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Pharmacotherapeutic monitoring of thromboprophylaxis in the Intensive Care Unit

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ABSTRACT

OBJECTIVE

To evaluate thromboprophylaxis in Intensive Care Unit patients.

METHODS

This is a quantitative, cross-sectional and retrospective study, based on the observation of the Pádua scale classification, prescriptions, medical and pharmaceutical progressions made available in the electronic medical records of patients hospitalized from June 5 to December 25, 2022.

RESULTS

12 patients were analyzed. Of these, 25% complied with the Pádua criteria and the prescription, while 75% did not comply. Of these, 50% underwent tracheostomy with anticoagulants, 41.66% were stratified as low risk with drug prophylaxis and 25% as high risk without prophylaxis. There were 21 pharmaceutical interventions, 9.52% of which were related to anticoagulants. UFH was found to be the most prescribed anticoagulant.

CONCLUSION

The study revealed total compliance in three patients (25%) and non-compliance in nine (75%). Clinical pharmacy action was observed with variable pharmaceutical recommendations to optimize pharmacotherapy, as well as the use of drugs in doses and frequencies in accordance with the literature. Bearing in mind that venous thromboembolism can debilitate the quality of life of individuals, increase their hospital stay and generate higher hospital costs, adequate prophylaxis can benefit and reduce negative impacts on the patient.

DESCRIPTORS

Venous thromboembolism, Prophylaxis, Prevention, Pharmacotherapeutic monitoring.

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INTRODUCTION

Venous thromboembolism (VTE) results from the formation of a blood clot (thrombus) in veins¹. The term includes deep vein thrombosis (DVT) as well as pulmonary embolism (PE). The former, commonly found in the lower limbs (85-90%) is the most widespread²⁻³, where thrombi from these deep veins can dislodge (in whole or in fragments), leading to the most dangerous and fatal complication of venous thromboembolism, i.e. pulmonary embolism⁴.

The onset of PE is associated with up to 60% during or after hospitalization⁵. It has high hospital mortality rates⁶ and is second only to acute myocardial infarction (AMI) and stroke as a trigger of cardiovascular mortality⁵. In addition to death from PE, other complications can be caused by VTE, such as post-thrombotic syndrome and chronic thromboembolic pulmonary hypertension^{2,7}.

The worldwide frequency of new episodes related to venous thromboembolism is close to 10 million/year⁵ and its incidence differs between clinical and surgical patients, with 1/1000 and 2/1000, respectively⁷. If clinical patients are compared with the non-hospitalized population (outpatient follow-up), the chances of VTE occurring are 20 times higher for the first group⁷.

The occurrence of VTE can be favored by risk factors⁸ such as obesity, advanced age, cancer, immobilization, surgery, stroke, pregnancy, puerperium, AMI, varicose veins, hypercoagulability, among others^{5,8}. In the hospital setting, the existence of various risk factors increases the likelihood of venous thromboembolism eightfold⁶. Some of these factors are used in risk assessment models (RAMs), which help guide prophylaxis in surgical, clinical and obstetric patients^{5-6,9}.

VTE risk assessment models (RAMs) for surgical patients include the Caprini and Rogers scores, the Pádua score for clinicians and the RCOG (Royal College of Obstetricians and Gynecologists) for obstetric patients^{5,9}. These scores contribute to recommendation of prophylaxis according to the VTE risk classification obtained⁹, defining the need or not for drug prophylaxis, and the application should be routine and individualized^{6,7}.

VTE prophylaxis has been shown to be effective^{7,10-11} and among the drugs used as prophylactics are unfractionated heparin (UFH), low molecular weight heparin (LMWH), fondaparinux, warfarin, rivaroxaban, apixaban and other anticoagulants. However, when contraindications are present, mechanical methods are effective, such as intermittent pneumatic compression and graduated elastic compression stockings⁷.

Bearing in mind that monitoring thromboprophylaxis is important for patient care, the study is justified by the fact that VTE is prevalent in hospital settings¹², where at least 1/3 of inpatients are at risk of developing DVT¹³, as well as the risk of PE, which is associated with high in-hospital mortality (5-15%)¹². It should be pointed out that prophylaxis (medication or non-pharmacological) reduces the number of cases of VTE in hospital⁷, making the disease a preventable cause of death^{2,14} and helping to reduce other associated problems, such as increased hospital costs, prolonged hospitalization^{12,15}, post-thrombotic syndrome in DVT and chronic thromboembolic pulmonary hypertension in PE^{7,12}.

Thereby, the study contributes to identifying whether there is a good percentage of prevention of VTE and its complications in the institution, as well as understanding the benefits of prophylaxis for patients during hospitalization, the role of the pharmacy in monitoring with the multidisciplinary team and raising awareness on the subject, thus aiming to prevent VTE.

The aim of this study was to evaluate the prescriptions of patients admitted to the intensive care unit, thus identifying the compliance and non-compliance of thromboprophylaxis, according to the risk stratification - Pádua scale, understanding whether the prescribed prophylaxis is in accordance with

the risk, verifying the need or not for pharmaceutical intervention and defining how many interventions were accepted or not through the pharmaceutical evolutions.

METHODS

This is a quantitative, cross-sectional, and retrospective study from June 5 to December 25, 2022, with patients admitted to the intensive care unit of a medium-complexity general hospital in the city of São Paulo. These patients were aged 18 or over, had been in the adult ICU for a week or more, were not pregnant, had not undergone surgery or had been admitted due to VTE.

Using Microsoft Excel software, the "PROCV" formula was applied to select the patients who remained in the retroactive censuses from one week to the next, i.e. from 5/6/22-12/6/22; 19/6/22-26/6/22, continuing until the last date 18/12/22- 25/12/22. With the results obtained, we tabulated a spreadsheet containing only eligible patients in terms of length of stay. The electronic medical records were then analyzed to identify the patients who met the other requirements of the study. Subsequently, 12 patients were selected for pharmacotherapeutic monitoring of thromboprophylaxis.

It was understood that before analyzing the prescriptions, it would be essential to observe each patient's risk classification for VTE, since all inpatients over the age of 18 must be assessed and classified as to their risk of developing venous thromboembolism at the time of admission and reassessed every week (on Wednesdays), since changes in prophylaxis may be necessary, such as the emergence of a contraindication due to a change in the clinical picture or a procedure to be carried out. This is assessed using the Pádua score (clinical patients) or the Caprini score (surgical patients), both of which must be included in the electronic patient record (EPR) system.

Therefore, the Padua score was evaluated, since clinical patients in the ICU are classified using this model. This score classifies the risk of VTE as low or high when the scores are 0-3 or > 4, respectively. If it is low risk, non-pharmacological prophylaxis is recommended, while if it is high risk, pharmacological prophylaxis with anticoagulants is recommended.

After observing Pádua's score, the prescriptions were analyzed and identifying the presence or absence of prophylactic methods for VTE. In addition, the patient's clinical situation was analyzed to better understand the lack of prophylaxis when classified as high risk, in cases of thrombocytopenia, hemorrhagic stroke and other conditions.

Therefore, the study did not apply an Informed Consent Form (ICF) since there was no direct contact with the patients. Therefore, a waiver form was used. The technique used was electronic medical record analysis, and data collection took place between July and December 2023, where patient identification was fully preserved throughout the verification of their electronic medical records.

RESULTS

Twelve intensive care unit (ICU) patients admitted between June and December 2022 were assessed, seven of whom were female (58.33%) and five male (41.66%), with an overall average age of 64.5 years. Risk stratification protocols were identified and carried out weekly for all patients.

Three patients (25%) were found to be fully compliant with the classification of the Pádua protocol and anticoagulants. Of these, one patient (33.33%) was classified as high risk, with prophylaxis and no need to suspend the drug throughout the ICU hospitalization and two patients (66.66%), also classified as high risk and with prophylaxis, at a certain point during their stay, gave reasons for not taking drug prophylaxis. Table 1

shows the reasons for the contraindications.

Table 1. Total compliance with Pádua classification and drug prophylaxis (N=3).

According to	Patients	Reason(s)/Contraindication(s)
High risk/with prophylaxis	3	Not applicable
High risk/no prophylaxis	2	Ischemic stroke with hemorrhagic transformation, major oral bleeding, thrombocytopenia (45.000). enlarged international normalized ratio (INR) (2.10), elevated activated partial thromboplastin time (aPTT) (>120s), post-central venous catheter (CVC) puncture hematoma in the right internal jugular vein (VJID)

Tracheostomy was required in four patients (33.33%). Non-compliance was identified in two patients (50%), classified, as high risk and with anticoagulants on prescription. In the other two patients classified as high risk, compliance was noted by the suspension of prophylaxis from the prescription in order to carry out the Tracheostomy. There was no evidence of bleeding in the evolutions after the procedures.

Non-compliance related to the classification of the Pádua protocol as low risk and the permanence of drug prophylaxis in the prescription was present in five patients (41.66%). All of them were over 50 years old and had characteristics such as chronic obstructive pulmonary disease (COPD), reduced mobility, suspected neoplasia, active infection, acute coronary syndrome and kidney disease, among others. Of these patients, if a new protocol had been provided on admission to the ICU, four (80%) could have been classified as fully compliant.

Only three patients (25%) received the classification of high risk and were without VTE prophylaxis at any given time. All were without anticoagulants for one day. The first patient ran out of the drug after the skull computed tomography (CT) report became available, the second patient had anticoagulants the day before and the day after the event and the third patient already had normalized hemoglobin (HB) levels. Therefore, non-compliance was identified in nine patients (75%), including those who were non-compliant with performing the tracheostomy, those classified as low risk with anticoagulant and those classified as high risk without anticoagulant.

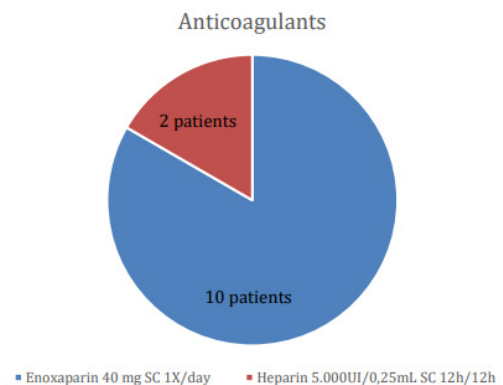
Of the 12 patients, pharmaceutical interventions were not found in only two (16.66%). In 10 patients (83.33%), 21 pharmaceutical recommendations were made, of which 13 were accepted (61.90%) and 8 were not accepted or not made (38.09%). Of these interventions, only 2 (9.52%) were related to anticoagulants, and only the suggestion to suspend anticoagulants was accepted. It was noted that the inclusion of VTE prophylaxis for the suggested patient was carried out the following day by another prescribing professional. Table 2 shows the interventions carried out and their frequencies.

Table 2. Pharmaceutical interventions in the ICU of a medium-complexity general hospital in the city of São Paulo (N= 10 patients).

Intervention	Frequency
Suitability of pharmaceutical form	1
Dose adjustment (subdose)	3
Dose adjustment (overdose)	1
Antibiotic adjustment according to renal function	3
Inclusion of VTE prophylaxis (anticoagulant)	1
Duplication of medication	3
Pharmacoeconomic	1
Inclusion of Laxative Measures	3
Inclusion of acute gastrointestinal mucosal lesions (AGML) prophylaxis	3
Anticoagulant suspension (coagulogram altered)	1
Medication reconciliation	1
Total	21

The drug prophylaxis used to prevent VTE can be seen in Graph 1. 10 patients (83.33%) used heparin (unfractionated heparin - UFH) and 2 patients (16.66%) used enoxaparin (low molecular weight heparin - LMWH). It should be noted that some patients used UFH and LMWH at different times. In addition, as non-pharmacological measures, most patients were prescribed motor physiotherapy when appropriate. In addition, as non-pharmacological measures, most were prescribed motor physiotherapy when appropriate.

Graph 1. Anticoagulants used to prevent VTE in the ICU of a medium-complexity general hospital in the city of São Paulo.



During hospitalization, three patients (25%) used anticoagulants for treatment. The first used enoxaparin 60 mg SC 12h/12h (1 mg/Kg), the second started with enoxaparin 60 mg SC 12h/12h and was later replaced by enoxaparin 40 mg SC 12h/12h. Both were diagnosed with AMI. The third patient used a heparin pump - UFH 5,000 UI/mL one 5 mL vial IV continuously, as he had deep vein thrombosis in his left lower limb. This patient was diagnosed with ischemic stroke with hemorrhagic transformation, and a new skull CT report showed an increase in the volume of the focus of this transformation. He was undergoing tests due to the suspicion of brain death (BD) and was started on heparin with a continuous infusion pump as soon as the left lower limb ultrasound report showed DVT. After a few days of use, the drug was discontinued due to significant oral bleeding, high INR and aPTT.

DISCUSSION

Considering that in the hospital environment preventing venous thromboembolism is of paramount importance for reducing the morbidity and mortality caused by this disease, that prophylactic measures are positive and that the use of risk stratification models can help in the proper application of preventive measures, it is important to carry out the risk stratification in a conscious manner^{7,15-16}.

Campos¹⁶, in his work on adherence to the protocol for VTE in the ICU of a hospital in Rio Grande do Sul, as well as Scaronatti et al.¹⁷ presented higher results than those shown here (25%) regarding the adequacy between prescriptions and what is suggested by the protocol, equivalent to 75.21% and 30.43%, respectively. However, it was noted that compliance could be higher if four of the patients stratified as low risk and with prophylaxis, had received a new application of the Pádua protocol on admission to the ICU, since the fact that they continued to use the protocols from the patient's previous sector, until the new application date (on Wednesdays), led to the categorization in the new unit (ICU) being non-conforming.

Therefore, a new risk assessment of the patient after admission to the ICU, as applied at Hospital do Coração (HCor)¹⁸, could help to adjust compliance, making it possible to assess their risk factors again, showing whether a new score has been

obtained and identifying the need for possible adjustment or not of pharmacological adjustments in the patient's current clinical situation. In addition, this could help to reduce the monthly non-conformities included in the ICU indicators, which in this case would be influenced by protocols generated in other sectors.

The average application of the protocol indicated by Campos¹⁶, was 74.55% in patients admitted to the ICU, in the period of January and June 2020. She added that cases of non-application were linked to short ICU stays (<24h, <48h, and 3 days), although pharmacological measures were present. Unlike what was found, risk assessment was obtained for all patients of the unit, even though it was not carried out on admission, but followed the flow established by the institution. However, this was helped by the inclusion of patients who had been in the ward for at least a week, giving more time for the protocols to be carried out.

Scaravonatti et al.¹⁷ showed a higher rate of non-compliance in their 48 ICU clinical patients (69.56%) than the compliance found in their 21 patients (30.43%). Similarly, non-conformities (75%) prevailed over conformities (25%). However, Scaravonatti et al.¹⁷ inadequacies were related to patients classified as low risk, with doses higher than required (over-treated) and high risk with low-dose anticoagulants or not receiving indicated mechanical prophylaxis (under-treated). In contrast, the present study did not show any difficulties in terms of the doses and frequencies administered, but rather in relation to the stratification of low risk with pharmacological measures, high risk without prophylaxis (with the need for inclusion) and high risk with prophylaxis (with the need for suspension).

Given that there is a contraindication to using UFH in the last 8 hours and LMWH in the last 12 hours¹⁹ for tracheostomy, where the withdrawal of anticoagulants before the procedure is recommended¹⁹ and that complications can occur²⁰, there were no complications found in the evolutions after the procedures were carried out. Therefore, the following question may arise: "was the medication really administered?". This information could only be confirmed by looking at the nursing technicians' records, which unfortunately were not examined.

The study by Lima et al.²¹ showed that 32.9% of their patients (10 clinical and 15 surgical) had prophylactic contraindications, most of whom were classified as high risk. They also pointed out that of the 27 clinical patients (ICU), 40.7% lacked pharmacological prophylaxis and 37% had contraindications to the anticoagulant. Among them, active bleeding, thrombocytopenia and INR >1.5 were mentioned, and these last two complications were also identified by Scaravonatti et al.¹⁷. Reflecting this, both showed similarities with the complications that were noted when prophylaxis was discontinued, shown in Table 1, as well as the similarity of having been classified as high risk, pointing to appropriate measures taken in the case of high-risk patients with contraindications, as in the case of the patient who presented with VTE.

It was concluded that there was a benefit from using UFH and LMWH in reducing VTE by 70% in a placebo study²², in addition to being drugs recommended by the American College of Chest Physicians (ACCP)²¹. And yet, various protocols^{18,23,24} determine the dosages for their use, as described in the document "Consenso de TEV da Sociedade Brasileira de Angiologia e de Cirurgia Vascular - Região São Paulo" (VTE Consensus of the Brazilian Society of Angiology and Vascular Surgery - São Paulo Region) - (SBACVSP)⁷.

Among the prophylactic forms mentioned, prophylaxis was applied as expected and recommended, unlike the findings of Scaravonatti et al.¹⁷, with 55% of patients treated with an inadequate form of UFH. It is believed that the increase in the use of UFH compared to enoxaparin is due to the fact that there are greater renal complications in patients in the intensive care

unit, giving preference to the former, given its recommendation in patients with renal insufficiency (CrCl <30mL/min)^{16,18}.

Studies corroborate the validation and verification of the clinical pharmacist as an important professional in assessing and detecting adjustments to medication²⁵⁻²⁶, contributing to safety, effectiveness and analysis of the need to include or discontinue medications, as well as offering ways of reducing hospital costs²⁵.

Silva et al.²⁶ reported 92.7% adherence to the instructions given, while Maciel et al.²⁵ reported 99.6%, showing higher percentages than those observed (61.90%). However, it became evident that acceptances prevail over non-executions. In this way, it's worth noting the importance of the professional in withdrawing the medication, adjusting the dose, including the medication²⁵ as pharmacological prophylaxis for VTE²¹, among many other behaviors²⁵. Thus, pharmaceutical interventions could contribute to the inclusion of prophylaxis in patients who received a day of non-compliance, due to a lack of medication, which was only observed in one of the patients, carried out again by another prescriber.

The study's limitations include the small number of patients analyzed, given the various pieces of information that had to be collected from each patient in order to establish the results. In this respect, the short study time is also noteworthy, as a longer study time would have made it possible to study a larger number of patients. In addition to these factors, the failure to carry out the protocol as soon as the patient is admitted to the ICU could also have led to more positive compliance results. The lack of a clinical pharmacist at weekends and on a specific week each month to carry out internal audits is also noteworthy, which may also have interfered with the number of interventions carried out in the sector.

CONCLUSION

The pharmaceutical assessment of patients in the ICU showed that three patients (25%) complied with the Pádua risk stratification, and nine patients (75%) did not comply, demonstrating the need for greater adherence to the application of protocols when changing sectors and their guidelines. The action of the clinical pharmacy was observed with variable pharmaceutical recommendations for the optimization of pharmacotherapy during the patients' stay in the unit, with the use of medicines in the doses and frequencies recommended in the literature and in hospital protocols, as well as with the SBACV guidelines. Due to the fact that only motor physiotherapy is used in the hospital, it was not possible to assess the use of other non-pharmacological measures and their benefits.

Given that venous thromboembolism can debilitate quality of life of individuals, increase their hospital stay and generate higher costs, adequate prophylaxis can benefit and reduce the impacts on the patient, where risk stratification favors a look at the adequacy of individualized prophylaxis and optimization of care.

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