of drug for VTE prophylaxis, at least in our country. A study published in 2010 showed a non-adherence rate ranging from 13% to 21% in outpatients receiving prophylaxis with LMWH after major orthopedic surgery.³¹ Non-adherent patients missed between 38% and 53% of LMWH injections, mainly due to forgetfulness, fear of self-administered LMWH injections, or occurrence of side effects (usually hematomas at the injection site).³²

An Italian survey on home prophylaxis with LMWH

To assess the problems that Italian patients and physicians may face with home prophylaxis with LMWH, a survey was launched among the readers of the «anticoagulazione.it» website, sponsored and funded by the «Arianna Anticoagulazione» Foundation, Bologna, Italy. There were two different surveys, one addressed to patients and the other to physicians (*Supplementary Material*).

Methods

The survey was conducted between March 2024 and October 2024. Participants were recruited through a weekly newsletter which is sent to about 6,000 registered users of the website, almost equally distributed among patients/caregivers and professionals

(clinicians, nurses, pharmacists, *etc.*). To maximize outreach and avoid limiting the sample to only active site users, posts were shared on our social media channels (e.g., Facebook and LinkedIn). These posts were additionally sponsored to reach users beyond those already following our pages. These combined efforts aimed to broaden the reach and engage a more diverse pool of respondents.

Statistical analysis

A descriptive analysis was performed, categorical variables are expressed as frequencies and percentages and were compared using the Chi-square test or Fisher exact test, as appropriate. The data were analyzed with the use of SPSS software for Windows, V.26 (IBM, Armonk, NY, USA).

Results

Patients survey

The patients (n=154) and caregivers (n=23) who participated in the survey lived in different geographical areas of Italy, but more frequently in the north (north 115, central 28, south and islands 34). The most common indication for home prophylaxis was the continuation of treatment started in hospital after surgery (74/177; 42%; 95% CI 34%-49%), followed by medical problems occurring at home (without hospitalization) (52/177; 29%; 95%CI 23%-36%), continuation of treatment started in hospital for medical illness (33/177; 19%; 95%CI 13%-25%), and home prophylaxis for orthopedic problems (trauma, bandages, *etc.*) (18/177; 10%; 95% CI 6%-15%). In most cases (154/177; 87%; 95% CI 0.8114 to 0.9158), chemoprophylaxis was prescribed by a hospital physician (even without hospitalization), in 7% of cases (13/177; 95%CI 4%-12%) it was prescribed in an outpatient clinic, and in only 6% of cases (10/177; 95%CI 3%-10%) it was a decision of the family physician. In the majority of cases (170/177; 96%;

95%CI 92-98%), participants reported that they had adhered to the prescription, including for the duration of treatment. Only 7 patients (4%) admitted that they had stopped the prophylaxis before it was prescribed. Three out of seven declared it was mainly due to difficulties in obtaining drug prescription by general practitioners (GP) and drug dispensing by the Italian National Health Service. This is likely due to strict regional rules on heparin prescriptions by GP which vary from one region to the other in Italy. Two of the three patients were from southern Italy and one from central Italy. Only two patients cited difficulties with injections or the occurrence of side effects (pain) as a reason for discontinuation (Table 1). However, these problems (pain and/or bruising at the injection site) were reported by eleven more patients who continued the treatment. Six people complained about the lack of proper instructions on the injection technique. In a few cases, patients were unable to self-administer the drug and needed the help of a nurse.

Professional survey

One hundred fifty-three health system professionals took part in the survey, living in 17 out of the 20 Italian regions. In most cases, they were hospital doctors (<5% were surgeons), and only 10% of cases were family doctors (15/153; 95%CI 6-16%). Differently from what was reported by patients, about 40% of doctors (58/153; 95%CI 30-46%) declared to have observed frequent arbitrary discontinuation of chemoprophylaxis by patients, which was ascribed to an insufficient perception of the seriousness of thromboembolic complications, as well as to a deficit in doctor-to-patient communication, by 74% of responders (43/58; 95%CI 61-85%). Seventeen percent of physicians (10/58; 95%CI 9-29%) attributed to fear of, or problems in self-administered injections the reason for discontinuation of treatment, while 9% of them (5/58; 95%CI 3-19%) believe that patients fear the risk of bleeding (Table 2). The difference between the percentages of arbitrary suspension of treatment reported by patients/caregivers or doctors was highly significant (4% vs 38%; $p < 0.0001$).

Table 1. Incorrect prophylaxis reported by patients.

Patient	Reason for early discontinuation	Possible intervention to avoid early discontinuation
Patient #1	Difficulty in obtaining the drug	Reduce Italian regional limitations to heparin prescription
Patient #2	Difficulty in obtaining the drug (cost) and lack of proper perception of thrombotic risk	Reduce Italian regional limitations to heparin prescription. Improve patient's education/communication.
Patient #3	Difficulty in obtaining the drug and lack of proper perception of thrombotic risk	Reduce Italian regional limitations to heparin prescription. Improve patient's education/communication.
Patient #4	Pain at the site of injection	Give proper instructions on the injection technique
Patient #5	Difficulty in injecting	Give proper instructions on the injection technique
Patient #6	Not specified	Not applicable
Patient #7	Lack of proper perception of thrombotic risk and mild discomfort at the site of injection	Improve patient's education/communication and give proper instructions on the injection technique

Table 2. Incorrect prophylaxis reported by professionals.

Professionals, n=58	Reasons for early discontinuation	Possible intervention
43 (74.1%)	Lack of proper perception of thrombotic risk by patients and lack of communication	Improve patient's education/communication on thrombotic risk and injection technique
10 (17.2%)	Difficulty in injecting	Improve patient's education on injection technique
5 (8.6%)	Fear for the risk of bleeding	Improve patient's education/communication

Most clinicians (72%) confirmed to prescribe prophylaxis in line with the relevant international guidelines, while 20% declared to follow primarily the hospital indications or guidelines, and only 8% admitted prescribing prophylaxis according to personal experience. However, many of them reported some doubts which still represent “gray areas” in the field of chemoprophylaxis, especially regarding the need for prophylaxis, its dose, and optimal duration, in particular settings of patients (e.g. chronic patients at home, after high-risk surgery, after minor orthopedic or arthroscopy surgery, patients with renal insufficiency, and patients with extreme body weight).

As expected, the majority of clinicians (105/153, 69%; 95%CI 61-76%) usually prescribed LMWH prophylaxis for up to 14 days, in line with the fact that a high proportion of respondents were internal medicine specialists (38%) and hematologists or angiologist (24%). Nonetheless, 31% of clinicians (48/153; 95%CI 24-39%) usually prescribe chemoprophylaxis for 4 or more weeks.

The most common indications for antithrombotic prophylaxis were acute medical illness, major orthopedic surgery, and abdominal-pelvic surgery but a remarkably high proportion of clinicians (42/153; 27%; 95%CI 20-53%) declared that the most frequent reason for prescribing LMWH prophylaxis was “chronic patients and/or reduced motility”. The survey revealed considerable doubts about the proper management of chronic patients. In fact, more than half of the physicians (83/149; 53%; 95%CI 51-68%) reported that the main “gray area” in thromboprophylaxis was the “chronic patient”. One-third (45/149; 30%; 95%CI 23-38%) of clinicians responded that the most important “gray area” was the need and duration of “home prophylaxis for acute patients with medical illness.”

Conclusions

Antithrombotic chemoprophylaxis is essential to prevent “provoked VTE” that can occur up to three months after surgery or medical illness.² Despite the wide availability of recommendations,³³⁻³⁵ problems of insufficient or incorrect prescribing¹³⁻¹⁵ and poor adherence to treatment, both in the hospital and after discharge, remain.^{29,30} Continuation of treatment at home presents many challenges regarding indications in medical patients and in a special subset of surgical patients, not specifically addressed in large, randomized clinical trials. In addition, self-injection difficulties and side effects from LMWH (pain or bruising at the site of injection) often contribute to poor adherence.³²

A survey conducted in Italy in 2024 by “Arianna Anticoagulazione” Foundation through its scientific dissemination website (www.anticoagulazione.it), aimed at both patients and professionals, revealed that the lack of information about the treatment and clear instructions about the technique of injection were a main problems for patients or caregivers who were dealing with home thromboprophylaxis with LMWH. In a few cases, a home nurse was needed to administer the drug. Since side effects, such as pain or bruising at the injection site, can be highly prevented by the correct injection technique, detailed instructions by doctors or nurses are strongly required when home thromboprophylaxis with LMWH is prescribed.

The lack of proper communication with patients was reported by clinicians themselves, who observed an early discontinuation of treatment in 38% of cases, mainly ascribed to an

insufficient patient’s perception of the seriousness of thromboembolic complications.

The discrepancy between the percentages of arbitrary suspension of treatment reported by patients/caregivers or doctors could be related to the increased health literacy of the patients who responded to the survey, published on a medical science dissemination website (www.anticoagulazione.it), commonly read by patients. On the contrary, what was observed by professionals refers to the totality of patients, extremely heterogeneous in terms of health literacy.

Another important issue that emerged from our survey is the need for strong indications from high-quality studies to cover “grey areas” such as “chronic patients” with reduced motility and “home prophylaxis for acute patients with medical illness”, which were reported as the main area of uncertainty by 53% and 30% of professionals, respectively.

The lack of convincing recommendations about the correct management of chronic patients with reduced motility is highlighted by the high percentage of doctors (27%) who declared to frequently prescribe LMWH prophylaxis in this subset of patients, in contrast to current guidelines.^{33,34} In fact, in chronically ill medical patients, including nursing home patients, the American Society of Hematology guideline panel suggests not using VTE prophylaxis, but this is a conditional recommendation due to the lack of robust evidence.³⁴ In these patients, a pragmatic approach based on individualized thrombotic and bleeding risk assessment is needed. If a patient’s status changes to acute, thromboprophylaxis should be taken into consideration. As regards the second most common grey area, that is the need and duration of “home prophylaxis for acute patients with medical illness”, the lack of clinical studies and specific guidelines for the patients treated at home makes it difficult for the physician to take an informed decision. Nonetheless, if severe and acute disease (like pneumonia, heart failure and others who generally require hospitalization) are treated at home, applying the same criteria of hospitalized patients would be reasonable.

Doubts about LMWH prophylaxis management in particular subsets of patients (e.g., after high-risk surgery, after minor orthopedic or arthroscopy surgery, subjects with renal insufficiency, and patients with extreme body weight) were a clinical concern reported by many professionals who took part in the survey. These issues should be addressed by robust large-size clinical trials.

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