Intervention targeted at nurses to improve venous thromboprophylaxis

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Abstract

Objective. To assess the effectiveness of an intervention targeting both physicians and nurses vs. physicians only in improving venous thromboprophylaxis for older patients.

Design. Cluster randomized trial.

Setting. Fifty hospital-based post-acute care departments in France.

Participants. Patients aged 65 years or older.

Intervention. A multifaceted intervention to implement a clinical practice guideline addressing venous thromboprophylaxis.

Main outcome measures. The effectiveness outcomes were elastic stocking use, ambulation or mobilization under the supervision of a physical therapist and anticoagulant-based prophylaxis. Patient outcomes included deep vein thrombosis and anticoagulant-related adverse events.

Results. One department allocated to the intervention targeted at physicians only and seven departments allocated to the intervention targeted at both physicians and nurses dropped out of the study. Compared with the intervention targeted at physicians only (n = 497 patients), the intervention targeted at both physicians and nurses (n = 315 patients) was associated with a higher rate of mobilization (62 vs. 37%, P < 0.001) and comparable levels of elastic stocking (32 vs. 39%, P = 0.74) and anticoagulant (55 vs. 48%, P = 0.36) use. The rates of deep vein thrombosis (15 vs. 13%, P = 0.50), bleeding (1 vs. 1%, P = 0.99) and thrombocytopenia (0 vs. 0.2%, P = 0.99) did not differ between the two groups.

Conclusions. A multifaceted intervention targeting nurses in addition to physicians can increase the frequency of mobilization of older patients to prevent venous thromboembolism but does not alter the use of elastic stockings and anticoagulant.

A differential drop-out of departments might have contributed to creating imbalances in baseline characteristics and outcomes in this study.

Keywords: aged, aged 80 and over, nurses, practice guidelines, randomized controlled trial, venous thrombosis

Old age and hospitalization are both independent risk factors for venous thromboembolism [1, 2]. Despite these observations, physical methods of thromboprophylaxis are underused in older patients [3], a setting in which physicians are, moreover, reluctant to order anticoagulant-based prophylaxis for fear of bleeding complications [4]. Physical methods of thromboprophylaxis include the use of elastic stockings and mobilization to improve venous blood flow in conditions predisposing to venous stasis [5]. When used properly, elastic stockings reduce the risk for deep vein thrombosis and are a cost-saving method of thromboprophylaxis in surgical patients [6, 7]. Despite limited evidence [8, 9], elastic stockings are also recommended for medical patients with contraindications to anticoagulant-based prophylaxis [10, 11]. Although not supported by evidence from randomized trials, mobilization of bed-ridden patients and ambulation are considered safe and effective thromboprophylactic measures, based on Virchow’s triad [5, 10, 12]. Improving thromboprophylaxis practices is difficult and the best intervention for reaching this goal is unclear [10, 13].

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The present study was conducted as part of the Association pour la Promotion de l’Angiologie Hospitalière (APAH) project, a collaborative project which involved geriatrics and vascular medicine physicians from 50 post-acute care facilities and internal or vascular medicine departments in France from 2001 to 2004. Briefly, the purposes of this project were: (i) to provide information on risk factors, thromboprophylaxis and prevalence of deep vein thrombosis that could be used to devise optimal prophylaxis against venous thromboembolism in the post-acute care setting [3, 14]; (ii) to derive a clinical practice guideline addressing venous thromboprophylaxis [15]; and (iii) to assess the effectiveness of quality improvement interventions [16].

Since non-pharmacological thromboprophylaxis often relies on nursing staff [12], we hypothesized that an intervention that targeted nurses in addition to physicians would increase the use of physical methods of thromboprophylaxis for older patients. This study aimed to compare the effectiveness and safety of two department-level interventions, which targeted both physicians and nurses or physicians only, in improving prophylaxis against venous thromboembolism in the post-acute care setting.

**Methods**

**Study design**

To avoid contamination between groups [17], we carried out a cluster randomized trial involving a cross-sectional study of prophylaxis and prevalence of deep vein thrombosis. The unit of randomization was the post-acute care department since the intervention targeted all the physicians and nurses in a department. Hospital-based post-acute care departments receive patients who typically have complicated conditions and require specialized care, rehabilitation services or other services associated with the transition between short-stay hospital care and home [18]. Departments that agreed to participate were recruited in teaching and non-teaching hospitals in France in 2003. The Institutional Review Board at Grenoble University Hospital approved the study and all enrolled patients provided written informed consent for participation.

**Study guideline**

The development of our study guideline was based on evidence from published medical literature and consensus guidelines. Physicians at participating post-acute care departments approved all recommendations. The guideline also received the approval of the French Vascular Medicine Society and the French Geriatrics Society [15]. Briefly, the guideline-recommended ambulation, mobilization of bed-ridden patients and the use of elastic stockings (15–20 mmHg) alone or in combination with pharmacological prophylaxis. The use of elastic stockings was recommended during daytime hours or longer for immobilized patients until they recovered ambulation. Pharmacological prophylaxis with either low-molecular weight heparin at the usual prophylactic dose (i.e. dalteparin 5000 U/day, enoxaparin 4000 U/day, nadroparin 2850 U/day, tinzaparin 4500 U/day), dose-adjusted vitamin K antagonist or unfractionated heparin was recommended for patients with a history of proximal deep vein thrombosis or pulmonary embolism within the previous 2 years, hip or knee replacement or other major surgical procedure within the previous 6 weeks, or two or more risk factors among the following: immobility in the previous 30 days, history of distal deep vein thrombosis, hemiplegia, cancer, acute infectious disease, acute heart failure, acute respiratory failure and myocardial infarction. Prophylaxis with low-molecular weight heparin at a lower dose was not recommended since there was no evidence that it performed better than placebo to prevent venous thromboembolism in medical patients [19].

**Randomization and study interventions**

Departments were randomly assigned to a guideline implementation intervention that targeted both physicians and nurses, or physicians only. Randomization was not stratified and was performed by our statistician using a computer-generated sequence with a one-to-one allocation ratio in order to obtain comparison groups of equal sample sizes. Allocation sequence was concealed until interventions were assigned.

In the departments allocated to the intervention that targeted both physicians and nurses, we implemented a multifaceted intervention that included educational presentation, dissemination of educational material and audit-feedback components. A registered vascular medicine physician conducted a 1-h on-site educational session on prophylaxis against venous thromboembolism directed at physicians and nurses. He presented data on prophylaxis use and deep vein thrombosis prevalence in the department when available, the clinical guideline, explained how to use it and described how it had been developed. All physicians and nurses were provided with a pocket plastic card summarizing the guideline and posters were displayed in nursing stations and physicians’ offices. Physicians were also mailed data on prophylaxis use and deep vein thrombosis prevalence in their department, the practice guideline and supporting medical literature.

In the departments allocated to the intervention that targeted physicians only, the intervention included the same components, but they were directed at physicians only. In both groups, all the components of the intervention were completed at every study site 6 weeks before patient enrolment. Given the nature of the intervention, physicians and nurses could not be blinded to intervention.

**Patients**

In each participating department, all the patients 65 years of age or older who were present on the day of the
cross-sectional study were screened for eligibility. Patients were excluded from the study if they had a positive diagnosis of deep vein thrombosis or pulmonary embolism at admission or if they required long-term anticoagulant therapy with heparin or vitamin K antagonist for reasons other than venous thromboembolism prophylaxis.

Study outcomes

Trained physicians, who were members of the research team, collected data on risk factors for deep vein thrombosis and prophylaxis using a standardized data abstract form. The primary effectiveness outcomes included the use of elastic stockings, ambulation or mobilization of bed-ridden patients under the supervision of a physical therapist, and anticoagulant-based thromboprophylaxis on the day of the cross-sectional study. Elastic stocking users were identified by direct observation on the day of the cross-sectional study. Daily duration of wearing and overall duration of elastic stocking use were assessed using a structured chart review. We defined elastic stocking users as patients who wore below-knee or thigh-length elastic stockings for daytime hours or more. We identified the patients who were mobilized by reviewing physical therapists’ notes in medical charts. Anticoagulant-based prophylaxis users were identified by reviewing physicians’ orders.

The secondary outcomes included deep vein thrombosis, bleeding and thrombocytopaenia. All patients underwent comprehensive compression ultrasonography on the day of the cross-sectional study. Compression ultrasonography was performed by registered vascular medicine physicians who were unaware of both risk factors and thromboprophylaxis. As described previously [20], all deep veins of the lower limbs were examined from the inguinal ligament to the malleolus, using a 3- to 7.5-MHz transducer. Only incompressible veins with a thrombus of an anteroposterior diameter of 5 mm or more were considered positive. We defined proximal deep vein thrombosis as popliteal or supra-popliteal deep vein thrombosis and distal deep vein thrombosis as isolated calf deep vein thrombosis (including gastrocnemius and soleal vein thrombosis). Bleeding was defined as major if it was intracranial or retroperitoneal, or if clinically significant overt venous thrombosis and distal deep vein thrombosis as isolated calf deep vein thrombosis (including gastrocnemius and soleal vein thrombosis). Bleeding and thrombocytopaenia were compared using Fisher’s exact tests for categorical variables and the Wilcoxon rank sum test for continuous variables.

Statistical analysis

All departments with available data were analyzed in the group to which they were allocated according to the intention-to-treat principle. Patients’ baseline characteristics were compared using the $\chi^2$ or Fisher’s exact tests for categorical variables and the Wilcoxon rank sum test for continuous variables.

Although the unit of randomization was the post-acute care department, primary and secondary outcomes were measured at the patient-level and the unit of analysis was the patient. To account for patient clustering within departments, we used random intercept logistic regression with the two levels defined by patient and department. In multivariable analysis, we estimated the adjusted odds ratios (ORs) of the primary outcomes and their 95% confidence intervals (CIs) to account for imbalances in patients’ baseline characteristics. Bleeding and thrombocytopaenia were compared using Fisher’s exact tests, due to the sparse number of events within comparison groups. Wherever appropriate we report intracluster correlation coefficients [21]. Two-sided $P$-values of less than 0.05 were considered statistically significant. Analyses were performed using Stata version 9.0 (Stata Corporation, College Station, TX, USA) and MLwiN 2.0 (Institute of Education, London, UK).

Results

Of 53 facilities approached, three declined to participate and 50 were randomized (Fig. 1). Of these, eight facilities dropped out of the study before intervention implementation and data collection, all citing nursing staff shortage. They were withdrawn from the study and the analysis was based on 42 facilities allocated to the intervention targeted at physicians only and 18 facilities allocated to the intervention targeted at both physicians and nurses (Table 1). Depending on the department, patients were enrolled from September 2003 to April 2004. Of 1134 patients screened for eligibility, 812 were enrolled, including 497 patients allocated to the intervention targeted at physicians only and 315 allocated to the intervention targeted at both physicians and nurses. The main reasons for non-enrolment were long-term anticoagulant therapy with heparin or vitamin K antagonist (117 patients), age less than 65 years (96 patients),
positive diagnosis of venous thromboembolism at admission (73 patients) and refusal to participate (36 patients). Women comprised 66% of the patients and the median age was 82 years [interquartile range (IQR) 77–89]. The patients allocated to the intervention targeted at physicians only tended to be older and were more likely to be female and to have chronic heart failure and inflammatory disorders, while relatively more patients allocated to the intervention targeted at both physicians and nurses had recent major surgery (Table 2).

Compared to the intervention targeted at physicians only, the intervention targeted at both physicians and

Table 1 Post-acute care department characteristics by intervention group

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<thead>
<tr>
<th>Characteristics</th>
<th>Intervention targeted at</th>
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<tbody>
<tr>
<td></td>
<td>Physicians only (n = 24)</td>
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<tr>
<td>Bed size &gt;40, no. (%)</td>
<td>7 (29)</td>
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<tr>
<td>Routine access to ultrasonography, no. (%)</td>
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<tr>
<td>&lt;24 h</td>
<td>9 (37)</td>
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<tr>
<td>24–72 h</td>
<td>11 (46)</td>
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<tr>
<td>&gt;72 h</td>
<td>4 (17)</td>
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<tr>
<td>Rehabilitation vs. skilled nursing facility, no. (%)</td>
<td>5 (21)</td>
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<tr>
<td>University-affiliated facility, no. (%)</td>
<td>13 (54)</td>
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nurses was associated with comparable levels of elastic stocking and anticoagulant use and with a higher rate of mobilization (Fig. 2), which remained significant in multivariable analysis (Table 3). Prophylactic anticoagulant regimens were not different for patients in the two study groups, with the exception of unfractionated heparin and vitamin K antagonist, which were not used in patients allocated to the intervention that targeted both physicians and nurses (Table 3).

A deep vein thrombosis was diagnosed by routine ultrasound examination in 113 patients (14%), with no significant differences between the two study groups (two-level OR, 1.21; 95% CI, 0.70–2.11; \( P = 0.50 \); intra-cluster correlation coefficient, 0.08). No differences were observed in the rates of bleeding and thrombocytopaenia (Table 4).

**Discussion**

In this cluster randomized trial designed to improve prophylaxis against venous thromboembolism, a multifaceted intervention that targeted nurses in addition to physicians was effective in increasing mobilization or ambulation under the supervision of a physical therapist but not elastic stocking or anticoagulant use, compared with an intervention that targeted physicians only.

Although restoration of mobility is a key objective for post-acute care patients, only 37% of the patients allocated to the intervention targeted at physicians only were mobilized under the supervision of a physical therapist. That the intervention targeted at physicians and nurses was associated with a more frequent use of physical therapy was expected, as nurses have a key role in mobilization of patients [12, 22].

In contrast, the lack of effect of the intervention targeted at nurses on elastic stocking use is somewhat surprising. There are several potential explanations for this observation. First, prophylaxis with elastic stockings require educating and training the patient and is associated with an increased workload for the nursing staff [14]. Secondly, our intervention might not have been intensive enough to affect the use of elastic stockings. Thirdly, this observation may also result from patient preferences. Indeed, patients often find elastic stockings uncomfortable and prefer low-molecular weight heparin prophylaxis [23].
Similar rates of anticoagulant-based prophylaxis were expected in the two groups since anticoagulant treatments are ordered by physicians in the post-acute care setting. Although the use of unfractionated heparin and oral anticoagulants was marginal in this study, their prescription was less frequent among patients allocated to the intervention targeted at physicians and nurses. Unfractionated heparin and oral anticoagulants, which are ordered by physicians but administered and monitored by nurses, are considered less convenient and safe than low-molecular weight heparin for elderly patients [24].

Our study failed to show any significant differences in the rates of deep vein thrombosis and anticoagulant-related adverse events between the two intervention arms. Actually, our study was designed to compare processes of care rather than patient outcomes and therefore was not powered to detect significant differences in patient outcomes. This is the same strategy as reported in previous guideline implementation trials [13, 25]. Processes are considered more appropriate measures than patient outcomes when assessing quality of care because patient outcomes have multiple determinants, are relatively insensitive to changes in quality of care, and therefore require large numbers of patients [26].

Only a few studies have focused on interventions that targeted nurses, although there is increasing interest in the use of guidelines to improve nursing practices [27]. Despite evidence supporting the effectiveness of guideline implementation interventions to improve physicians’ practices [28], it cannot be assumed that interventions proved to work for physicians will transfer directly to nurses [27]. Recent studies have demonstrated the effectiveness of interventions that targeted both physicians and nurses in comparison with no intervention for various settings including orthopedic surgery departments [29] and nursing homes [30]. Our study further demonstrates that an intervention targeting both physicians and nurses is more effective in altering professional practices than an intervention targeting physicians only. This observation might reflect improved communication between physicians and nurses [31, 32] and strong nursing leadership in our quality improvement intervention [33].

The limitations of our study should be acknowledged. First, participating departments were recruited on a voluntary basis, a fact that may limit the generalizability of our findings although they reflected a wide range of departments and patients. Secondly, the estimates of intracluster correlation coefficients were higher than expected and our study was likely to be underpowered. Thirdly, randomization of the departments did not ensure balance at the patient level, although the $P$-values should be interpreted with caution because of multiple testing. In addition, eight facilities dropped out of the study and might have contributed to creating imbalances in baseline characteristics. Fourth, observers could not be blinded to the treatment allocation in this cluster-randomized trial and we cannot rule out the possibility of observer bias. Fifth, assessing mobilization is challenging in the post-acute care setting. We relied on physical therapists’ notes to identify the patients who were mobilized. Although this was an objective measure that could be reliably assessed using a structured chart review, we could not determine by direct observation whether these patients were actually mobilized. Sixth, assessment of knowledge and attitude toward our guideline could have helped understand the limited impact of our study intervention [34]. However, this would have required validated instruments that were not available at the time our study was conducted. Seventh, it is possible that our intervention was not intensive enough to cause any changes in physicians’ behavior [34]. Eighth, we did not collect pre-intervention data and therefore we cannot exclude baseline differences in venous thromboprophylactic measures across departments. Ninth, we did not assess the long-term effects of our intervention, although evidence

Figure 2 Department use of prophylactic measures by intervention group.

Similar rates of anticoagulant-based prophylaxis were expected in the two groups since anticoagulant treatments are ordered by physicians in the post-acute care setting. Although the use of unfractionated heparin and oral anticoagulants was marginal in this study, their prescription was less frequent among patients allocated to the intervention targeted at physicians and nurses. Unfractionated heparin and oral anticoagulants, which are ordered by physicians but administered and monitored by nurses, are considered less convenient and safe than low-molecular weight heparin for elderly patients [24].
exists that posters alone can sustain the effect of a guideline [29].

In conclusion, a multifaceted intervention that targets nurses in addition to physicians can increase the frequency of mobilization and ambulation of older patients to prevent venous thromboembolism in the post-acute care setting but does not alter the use of elastic stockings and anticoagulant-based prophylaxis.

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