A clinical decision support system for venous thromboembolism prophylaxis at a general hospital in a middle-income country*,**

Sistema de suporte à decisão clínica para um programa para profilaxia de tromboembolia venosa em um hospital geral de um país de renda média

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Abstract

Objective: To determine the impact that implementing a combination of a computer-based clinical decision support system and a program of training seminars has on the use of appropriate prophylaxis for venous thromboembolism (VTE). **Methods:** We conducted a cross-sectional study in two phases (prior to and after the implementation of the new VTE prophylaxis protocol) in order to evaluate the impact that the combined strategy had on the use of appropriate VTE prophylaxis. The study was conducted at *Nossa Senhora da Conceição* Hospital, a general hospital in the city of Porto Alegre, Brazil. We included clinical and surgical patients over 18 years of age who were hospitalized for ≥ 48 h. The pre-implementation and post-implementation phase samples comprised 262 and 261 patients, respectively. **Results:** The baseline characteristics of the two samples were similar, including the distribution of patients by risk level. Comparing the pre-implementation and post-implementation periods, we found that the overall use of appropriate VTE prophylaxis increased from 46.2% to 57.9% (p = 0.01). Looking at specific patient populations, we observed that the use of appropriate VTE prophylaxis increased more dramatically among cancer patients (from 18.1% to 44.1%; p = 0.002) and among patients with three or more risk factors (from 25.0% to 42.9%; p = 0.008), two populations that benefit most from prophylaxis. **Conclusions:** It is possible to increase the use of appropriate VTE prophylaxis in economically constrained settings through the use of a computerized protocol adhered to by trained professionals. The underutilization of prophylaxis continues to be a major problem, indicative of the need for ongoing improvement in the quality of inpatient care.

Keywords: Venous thrombosis/prevention & control; Venous thromboembolism/prevention & control; Heparin/therapeutic use.

Resumo

Objetivo: Determinar o impacto da implantação de um sistema informatizado de suporte à decisão clínica combinado com seminários instrucionais na utilização de profilaxia para tromboembolia venosa (TEV) de forma adequada. **Métodos:** Estudo transversal em duas fases (antes e depois da implantação de um novo protocolo de profilaxia para TEV) para avaliar o impacto que a estratégia combinada teve na utilização adequada da profilaxia para TEV. O estudo foi conduzido no Hospital Nossa Senhora da Conceição, um hospital geral localizado em Porto Alegre (RS). Foram incluídos pacientes clínicos e cirúrgicos com mais de 18 anos com tempo de hospitalização ≥48 h. Nas fases pré e pós-implantação, foram incluídos 262 e 261 pacientes, respectivamente. **Resultados:** As características de base das duas amostras foram semelhantes, inclusive em relação à distribuição dos pacientes por nível de risco. Comparando-se os períodos pré e pós-implantação, verificou-se que a adequação da profilaxia para TEV aumentou de 46,2% para 57,9% (p = 0,01). Ao se observar populações específicas de pacientes, o uso adequado da profilaxia para TVE aumentou dramaticamente em pacientes com câncer (de 18,1% para 44,1%; p = 0,002) e em pacientes com três ou mais fatores de risco (de 25,0% para 42,9%; p = 0,008), populações essas que mais se beneficiam da profilaxia. **Conclusões:** É possível aumentar o uso de profilaxia adequada para TEV em cenários economicamente desfavoráveis através do uso de protocolos informatizados e de profissionais treinados. A subutilização da profilaxia permanece como um problema importante, destacando a necessidade da melhora continuada na qualidade da assistência hospitalar.

Descritores: Trombose venosa/prevenção & controle; Tromboembolia venosa/prevenção & controle; Heparina/uso terapêutico.

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* Study carried out at the *Nossa Senhora da Conceição* Hospital, Porto Alegre, Brazil.

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Introduction

Venous thromboembolism (VTE) comprises two related conditions—deep-vein thrombosis and pulmonary embolism—and is responsible for a great number of complications in hospitalized patients. Pulmonary embolism accounts for 5-10% of all deaths in hospitalized patients, making VTE the most common preventable cause of in-hospital death.[1,2]

Prevention is the most effective strategy to reduce the burden of VTE. There is considerable evidence that primary prophylaxis with heparin significantly reduces the incidence of VTE without increasing the risk of major bleeding.[3,4] In addition, VTE prophylaxis has proven to be cost effective, reducing treatment costs and shortening hospital stays.[5]

Over the last decade, several guidelines aimed at improving preventive strategies and increasing their use have been published.[5-7] Although the majority of medical and surgical inpatients have multiple risk factors for VTE, large prospective studies have demonstrated that methods of preventing VTE are underutilized.[8,9] In a multinational cross-sectional study, the proportion of hospital patients at risk for VTE ranged from 36% to 73% and the proportion of patients receiving VTE prophylaxis ranged from 2% to 84%.[10] This illustrates the difficulty of translating into practice knowledge disseminated in the literature. This situation has also stimulated new research to identify possible obstacles that limit the effectiveness of VTE prevention measures and to evaluate strategies to implement changes.[11]

Passive strategies and isolated measures, such as the distribution of guidelines and protocols or the staging of one-time trainings, have little impact on practices, whereas the use of multiple strategies with tools that work at the various stages of knowledge dissemination has been shown to be highly effective.[5,12,13] Computer-based clinical decision support systems (CDSSs) and computer reminders are currently in use as strategies to improve the quality of healthcare and have been especially effective for VTE prophylaxis.[14]

The objective of the present study was to evaluate the effects that a combined strategy of implementing a CDSS and organizing training seminars has on the use of appropriate VTE prophylaxis. We hypothesized that real-time presentation of VTE prophylaxis guidelines through a CDSS would increase the proportion of patients receiving appropriate prophylaxis.

Methods

We devised a strategy for improving VTE prophylaxis that involved the creation of a CDSS and the organization of training seminars. We conducted a cross-sectional study in two phases (prior to and after the implementation of the new strategy) in order to assess the proportion of patients receiving appropriate VTE prophylaxis.

The study was conducted at the *Nossa Senhora da Conceição* Hospital, which is located in the city of Porto Alegre, Brazil, and is the largest general hospital in the southern region of the country. The hospital is affiliated with the Brazilian National Ministry of Health and provides treatment only via the Brazilian Unified Health Care System. It is a teaching hospital, with 750 adult inpatient beds available for use in a number of medical and surgical specialties, except for orthopedics, trauma, and neurosurgery.

In August of 2008, a group of physicians from the internal medicine department was given the challenge of developing a VTE prevention protocol. The group created a protocol, adapted from existing guidelines, to guide the prescription of VTE prophylaxis. The consensus guidelines of the American College of Chest Physicians, published in June of 2008,[5] was selected as the primary source of recommendations for the protocol to be implemented.

We reviewed the current evidence in order to clarify areas of concern, such as major risk factors, contraindications, prophylaxis in post-stroke patients, cancer, and some types of surgery. To incorporate new evidence, we searched the Medline and Cochrane databases, as well as meeting with teams of internists and other specialists to discuss articles pertaining to their practice. To launch the protocol recommendations, physicians from all departments of the hospital were invited to attend a final consensus meeting.

The VTE prevention protocol established risk factors, heparin contraindications, and appropriate prophylaxis measures in accordance with patient risk of VTE. We adopted a model that could be easily followed by the prescribing physician, using a CDSS in which VTE risk was stratified into three levels. Each level of VTE risk was linked to a menu of acceptable prophylaxis options (Chart 1). The protocol did not include trauma,

neurosurgery, or orthopedic patients. In addition, we excluded pregnant and postpartum women.

At our hospital, unfractionated heparin (UFH) and low-molecular-weight heparin (LMWH, enoxaparin) are available for VTE prophylaxis. Because of the higher cost of LMWH, only UFH was included in the VTE prevention protocol, given that UFH is the therapeutic equivalent of LMWH in terms of efficacy and safety in the general medical and surgical population.[5]

We estimated that, assuming a 50% prevalence of appropriate prophylaxis in the first phase of the study, two samples of at least 227 patients each would be needed in order to detect differences of at least 15% in that prevalence between the two periods with sufficient precision (two-tailed alpha = 0.05 and beta = 0.10).

In the first phase of the study, conducted between April and July of 2009 (prior to the implementation of the VTE prevention protocol), the patient sample comprised 262 patients, whereas that of the second phase of the study, conducted between December of 2009 and February of 2010 (after the implementation of the protocol), comprised 261 patients. In both phases, the data were collected by six residents in internal medicine, previously trained in the appropriate techniques, who reviewed patient charts and prescription forms in order to obtain the pertinent data. No attending physicians were informed of the study.

We used a two-stage approach in order to implement the strategies and integrate the VTE prevention protocol as a mandatory electronic CDSS. First, one-hour seminars were held to present the protocol, emphasizing the importance of prophylaxis and its indications, as well as to explain how the CDSS would work. Residents and attending physicians from the various medical specialties were invited to attend. The protocol established was then included as a standardized VTE prevention module interfaced with the electronic medical records entry system of the hospital.

The standardized VTE prevention module was activated automatically at the second access of the electronic medical record after an admission or transfer between units, the first access typically being made by the admitting (staff) physician and the second access being by the attending physician. Physicians were prompted to select a VTE risk level for each patient, according to the predetermined risk profiles (Chart 1), and to determine whether there were any contraindications to pharmacologic prophylaxis. When the risk level was selected, the recommended dose of UFH was automatically added to the electronic prescription for that patient. In patients with contraindications, UFH was not included in the prescription and the standardized VTE prevention module was automatically activated every 48 hours in order to identify the persistence or resolution

Chart 1 - Venous thromboembolism prophylaxis protocol.

Risk Level	Characteristics	Prophylaxis
Low	Postoperative period following minor surgery[a] in patients who are not bedridden Postoperative period following laparoscopic surgery in patients without risk factors No acute disease or bedridden status in medical patients	Early ambulation
Moderate	Postoperative period following major surgery Postoperative period following laparoscopic surgery in patients with risk factors Acute disease in medical patients Bedridden status and risk factors in medical patients	Unfractionated heparin, 5,000 IU subcutaneously every 12 h
High	Postoperative period following major surgery in patients with multiple (3 or more) risk factors Postoperative period following bariatric surgery Postoperative period following major cancer surgery Medical patients with multiple risk factors (3 or more), active cancer, thrombophilia or previous venous thromboembolism episode.	Unfractionated heparin, 5,000 IU subcutaneously every 8 h

[a]Procedures that do not involve the opening of large cavities, risk of severe hemorrhage, or extensive dissections.

of the contraindication. The physician could also choose not to use prophylaxis in patients on anticoagulation. Physicians who chose not to follow the protocol recommendations were required to fill out a form justifying that choice.

The main outcome measure was an increase in the proportion of patients receiving appropriate VTE prophylaxis, comparing the pre-implementation and post-implementation periods. In both phases, patients were randomly selected from among those admitted to the medical or surgical wards, including the ICU. Randomization was performed by drawing bed numbers, with the number of beds used in each specialty proportional to the ratio between the number of beds available to that specialty and the total number of beds in the hospital. The inclusion criteria were being over 18 years of age and having been hospitalized for ≥ 48 h on any of the wards. The exclusion criteria were current anticoagulation, pregnancy, puerperium, and a history of acute thromboembolic disease.

The main variables studied, the risk factors, and the contraindications are cited in a previously published article.[15] Each prescription was classified as appropriate or inappropriate on the basis of whether it followed the protocol, after considering the patient risk of VTE and the presence of contraindications to heparin. Two of the authors assessed the appropriateness of prophylaxis, and questionable cases were discussed by the research group as a whole.

Patients were stratified by medical or surgical ward and by the risk of VTE (low, medium, or high). The absolute difference in the proportion of patients receiving appropriate VTE prophylaxis between the two periods and the 95% confidence interval for that difference were calculated for each stratum. Comparisons between the two periods in terms of the clinical characteristics of the patients were tested using the chi-square test or t-test, as appropriate. The analysis included all eligible patients. Values of $p < 0.05$ were considered statistically significant. All data were analyzed using the Statistical Package for the Social Sciences, version 17.0 (SPSS Inc., Chicago, IL, USA), and WINPEPI, version 11.4 (http://www.brixtonhealth.com/pepi4windows.html).

The study was approved by the Research Ethics Committee of the *Nossa Senhora da Conceição* Hospital, and all of the authors signed a data use agreement.

Results

Except for a few risk factors, the baseline characteristics of the patients were similar in the two phases of the study (Table 1). The distribution of the patients by risk level was also similar between the two phases. In the first and second phases, respectively, 21.4% and 20.3% of patients were postoperative patients, those having undergone major surgery accounting for 66% and 45%, respectively.

Nearly all of the patients included in the study were classified as being at moderate or high risk of VTE (43.4% and 55.4%, respectively). The main contraindications were coagulopathy, active bleeding, and active peptic ulcer disease. No other contraindications were identified.

Comparing the pre-implementation and post-implementation data, we found that the use of appropriate VTE prophylaxis increased from 46.2% to 57.9% (Table 2). The absolute difference between the two study periods was 11.7% (95% CI: 3.2% to 20.3%), which was statistically significant ($p = 0.01$).

In cancer patients, the use of appropriate VTE prophylaxis increased from 18.1% in the pre-implementation phase of the study to 44.1% in the post-implementation phase (absolute difference, 26%; 95% CI: 9.9% to 42.3%; $p = 0.002$). As can be seen in Table 2, a significant increase was also observed in patients with multiple risk factors (from 25.0% to 42.9%; absolute difference, 17.9%; 95% CI: 4.8-30.9%; $p = 0.008$). In addition, there was a post-implementation increase in the use of appropriate VTE prophylaxis in patients at high risk of VTE (Table 3). Among surgical patients in the postoperative period (defined as those who had undergone a surgical procedure in the last 30 days), there was a small post-implementation increase in the use of appropriate VTE prophylaxis (from 53.6% to 60.4%), which was not statistically significant (absolute difference, 6.8%; 95% CI: −13.6% to 27.2%; $p = 0.6$). However, among medical patients, there was a significant improvement (from 44.2% to 57.2%; absolute difference, 13%; 95% CI: 3.0% to 23.1%; $p = 0.011$).

Discussion

Our study demonstrates that the implementation of a CDSS accompanied by training seminars had a positive effect on the

Table 1 - Characteristics of the patients included in the two phases of the study.

Characteristic	Phase 1[a] (n = 262)	Phase 2[b] (n = 261)	p
Age, mean ± SD	59.1 ± 16.6	52.2 ± 17.1	0.539
Male gender, n (%)	137 (52.3)	138 (52.9)	0.963
Postoperative patients, n (%)	56 (21.4)	53 (20.3)	0.847
Major specialties, n (%)			
Internal medicine	58 (22.1)	51 (19.5)	0.855
Medical specialties	102 (38.9)	110 (42.1)	
General surgery	35 (13.4)	37 (14.2)	
Surgical specialties	50 (19.1)	50 (19.2)	
Gynecology	17 (6.5)	13 (5)	
VTE risk, n (%)			
High	143 (54.6)	147 (56.3)	0.626
Moderate	117 (44.7)	110 (42.1)	
Low	2 (0.8)	4 (1.5)	
Risk factors, n (%)			
Immobilization	185 (70.6)	219 (83.9)	< 0.0001*
Infection	116 (44.3)	136 (52.1)	0.88
Active cancer	72 (27.5)	68 (26.1)	0.787
Use of a central venous catheter	35 (13.4)	56 (21.5)	0.020*
Major surgery	37 (14.1)	24 (9.2)	0.105
Severe lung disease	20 (7.6)	25 (9.6)	0.524
Heart failure	21 (8)	23 (8.8)	0.864
Acute myocardial infarction	22 (8.4)	8 (3.1)	0.015*
Stroke	13 (5)	24 (9.2)	0.86
Limb paralysis/paresis	21 (8)	21 (8)	1
ICU admission	16 (6.1)	17 (6.5)	0.991
Obesity			
BMI 30-35 kg/m^2	45 (17.2)	27 (10.3)	0.032*
BMI > 35 kg/m^2	16 (6.1)	17 (6.5)	0.991
Chemotherapy/radiotherapy	7 (2.7)	14 (5.4)	0.179
History of VTE	3 (1.1)	11 (4.2)	0.57
Use of oral contraceptives	3 (1.1)	3 (1.1)	1
Use of hormone replacement therapy	2 (0.8)	3 (1.1)	0.686
Myeloproliferative disease	5 (1.9)	1 (0.4)	0.216
Inflammatory bowel disease	0 (0)	2 (0.8)	0.249
Contraindications, n (%)			
Coagulopathy	10 (3.8)	17 (6.5)	0.232
Active peptic ulcer disease	2 (0.8)	0 (0)	0.499
Active bleeding	13 (5)	8 (3.1)	0.378

VTE: venous thromboembolism; and BMI: body mass index. [a]From April through July of 2009 (prior to the implementation of the VTE prevention protocol). [b]From December of 2009 through February of 2010 (after the implementation of the VTE prevention protocol). *< 0.05 (statistically significant).

practices of physicians, increasing the proportion of patients receiving appropriate prophylaxis for VTE.

Our samples were representative of the risk profile of the patients seen at our hospital, most of whom are classified as being at moderate to high risk of VTE, underscoring the need to implement measures to improve VTE prophylaxis. Neither sample included patients classified as being at very high risk of VTE (orthopedic, neurosurgery, and trauma patients), because such patients are not treated at our hospital. Most of the patients admitted to our hospital are referred from emergency rooms, which leaves few beds

Table 2 - Use of appropriate venous thromboembolism prophylaxis in the two phases of the study.

Category	Phase 1[a]			Phase 2[b]			Difference		
	N	Total	%	N	Total	%	Absolute (%)	95% CI	p
All patients	121	262	46.2	151	261	57.9	11.7	3.2-20.3	0.01*
Patients with cancer	13	72	18.1	30	63	44.1	26	9.9-42.3	0.002*
Patients with 3 or more risk factors	26	104	25	51	119	42.9	17.9	4.8-30.9	0.008*

[a]From April through July of 2009 (prior to the implementation of the venous thromboembolism prevention protocol). [b]From December of 2009 through February of 2010 (after the implementation of the venous thromboembolism prevention protocol). *< 0.05 (statistically significant).

Table 3 - Use of appropriate venous thromboembolism prophylaxis according to patient risk level.

VTE risk	Phase 1 (Before)			Phase 2 (After)			Difference		
	N	Total	%	N	Total	%	Absolute %	95% CI	p
High	32	143	22.4	63	147	42.9	20.5	9.3 to 31.7	0.0001*
Moderate	88	117	75.2	85	110	77.3	2.1	−9.9 to 14.0	0.835
Low	1	2	50	3	4	75	25	−93.0 to 100.0	1

VTE: venous thromboembolism. *< 0.05 (statistically significant).

available for elective admissions. This explains the low number of low-risk patients in our samples. The increase in the use of appropriate VTE prophylaxis was most pronounced among patients with cancer and among patients with three or more VTE risk factors, populations that benefit the most from such prophylaxis.

Various health advocacy groups have recommended measures of prophylaxis for VTE. Such recommendations include evaluating VTE risk for every patient at admission and regularly during hospitalization, especially after transfer to the ICU.[16] Considering these recommendations, the CDSS created in our hospital is automatically activated at the second access of the electronic medical record after an admission or transfer between units (i.e., the first access by the attending physician). In addition, it is triggered whenever it detects that heparin has not been prescribed.

There are studies currently underway that are aimed at identifying the characteristics that make a protocol effective. Protocols for VTE prophylaxis should consider many aspects of the decision-making process: VTE risk factors; the primary illness (cause of hospitalization); patient immobilization; and the type of surgery the patient is scheduled to undergo. Considering these aspects, protocols should include many features and yet must keep things efficient and simple enough for everyday use. Possible errors include listing options for VTE prophylaxis without providing any guidance about which choice is most appropriate or desirable, as well as supplying too much information, making the protocol too complicated. Some order sets offer four to six levels of VTE risk, but the evidence to distinguish the levels of risk, as well as the differences among the types of prophylaxis, is often weak. Two to three levels of VTE risk are sufficient.[17] Another possible error is to offer non-pharmacologic VTE prophylaxis as a first-line option in patients without contraindications to pharmacological methods.

In the creation of our protocol, we considered all these possible errors and built a concise tool that allows physicians to make a quick decision. In addition, because risk level and contraindications change frequently in acutely ill patients, a link to the protocol was permanently available in the electronic record for re-evaluation. When contraindications were reported, the protocol was automatically triggered for reassessment within 48 h.

Several studies have attempted to demonstrate the improvement in the appropriateness of VTE prophylaxis after implementation of various strategies. In a randomized controlled trial involving 6,371 hospitalized patients, the use of

electronic alerts has increased the use of heparin from 18.9% to 32.2%.[18] In a French study of orthopedic patients, the use of electronic alerts increased the adherence to guidelines from 82.8% to 94.9%.[19] Kucher et al. demonstrated that the application of a CDSS reduces the rates of deep vein thrombosis and pulmonary embolism.[20]

To our knowledge, ours is the first study to report testing the effects of a CDSS for VTE prophylaxis in a middle-income country. In Brazil, studies conducted in the cities of São Paulo[21] and Salvador[22] showed that the distribution of written guidelines for physicians was not effective in increasing adherence to prophylactic measures. A meta-analysis that evaluated the effectiveness of different strategies to increase adherence to prophylactic measures for VTE also showed that passive measures, such as the distribution of guidelines, were ineffective.[13] The authors of that study found that the use of multiple strategies is more effective than is that of either strategy in isolation. Among the studies evaluated in that meta-analysis, there were five that had rates of adherence to guidelines of more than 90%. All five of those studies utilized interactive processes of audit and feedback, as well as incorporating warning systems as reminders of VTE risk assessment.[13] Kawamoto et al. identified characteristics of systems that are predictive of effective decision support: generating decision support automatically as part of the normal clinical workflow, at the time and place of decision making; using computers to deliver support; and offering specific recommendations rather than mere assessments. The authors found that 94% of CDSSs presenting those characteristics were successful in improving physician practices.[12]

Our strategy involved the use of UFH for two main reasons. First, patients at very high risk of VTE, for whom the evidence of LMWH superiority is more robust, are not admitted to our hospital. Second, although economic analyses have marginally favored the use of enoxaparin,[23,24] there have been no similar analyses of VTE prevention in the context presented here—only studies addressing the treatment of an established thromboembolism.[25] Our local evaluations, focusing on hospital costs, support the use of UFH, mainly due to considerable differences in terms of drug acquisition costs.

Our study has several limitations. The major limitation is inherent in the observational design and the lack of a control population. We studied two populations sequentially, and it is therefore possible that some unrecognized temporal trend biased our results. We cannot exclude hidden confounding factors. Data were obtained from reviews of patient charts, making it difficult to control for differences in data collection. In addition, we evaluated the effects of the implementation of the protocol only in terms of the proportional use of appropriate VTE prophylaxis and did not evaluate patient outcomes. However, some authors now consider it preferable to evaluate processes rather than outcomes when assessing quality of care.[26]

Although the use of a CDSS increases the use of appropriate VTE prophylaxis, it is still far from optimal. Even with a simple and quick tool, the erroneous evaluation of the risk factors and contraindications can lead the physician to misclassify the level of the patient risk and make an inappropriate choice regarding the prophylaxis.

Another major limitation of our study is the fact that we used a protocol that was developed locally from the current guidelines and was not validated prospectively. In the literature, there are many models to assess VTE risk, most of which have yet to be validated and are complex.[27] Maynard et al. recently published a study validating a model of risk stratification for VTE.[28] The authors demonstrated that a simple model with three levels of risk, implemented through a CDSS, accompanied by educational measures, audit, and feedback, increased the use of appropriate VTE prophylaxis from 58% to 98% over a three-year period and reduced the number of thromboembolic events occurring at the hospital under study.[28]

The results of our study show that it is possible to increase the use of appropriate VTE prophylaxis at a general hospital in a middle-income country by implementing a CDSS and by educating the hospital staff. The same CDSS might be useful at other institutions, if the software were adapted to local conditions. Our findings suggest that other hospitals in Brazil should consider implementing a CDSS to increase the use of VTE prophylaxis, given that studies evaluating the use of non-computerized protocols have shown that such protocols provide no benefit.[21,22]

The underutilization of VTE prophylaxis remains a major problem. Although the strategy employed in the present study produced significant results, it is still less than ideal and calls for ongoing

staff training, as well as constant improvement of the CDSS.

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