Risk factors and prophylaxis for venous thromboembolism in hospitals in the city of Manaus, Brazil*

Fatores de risco e profilaxia para tromboembolismo venoso em hospitais da cidade de Manaus

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Abstract

Objective: To identify and classify risk factors for venous thromboembolism (VTE) in hospitalized patients, as well as to evaluate medical practices regarding prophylaxis for the disease. **Methods:** An observational cross-sectional study, carried out between January and March of 2006, involving inpatients at three hospitals in the city of Manaus, Brazil. Risk stratification for VTE was based on the criteria established by the Brazilian Society of Angiology and Vascular Surgery and by the International Union of Angiology. Clinical, surgical and medication-related risk factors were analyzed. The statistical analysis of the data obtained was conducted, adopting an alpha error of 5% and 95% CI. Qualitative data were analyzed using the chi-square test, whereas quantitative data were analyzed using Student's t-test. **Results:** Of the 1,036 patients included (total number of admissions, 1,051), 515 (49.7%) were male, and 521 (50.3%) were female. A total of 23 risk factors for VTE were identified (total number of occurrences, 2,319). The stratified risk for VTE was 50.6%, 16.6% and 30.8% among the admissions of high-, moderate- and low-risk cases, respectively. In 73.3% of the admissions, nonpharmacological prophylaxis was not employed at any point during the study period. In 74% of those classified as high- or moderate-risk cases, no prophylactic medications were administered. **Conclusions:** This study showed that, in the population studied, risk factors were common and that prophylactic measures were not employed in patients prone to developing VTE and its complications.

Keywords: Venous thromboembolism; Risk factors; Venous thrombosis/prevention & control.

Resumo

Objetivo: Identificar e classificar os fatores de risco para tromboembolismo venoso (TEV) em pacientes internados, avaliando as condutas médicas adotadas para a profilaxia da doença. **Métodos:** Estudo observacional, de corte transversal no período de janeiro a março de 2006, envolvendo uma população de pacientes internados em três hospitais na cidade de Manaus (AM). A estratificação do risco para TEV foi feita com base nos critérios da Sociedade Brasileira de Angiologia e Cirurgia Vascular e da *International Union of Angiology*. Foram avaliados variáveis sobre os fatores de risco clínicos, cirúrgicos e medicamentosos, assim como os métodos profiláticos para TEV. Os dados foram analisados estatisticamente, adotando-se um alfa de 5% e IC95%. Os dados qualitativos foram analisados pelo teste do qui-quadrado e os dados quantitativos pelo teste t de Student. **Resultados:** Foram estudados 1.036 pacientes num total de 1.051 internações, sendo 515 (49,7%) homens e 521 (50,3%) mulheres. Um total de 23 de fatores de risco para TEV foram identificados (número total de eventos, 2.319). O risco estratificado para TEV foi de 50,6%, 18,6% e 30,8% das internações para risco alto, moderado e baixo, respectivamente. Em 73,3% das internações, não foram adotadas medidas profiláticas não-medicamentosas durante o período do estudo, e em 74% das internações que apresentavam risco moderado ou alto, não foram adotadas quaisquer medidas terapêuticas medicamentosas. **Conclusões:** Este estudo evidenciou que, na população estudada, os fatores de risco foram frequentes e que medidas profiláticas não foram utilizadas para pacientes com riscos potenciais de desenvolverem TEV e suas complicações.

Descritores: Tromboembolia venosa; Fatores de risco; Trombose venosa/prevenção & controle.

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Introduction

Venous thromboembolism (VTE) comprises deep venous thrombosis (DVT) and its most severe consequence, pulmonary embolism (PE).[1] The acute phase of PE is associated with a high probability of severe complications, which are often fatal.[2]

Approximately 50% of patients with documented DVT have PE. Silent DVT has been reported in 70% of patients with clinically symptomatic, objectively diagnosed PE, probably because these patients presented impaired mobility.[3,4] Among patients hospitalized for at least 48 h, the documented incidence of DVT, which is a common complication in hospitalized patients, is 33%.[5] Acute PE is associated with high morbidity and mortality rates, particularly among inpatients, and hospital autopsy studies have shown acute PE rates ranging from 9 to 21%.[6,7]

According to one author,[8] the estimated incidence of venous thrombosis is 0.6 cases per 1,000 population/year. A European consensus on the prevention of VTE estimated that the incidence of venous thrombosis and PE in western countries is, respectively, 160 and 60 cases per 1,000 population/year.[9]

The prevention of VTE has been neglected in hospitalized patients with congestive heart failure, COPD, cancer or infections. Even in renowned hospitals, omissions and ineffective interventions have been reported.[10]

The use of prophylactic regimens in situations of known risk for PE is a cost effective measure,[11] widely recommended by international committees,[12] the implementation of which is supported by the findings of large double-blind, placebo-controlled clinical trials.[13-15] Although scientifically based, prophylaxis for PE is not effectively employed in general hospitals, since, according to most studies, it is only used in 9 to 56% of such facilities.[16-18] Although PE is a common clinical condition among hospitalized patients, it often goes undiagnosed and can therefore evolve to severe or fatal complications. Among patients who are at high risk for DVT and who develop PE, death occurs rapidly, often before the diagnosis is even considered.[4]

Therefore, it is extremely important that the health team have the necessary technical and scientific knowledge to approach and manage patients at risk for developing PE. The purpose of this study was to assess qualitatively and quantitatively the risk factors for VTE and the prophylactic regimens prescribed by health professionals when treating inpatients in the city of Manaus, Brazil, in order to contribute to a better understanding of the health-illness continuum and consequently allow health care facilities to provide treatment that is more effective.

Methods

This was an observational cross-sectional study, carried out between January and March of 2006, at the *Hospital Maternidade Unimed Manaus* (HMU, Unimed Manaus Maternity Hospital), a private health institution; the *Fundação Hospitalar Adriano Jorge* (FHAJ, Adriano Jorge Hospital Foundation), a public health institution employing specialists in the

Table 1 - Frequency of risk factors for the development of venous thromboembolism in patients hospitalized in the city of Manaus, Brazil, between January and March of 2006.

Higher/lower risk factors	n	%
Surgical time exceeding 30 min	456	19.6
Systemic arterial hypertension	363	15.6
Major abdominal or pelvic surgery	283	12.0
Bedbound	243	11.0
Impaired mobility	232	10.0
Leg fracture	130	6.0
Varicose veins in legs	113	4.8
Malignant neoplasia	203	8.7
Neurologic diseases	91	3.9
Congestive heart failure	57	2.4
COPD	43	1.8
Obesity	28	1.2
Use of birth control medication	19	0.8
Atrial fibrillation	15	0.6
Use of orthopedic prosthesis	8	0.3
Hormone replacement therapy	7	0.3
Nephrotic syndrome	6	0.2
Use of central venous catheter	5	0.2
Peripheral venous thrombosis	5	0.2
Thrombotic disease	4	0.1
Inflammatory bowel disease	3	0.1
Postoperative care in ICU	3	0.1
Congenital cardiopathy	2	0.1
Total	2,319	100.0

ICU: intensive care unit.

Table 2 - Risk stratification of hospitalized patients according to the hospital studied.

Hospital	General risk				p
	High	Moderate	Low	Total	
FCECON					
Frequency	117	38	7	162	< 0.001*
% of the hospital studied	72.2	23.5	4.3	100.0	
% of the total	11.1	3.6	0.7	15.4	
FHAJ					
Frequency	404	148	312	864	> 0.05
% of the hospital studied	46.8	17.1	36.1	100.0	
% of the total	38.4	14.1	29.7	81.2	
HMU					
Frequency	11	9	5	25	> 0.05
% of the hospital studied	44	36.0	20.0	100.0	
% of the total	1	0.9	0.5	2.4	
Total					
Frequency	532	195	324	1051	< 0.001
% of the total	50.6	18.6	30.8	100.0	

FCECON: *Fundação Centro de Controle de Oncologia do Amazonas* (Amazonas State Foundation Center for Cancer Research, Prevention, Education and Treatment); FHAJ: *Fundação Hospitalar Adriano Jorge* (Adriano Jorge Hospital Foundation); and HMU: *Hospital Maternidade Unimed Manaus* (Unimed Manaus Maternity Hospital). *A significant difference was observed among the hospitals in terms of the proportion of high-risk group patients.

various fields of medicine, associated with Amazonas State University and other teaching institutions; and the *Fundação Centro de Controle de Oncologia do Amazonas* (FCECON, Amazonas State Foundation Center for Cancer Research, Prevention, Education and Treatment), a public referral center for the treatment of cancer. All of these institutions are located in the city of Manaus, Brazil.

Our cohort comprised patients who were admitted to the aforementioned hospitals during the study period. All patients included were ≥ 18 years of age and willing to participate in the present study. The selection of patients was based on the following exclusion criteria: being < 18 years of age; having been diagnosed with DVT or PE upon admission; being mentally incompetent; declining to participate in this study or not giving written informed consent after the researchers explained the study objectives and procedures; making use of anticoagulants due to other clinical conditions; presenting any contraindication to the use of prophylactic doses of heparin (such contraindications including active bleeding and coagulation disorders, as well as a history of hemorrhagic cerebrovascular accident, eye surgery and neurosurgery, and being in the postoperative period of obstetric surgery); and being pregnant.

The patients were divided into two groups by whether they would receive clinical or surgical treatment. A surgical case was defined as that in which a hospitalized patient had been submitted to any surgical procedure during the study period.

The method consisted of analyzing patient medical charts and administering a previously prepared questionnaire to obtain information

Table 3 - Risk stratification for venous thromboembolism among hospitalized patients, by hospital sector.

Sector	High risk, n (%)	Moderate risk, n (%)	Low risk, n (%)	Total
Surgery	295 (52.3)	99 (17.6)	169 (30.1)	563 (100.0)
General practice (clinical patients)	237 (48.5)	96 (19.6)	155 (31.9)	488 (100.0)
Total	532 (50.6)	195 (18.6)	324 (30.8)	1,051 (100.0)

p > 0.05.

on clinical, surgical and medication-related risk factors, as well as on prophylaxis for VTE.

Data collection was carried out between January and March of 2006. For each patient, data were collected in two time frames: at the time of admission; and from admission, for a maximum of three months, until discharge or death. Upon admission, patients were identified, evaluated according to the selection criteria, interviewed using the questionnaire and stratified based on their risk for VTE. In the second time frame, patient medical charts were reviewed to determine whether prophylaxis for VTE had been administered. The time limit was imposed because we believe that, after three months, medical practices might be influenced by the objectives of the present study, thus altering the results.

To determine the risk for each patient, we used VTE risk stratification based on the criteria established in 2001 by the *Sociedade Brasileira de Angiologia e Cirurgia Vascular* (SBACV, Brazilian Society of Angiology and Vascular Surgery) and the International Union of Angiology.[19,20] The risk factors considered were as follows: advanced age; being bedbound; having undergone surgery; presenting a history of VTE, cancer, thrombophilia, varicose veins, obesity, infection or trauma; being pregnant or in puerperium; prolonged surgical time; anesthesia time longer than 30 min; having been submitted to general anesthesia; current use of estrogens; presenting a history of heart failure, cerebrovascular accident, paralysis, severe respiratory disease, inflammatory bowel disease, myocardial infarction, arterial insufficiency, chemotherapy or nephrotic syndrome; and use of central catheters.

The data collected were statistically analyzed using the program Statistical Package for the Social Sciences, version 13.0 (SPSS Inc., Chicago, IL, USA), with an alpha error of 5% and 95% CI. Qualitative data were submitted to the chi-square test, and quantitative data were submitted to the Student's t-test.

This study was approved by the FCECON Research Ethics Committee.

Results

We studied 1,036 patients, in a total of 1,051 admissions. Of those 1,036 patients, 515 (49.7%) were male and 521 (50.3%) were female. Ages ranged from 18 to 95 years (mean, 53.31 years).

Of the 1,051 admissions evaluated, 864 (82.2%) were to the FHAJ, 162 (15.4%) were to the FCECON, and only 25 (2.4%) were to the HMU. The lower number of patients from the HMU was due to the fact that pregnant women represent a large proportion of the patients admitted there, and pregnant women were excluded from the study.

Risk factors for VTE (classified as major or minor risk factors) were identified in 2,319 instances, as shown in Table 1. Surgical time longer than 30 min presented the highest prevalence (19.6%), followed by systemic arterial hypertension (15.6%), major abdominal or pelvic surgery (12%), being bedbound (11%) and malignant neoplasia (8.7%).

Table 4 - Use of prophylactic medication according by hospital sector.

Sector	Prophylactic medication		Total
	No	Yes	
Surgery			
Frequency	501	61	562
% of hospital sector	89.1	10.9	100.0
% of general risk	47.7	5.8	53.5
General practice			
Frequency	354	135*	489
% of hospital sector	72.4	27.6	100.0
% of general risk	51.2	12.8	46.5
Total			
Frequency	855	196	1,051
% of general risk	81.4	18.6	100.0

*$p < 0.001$ *vs.* surgery.

Table 5 - Use of nonpharmacological prophylaxis according to the hospital sector.

Sector	Nonpharmacological prophylaxis		Total
	No	Yes	
Surgery			
Frequency	387	175*	562
% of hospital sector	68.9	31.1	100.0
% of general risk	36.8	16.7	53.5
General practice			
Frequency	383	106	489
% of hospital sector	78.3	21.7	100.0
% of general risk	36.4	10.1	46.5
Total			
Frequency	770	281	1,051
% of general risk	73.3	26.7	100.0

*$p < 0.001$ *vs.* general practice.

As can be seen in Table 2, the stratified risk for VTE was as follows: high risk, 532 admissions (50.6%); low risk, 324 (30.8%); and moderate risk, 195 (18.6%).

The greatest proportion of high-risk patients was observed at the FCECON (72.2%; $p < 0.001$), as shown in Table 2. At the FHAJ, risk distribution was as follows: 404 high-risk cases (48.6%), 148 moderate-risk cases (17.1%) and 312 low-risk cases (36.1%). At the HMU, there were 11 high-risk cases (44%), nine moderate-risk cases (36%) and five low-risk cases (20%).

When the cases were analyzed according to the type of treatment applied (clinical or surgical), no significant difference in risk stratification was observed between the clinical and surgical cases (Table 3).

Of the 727 patients presenting moderate or high risk, only 189 (26%) received pharmacological prophylaxis for VTE.

General practitioners made use of pharmacological prophylaxis more often than did surgeons ($p < 0.001$), whereas surgeons made use of nonpharmacological prophylaxis more often than did general practitioners ($p < 0.001$), as shown in Tables 4 and 5. We also observed that, in 770 admissions (73.3%), no nonpharmacological prophylaxis was used during the study period.

Discussion

The patients in our sample were older (mean age, 53.31 years) than those evaluated in other studies.[1,21,22] Patients over 40 years of age are at a higher risk of developing VTE, and this risk doubles with every decade of life. Therefore, patients over the age of 75 have an 18.5% risk of developing VTE. Pharmacological and nonpharmacological prophylaxis can reduce this risk to 4.1%.[23] Among obstetric patients, VTE is a major cause of morbidity and mortality. Pregnant women have a six-fold greater risk of developing VTE. In addition, DVT occurs in one or two of every 1,000 pregnancies.[24-26]

In the present study, the stratified risk for VTE was different from that of two other studies carried out in Brazil,[21,22] in which the prevalence of the different categories of risk of developing VTE was found to be, respectively, as follows: 52.43% and 39.91% for low risk; 42.87% and 30.70% for moderate risk; and 4.70% and 29.39% for high risk.

As previously mentioned, the greatest proportion of high-risk patients was observed at the FCECON. This is due to the fact that the FCECON treats cancer patients, who are more prone to thromboembolic events, which creates a local epidemiological bias. Patients with neoplasia have a higher risk (RR, 15-20) of developing VTE.[27]

Cancer patients undergoing chemotherapy or radiotherapy have a risk of developing VTE three to six times greater than that of the normal population.[28]

Among the 727 patients at high or moderate risk for VTE, only 189 (26%) received prophylactic medication. According to the SBACV clinical guidelines for the prevention of DVT,[19] all patients at high or moderate risk for DVT

should receive prophylactic medication if there are no contraindications. In addition, nonpharmacological prophylaxis should be used in every hospitalized patient, regardless of the risk for VTE. In a study carried out at the Santa Casa de Misericórdia Hospital, in the city of Curitiba, Brazil, only 19.7% of the patients at moderate or high risk for DVT received prophylaxis.[22] A study conducted in the United States, which included over 2,000 inpatients from 16 hospitals, showed that only one third of the patients received prophylaxis, although they had several risk factors for DVT. In that same study, the authors observed that prophylaxis was more often employed in teaching hospitals.[23] A similar result was obtained in the present study, in which the highest percentage of use of pharmacological prophylaxis (21.4%) was observed at the FHAJ, an institution associated with Amazonas State University. Nevertheless, no significant differences were observed among the three hospitals investigated in our study with regard to the use of nonpharmacological prophylaxis.

General practitioners made use of prophylactic medication more often than did surgeons ($p < 0.001$), whereas surgeons made use of nonpharmacological prophylaxis more often than did general practitioners ($p < 0.001$). One possible explanation for not prescribing prophylactic medication for VTE in surgical patients is surgeon concern over the risk of intraoperative bleeding, which can, in theory, occur as a result of the use of anticoagulants. However, data from meta-analyses and double-blind, randomized, placebo-controlled studies have shown that the administration of low doses of heparin (unfractionated heparin or, especially, low-molecular-weight heparin) does not significantly increase the incidence of intraoperative bleeding.[29]

Another possible explanation for not prescribing prophylactic medication is its allegedly high cost. However, the correct use of pharmacological prophylaxis presents a favorable cost-benefit ratio. The financial issue concerning the appropriate allocation of funds is relevant. However, from an ethical and scientific standpoint, it should not be placed above patient needs. In the ethical practice of medicine, patient well-being must always take precedence.

Of the 1,051 cases of hospitalization investigated in the present study, there were 770 (73.3%) in which no nonpharmacological prophylaxis was used (Table 5).

Nonpharmacological prophylaxis consists of simple measures, such as walking, and should be used in all patients, even those at low-risk. Uncontrolled studies have shown that when the clinical condition of the patient does not allow the use of pneumatic compression, or when the hospital does not offer this system, elevation of the legs in the supine position, in order to maintain the popliteal and femoral veins at equal heights, is useful in preventing VTE, at no cost to the hospital.[23]

We observed that prophylactic measures are taken less frequently than recommended, which can lead to the development of PE, a potentially fatal disease that merits concern on the part of physicians. Although prophylactic measures against thromboembolic phenomena are well known and effective, such measures are not taken as frequently as they should be.

In the present study, it is important to point out that: a) the prevalence of risk factors among the population studied was high; b) the percentage of stratified high- and moderate- risk factors was 69.2% (727 hospitalizations); and c) prophylactic medication was given to only 26% of the patients who required it. In conclusion, the present study clearly showed that prophylaxis was not used appropriately in the hospitals investigated, even in patients at potential risk for VTE and its main complication, PE.

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