

**ASSESSMENT OF THROMBOEMBOLIC RISK IN PATIENTS WITH
GYNECOLOGICAL CANCER IN A HOSPITAL IN
SALVADOR, BAHIA, BRAZIL**

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Highlights: (1) The Onkotev score showed the best predictive performance of thromboembolic risk. (2) Almost 50% of patients who died had malignant neoplasia of the uterine cervix. (3) In more than 90% of cases, thromboembolism developed during hospital stay. (4) Only the PROTECHT score classified patients as high risk (>3).

PRE-PROOF

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ABSTRACT

Introduction: Among acute cardiovascular diseases, venous thromboembolism is one of the most common complications in patients with gynecological cancer, due to prothrombotic state and exposure to vasculotoxic therapies. **Objective:** To evaluate the thromboembolic risk and the profile of anticoagulant use for prevention or treatment of VTE in patients with gynecological cancer, followed up in a specialized hospital. **Methods:** A cross-sectional study was carried out at the Hospital da Mulher, located in Salvador, Bahia in 1 year, consisting of analysis of medical records to track the profile of use and application of the Khorana, PROTECHT and Onkotev scores. **Results:** The electronic medical records of a population of 2,865 women were evaluated, and 117 patients were selected, with a mean age of 57.20 years. Malignant neoplasm of the cervix (42.74%) was the most frequent. The ROC curve determined that Onkotev score presented a better performance predictive of thromboembolic risk (AUC = 0.742; $p = 0.000$; CI-95: 0.651-0.833) in this sample than the Khorana (AUC = 0.567; $p = 0.208$; CI-95: 0.463-0.671) and PROTECHT (AUC = 0.517, $p = 0.730$, CI-95: 0.413-0.624) scores. **Conclusion:** This study is one of the first in Bahia to investigate the profile of anticoagulant use in this group. Onkotev presented itself as the one with the best performance among the others, however, its predictive accuracy remains limited, since it would be able to predict approximately 75% of the VTE cases that occurred. Further studies are needed to evaluate this topic.

Keywords: Anticoagulants; Female Genital Neoplasms; Venous Thromboembolism; Hematology

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CANCER IN A HOSPITAL IN SALVADOR, BAHIA, BRAZIL

AVALIAÇÃO DO RISCO TROMBOEMBÓLICO EM PACIENTES COM
CÂNCER GINECOLÓGICO EM UM HOSPITAL DE
SALVADOR, BAHIA, BRASIL

RESUMO

Introdução: Dentre as doenças cardiovasculares agudas, o tromboembolismo venoso é uma das complicações mais comuns em pacientes com câncer ginecológico, devido ao estado pró-trombótico e à exposição a terapias vasculotóxicas. **Objetivo:** Avaliar o risco tromboembólico e o perfil de uso de anticoagulantes para prevenção ou tratamento de TEV em pacientes com câncer ginecológico, acompanhadas em um hospital especializado. **Método:** Foi realizado um estudo transversal no Hospital da Mulher, localizado em Salvador, Bahia, durante 1 ano, consistindo na análise de prontuários para traçar o perfil de utilização e aplicação dos escores de Khorana, PROTECHT e Onkotev. **Resultados:** Foram avaliados os prontuários eletrônicos de uma população de 2.865 mulheres, sendo selecionadas 117 pacientes, com média de idade de 57,20 anos. Neoplasia maligna do colo do útero (42,74%) foi a mais frequente. A curva ROC determinou que o escore Onkotev apresentou melhor desempenho preditivo de risco tromboembólico (AUC = 0,742; $p = 0,000$; IC-95: 0,651-0,833) nesta amostra do que os escores Khorana (AUC = 0,567; $p = 0,208$; IC-95: 0,463-0,671) e PROTECHT (AUC = 0,517; $p = 0,730$; IC-95: 0,413-0,624). **Conclusão:** Este estudo é um dos primeiros na Bahia a investigar o perfil de uso de anticoagulantes neste grupo. O Onkotev apresentou-se como o de melhor desempenho entre os demais, porém, ainda é considerado um desempenho ruim, visto que seria capaz de prever aproximadamente 75% dos casos de TEV ocorridos. Mais estudos são necessários para avaliar este tópico.

Palavras-chave: Anticoagulantes; Neoplasias dos Genitais Femininos; Tromboembolia Venosa; Hematologia

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1. INTRODUCTION

Cardiovascular diseases and cancer are the leading causes of mortality worldwide¹. Among acute cardiovascular diseases, venous thromboembolism (VTE) is one of the most common complications in cancer patients, due to the prothrombotic state resulting from neoplastic cell changes, exposure to often vasculotoxic therapies, and prolonged hospitalization. Among neoplasms, gynecological cancer has a high incidence of VTE².

The most common gynecological cancers are cervical cancer and ovarian cancer. In a global context, 314,000 cases were diagnosed in 2022, and in Brazil, it is estimated that more than 6,000 new cases of ovarian cancer were diagnosed³. Regarding cervical cancer, in 2020, it is estimated that more than 600,000 women were diagnosed with this neoplasm worldwide⁴. In Brazil, it is estimated that more than 17,000 new cases will be diagnosed in the three-year period from 2023 to 2025.⁵

Considering that VTE prevention is achieved through the use of anticoagulants, it is necessary to evaluate the profile of use of these medications, considering the risk of adverse drug events (ADE), which are defined as any harm suffered by a patient when using a medication, from the time of prescription to the time of use.⁶ Cancer patients are those most at risk of adverse events due to the low therapeutic index of antineoplastics and frequent polypharmacy.⁷

Since cancer patients with inadequate use may present complications; and patients without access to any type of treatment or prophylaxis may have an increased risk of mortality (from 5.5 to 15%)⁸, the aim of this study is to evaluate the thromboembolic risk and the profile of anticoagulant use for the prevention or treatment of VTE in patients with gynecological cancer, monitored in a specialized hospital.

2. METHODS

This was a cross-sectional and retrospective study using medical records analysis. The study was conducted at the Casa de Apoio do Hospital da Mulher, in the city of Salvador, Bahia, Brazil, during one year (august 2023 to august 2024).

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Patients diagnosed with any of the following types of gynecological cancer were included: vaginal cancer, fallopian tube cancer, vulvar cancer, cervical cancer, endometrial cancer and/or ovarian cancer who were receiving oral or injectable anticoagulants, with indication for prophylaxis or treatment of venous thromboembolism, and who were undergoing cancer treatment at the hospital.

Data on anticoagulants, such as drug name, dose, posology and indication, were collected. Regarding the patients, data were collected from medical records, including demographic and clinical data. Data on laboratory tests were also collected in order to monitor treatment. The risk of thrombotic events in patients was assessed using the Khorana, PROTECHT and Onkotev scores, calculated retrospectively based on the data available on medical records, and are described on Figure 1.

Figure 1. VTE Risk Scores.

VTE Risk Scores			
Parameters	Khorana	PROTECHT	Onkotev
Very high risk (stomach, pancreas)	+2	+2	-
High risk (lung, lymphoma, gynecologic, bladder, testicular)	+1	+1	-
Pre-chemotherapy platelet count $\geq 350 \times 10^9/L$	+1	+1	-
Hemoglobin level $< 100 \text{ g/L}$ or use of erythropoiesis-stimulating agents	+1	+1	-
Pre-chemotherapy leukocyte count $> 11 \times 10^9/L$	+1	+1	-
BMI $\geq 35 \text{ kg/m}^2$	+1	+1	-
D-dimer $> 1,44 \text{ } \mu\text{g/L}$	-	-	-
Soluble P-selectin $> 53,1 \text{ ng/L}$	-	-	-
Chemotherapy with gemcitabine	-	+1	-
Platinum-based chemotherapy	-	+1	-
Khorana score > 2	-	-	+1
Previous venous thromboembolism	-	-	+1
Metastatic cancer	-	-	+1
Macroscopic vascular/lymphatic compression	-	-	+1

Source: As seen on original studies^{8,9}, adapted by authors, 2025.

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Statistical analysis was performed using IBM SPSS Statistics 30.0.0.0 software. In addition to basic descriptive statistics, such as standard deviation, mean, frequency, minimum and maximum values, Pearson's Chi-square test, one-way and two-way Analysis of Variance (ANOVA) and construction of a ROC (Receiver Operating Characteristic) and Precision-Recall curve were performed, with the Tukey and Bonferroni tests being used as post-hoc tests, when applicable. Distribution was determined by the Komolgorov-Smirnov test before the realization of ANOVAs. All statistical analyses were performed considering a 95% confidence interval (CI) and an α value of $p < 0.05$ or $p < 0.0001$.

All sensitive data that could lead to possible patient identification were excluded. This research is part of the ongoing umbrella project entitled "Study of anticoagulants used by cancer patients treated by the Unified Health System", led by Dr. Maria Teresita Bendicho and approved by no. 52710421.3.0000.0057. The actual research was funded by the Fundação de Amparo à Pesquisa do Estado da Bahia (FAPESB) under term number BOL0249/2023, in addition to being part of the Multiprofessional Research Group in Oncology, at the Universidade do Estado da Bahia (UNEB).

3. RESULTS

In this study, the electronic medical records of a population of 2,865 women were evaluated, of which 117 were selected, with a mean (SD) age of 57.20 (12.65) years, ranging from 29 to 86 years, as seen in Table 1. The excluded patients (2,748) were due to missing data (47), presentation of another type of cancer, such as breast cancer, gastrointestinal (2,034) and/or were not using anticoagulants (714). The variables of education and occupation were often ignored when filling out the electronic medical records, which led to the exclusion of both in the construction of the demographic and clinical profile of the patients.

Patients with malignant ovarian neoplasia presented a higher frequency of stage III (55.9%) and stage IV (35.3%), a similar trend for malignant neoplasia of the cervix, with stage III (40.0%) and stage IV (30.0%). For patients with malignant endometrial

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neoplasia, stage IV was the most frequent (48.4%), followed by stage III (29.0%), which was significant ($p < 0.001$, CI-95%, Qui-quadrado de Pearson).

Malignant ovarian neoplasia had the same frequency for the age groups between 46 to 60 years (44.1%) and between 61 to 75 years (44.1%), malignant endometrial neoplasia was more frequent in patients between 61 and 75 years (63.1%) and malignant cervical neoplasia was more frequent in patients between 46 and 60 years (44.0%) ($p < 0.001$, CI-95%, Qui-quadrado de Pearson).

The most frequent histological type in malignant cervical neoplasia was moderately differentiated invasive squamous cell carcinoma (7.69%), and in malignant ovarian neoplasia, high-grade serous carcinoma (18.80%). Patients with malignant endometrial neoplasia had the most frequent histological type, grade III endometrioid adenocarcinoma (5.98%), with a statistically significant association ($p < 0.001$). There was no statistical significance observed between BMI (evaluated as a categorical variable as described on Table 1) and development of venous thromboembolism (VTE) ($p=0.222$), nor with the main outcome being death ($p=0.080$, CI-95%, Qui-quadrado de Pearson).

Considering an important part of patients (40%) used more than one anticoagulant, it's described in the table 1 the times each anticoagulant was used. It is worth noting that more than 60% of patients (64.1%) used only a single anticoagulant, with enoxaparin being the most frequent, approximately 30% used two anticoagulants during their hospital stay (30.1%), with the combination of enoxaparin in-hospital and rivaroxaban at discharge being the most frequent. Only six patients (5.13%) used three anticoagulants, with heparin being replaced by enoxaparin being the most frequent use.

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Table 1. Clinical and general profile of the patients studied

Clinical and general profile of the patients studied		
Variable	Absolute Frequency	Relative Frequency
Age group		
<30 years old	5	4,3%
31-45 years old	14	12,0%
46-60 years old	45	38,5%
61-75 years old	46	39,3%
>76 years old	7	6,0%
Body Mass Index (BMI)		
Underweight (<18,5)	13	11,2%
Normal (18,6-24,9)	53	45,7%
Overweight (25-29,9)	32	27,6%
Obese Class I (30-34,9)	16	13,8%
Obese Class II (35-39,9)	0	0%
Obese Class III (>40,0)	2	1,7%
Cancer Diagnosis		
Malignant ovarian neoplasm	34	29,0%
Malignant endometrium neoplasm	31	26,4%
Malignant cervix neoplasm	50	42,7%
Malignant fallopian tubes neoplasm	1	0,8%
Malignant vulvar neoplasm	1	0,8%
Cancer Staging		
Stage I	5	4,3%
Stage II	22	18,8%
Stage III	48	41,0%
Stage IV	42	35,9%
Follow-Up Status		

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Active	44	37,6%
Inactive (abandonment or transference)	9	7,7%
Death	64	54,7%
Treatment Regimen in Addition to Chemotherapy		
No (Chemotherapy Only)	35	29,9%
Surgery	33	28,2%
Radiotherapy	21	17,9%
Surgery, Brachytherapy and Radiotherapy	7	5,9%
Brachytherapy and Radiotherapy	12	10,2%
Surgery and Radiotherapy	9	7,7%
VTE Occurrence		
No	70	59,8%
Deep Venous Thrombosis (DVT)	32	27,3%
Pulmonary Embolism (PE)	4	3,4%
DVT and PE	11	9,4%
Anticoagulants*		
Enoxaparin	93	79,5%
Sodium Heparin	23	19,6%
Rivaroxaban	42	35,9%
Sodium Warfarin	7	5,9%

Source: Authors, 2025. DVT: Deep Vein Thrombosis. PE: Pulmonary Embolism.

*Represented by the times used by all patients included.

Among the patients who were on VTE prophylaxis, enoxaparin was the most used medication (87.14%), followed by sodium heparin (15.71%). Although it was used by all patients diagnosed with VTE at some point during treatment (72.34%), in cases

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where rivaroxaban was used as VTE prophylaxis, the patients were considered by the attending physician to be at high risk according to observations in the medical records.

Among the cases of warfarin use, all patients using it had an indication due to VTE. Only one patient used warfarin as the first-choice home medication after discharge (14.28%). For the treatment of VTE, enoxaparin was used in 63.83% of cases. Similarly, among the patients who used heparin, 39.13% used it for the treatment of VTE, and in 43.48% of cases heparin was used as a replacement for enoxaparin due to some adverse event. In only one case was heparin used as a replacement for warfarin due to anemia.

In more than 90% of cases (94.02%), VTE developed during the hospital stay, and in only 7 (5.98%) cases, patients were transferred with a previous diagnosis and anticoagulant for treatment of DVT, with frequent use of rivaroxaban (57.14%). This association between VTE and previous use of anticoagulants, however, was not relevant ($p=0.630$, CI-95%, Qui-quadrado de Pearson).

Regarding the type of malignant neoplasm and the development of VTE, 51.06% had cervical malignant neoplasm, 25.53% of patients had ovarian malignant neoplasm, and 21.27% had endometrial malignant neoplasm. The two patients with vulvar malignant neoplasm and fallopian tube malignant neoplasm did not have VTE. The association between malignant neoplasm and the occurrence of VTE was not statistically significant ($p=0.478$, CI-95%, Qui-quadrado de Pearson).

Regarding the type of cancer and progression to death, almost 50% of the patients who died had malignant neoplasia of the cervix (46.87%), approximately 30% had malignant neoplasia of the ovary (29.69%), and the third significant portion was malignant neoplasia of the endometrium (21.87%). The only patient who had malignant neoplasia of the vulva died (1.57%). However, there was no statistical significance between the type of neoplasia and the occurrence of death ($p=0.857$, CI95%, Qui-quadrado de Pearson).

Among the patients who developed VTE, 42.18% died, with 34.38% of these patients having an episode of DVT and 3.12% of the patients having PE, a value close to that of patients who developed PE after DVT (4.68%). The remainder corresponded to patients undergoing prophylaxis who died due to complications of the disease (57.81%),

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but without a relationship ($p=0.978$). This association between the type of neoplasia and other treatment regimens was statistically significant ($p < 0.001$, CI-95%, Qui-quadrado de Pearson).

Similarly, clinical staging also presented the same p-value, with stage III and IV being more frequent among patients who underwent surgery (41.7%) and radiotherapy (21.4%), respectively. Regarding the performance of the scores, the average points observed among the patients are shown in Table 2, as well as the minimum and maximum values presented in the sample.

Table 2. Risk Scores Performance

Scores	Mean	SD	MIN	MAX
Khorana	2,20	0,95	1,00	4,00
PROTECHT	3,26	1,04	1,00	5,00
Onkotev	1,51	0,90	0,00	4,00

Source: Authors, 2025. SD: Standard Deviation. Min: Minimum value. Max: Maximum value.

Considering the classifications for each score, it is observed that, on average, patients, according to the Khorana score, would be classified as having intermediate risk for developing VTE (between 1 and 2), for PROTECHT, high risk (>3) and, for Onkotev, also intermediate risk (between 1 and 2). In relative terms, a good portion of the patients presented a score of +2 for Khorana (37.6%, intermediate risk); +3 for PROTECHT (31.6%, which would configure high risk) and +1.00 for Onkotev (39.3%, intermediate risk).

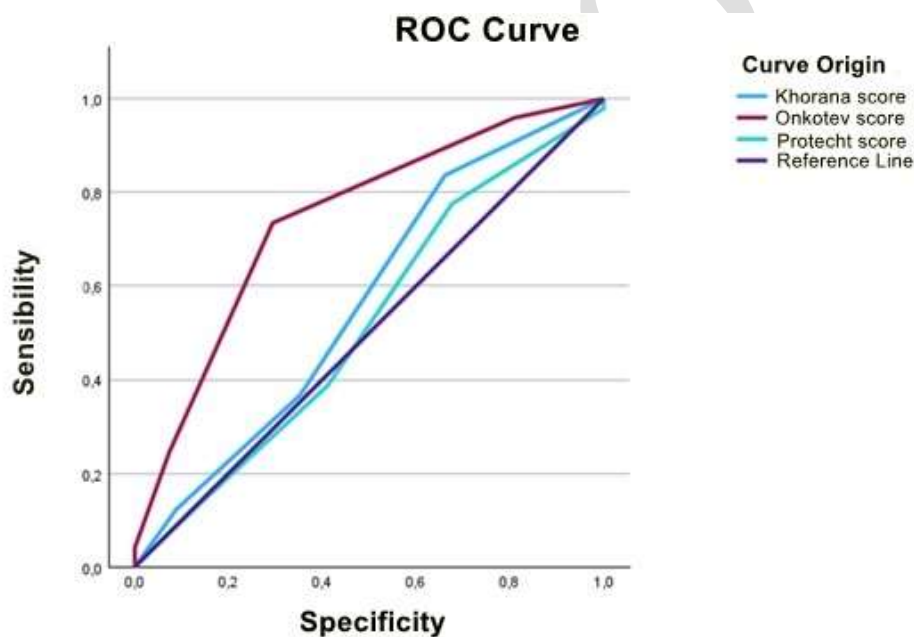
In terms of the performance of the scores to predict the occurrence of VTE, considering the real positive status as YES, the ROC curve observed in Figure 2 determined that the Onkotev score presented a better predictive performance of thromboembolic risk ($AUC = 0.742$; $p < 0.001$; CI-95%: 0.651-0.833, One Way ANOVA) in this sample than the Khorana ($AUC = 0.567$; $p = 0.208$; CI-95%: 0.463-0.671, One Way

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ANOVA) and PROTECHT (AUC = 0.517, $p = 0.730$, CI-95%: 0.413-0.624, One Way ANOVA) scores.

Regarding a Precision-Recall curve as seen in Figure 3, Onkotek maintained a positive performance in relation to the Khorana and PROTECHT scores. The low number of low points on the curve indicates that there is a low presence of false positives compared to the other scores, which barely touch the 1.0 line. Regarding the classifications on the ROC curve, however, it would still be classified as poor because it presents an AUC between 0.7 and 0.8. Khorana and PROTECHT, in turn, would be classified as very poor (AUC between 0.5 and 0.6), regarding the AOC classifications.

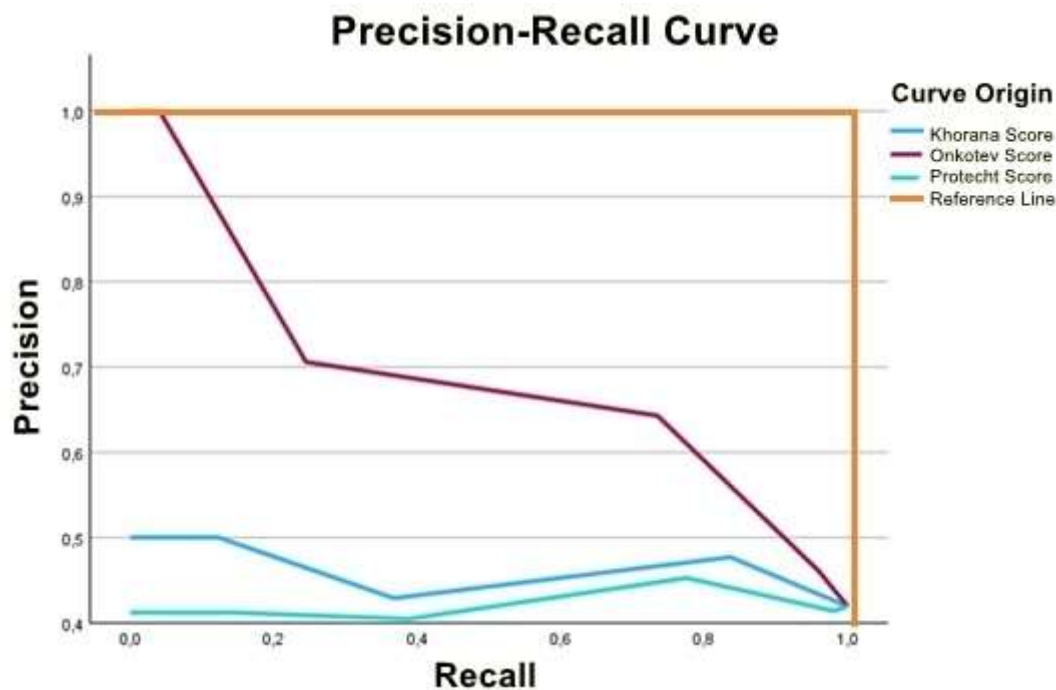
Figure 2. ROC Curve for the venous thromboembolism risk scores



Source: SPSS, adapted and authors, 2025. **ROC:** Receiver Operating Characteristic

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Figure 3. Precision-Recall Curve for the venous thromboembolism risk scores



Source: Authors, 2025

4. DISCUSSION

The data revealed the predominance of malignant neoplasia of the cervix, which reinforces the statistics of the national panorama where cervical cancer is the third most frequent cancer among female patients, and is also the second most common cancer in the Northeast region (risk of 16.10 cases per 100,000 inhabitants) in 2019.⁹

According to the estimates of the National Cancer Institute for 2023 to 2025 for Brazil, cervical cancer accounts for 17,010 of the new cases of malignant neoplasia in women, with 5,280 cases in the Northeast, followed by malignant neoplasia of the ovary, with 1,960 cases, and malignant neoplasia of the endometrium, or body of the uterus, with 1,550 cases.¹⁰ This trend was similar to that found in the present study in terms of the most frequent malignant neoplasia.

The two least frequent neoplasms in this study, malignant neoplasm of the vulva and malignant neoplasm of the fallopian tubes, are neoplasms considered rare, with the

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first corresponding to less than 4.0% of worldwide cancer cases¹¹, and the second frequently treated as a manifestation of ovarian or primary peritoneal malignant neoplasm as it is even rarer, corresponding to 1 to 2% of worldwide cases.¹²

The age range follows similar trends in the literature. For malignant ovarian neoplasia, a study¹³ found that between 1990 and 2012, the age range most affected by ovarian cancer in Latin America were patients over 60 years of age, a range that was also tied in this study with patients between 46 and 60 years of age. Some possible reasons are the high levels of estrogen, which are often higher at this age, decreasing after 60; therefore, neoplasias that have a greater hormonal influence, such as endometrial cancer and cervical cancer, have averages at these ages.

In a similar trend¹⁴, malignant neoplasia of the cervix also showed invasive squamous cell carcinoma as the most frequent (more than 70% of cases); in ovarian malignancy, serous adenocarcinoma (23.6%) and, for patients with endometrial malignancy, the most frequent histological type differed from the present study, with type I endometrioid adenocarcinoma being the most frequent (76.0%).

The frailty and general condition of the patients may also have influenced the fact that half of the population in this study was using anticoagulants only for prophylaxis of venous thromboembolism. The risk factors for VTE, as previously discussed, mainly include advanced age, obesity, presence of cardiovascular diseases, neoplasms, prolonged immobilization and major surgeries, factors present in the sample studied¹⁵.

The use of thromboembolic scores is recommended by the health guidelines as well as several associations to introduce the best anticoagulant therapy and improve the management of these patients^{15, 16}. The Khorana score is the most widespread and probably the most used, as it was one of the first to be developed for this purpose. With the advancement of health technologies, however, other laboratory and diagnostic parameters have been associated with neoplasms, leading to the development of other scores, such as PROTECHT and Onkotev, aiming at better sensitivity and specificity for better evaluation of these patients.

In this study, considering that the closer the AUC is to one, the better, and AUCs between 0.5 and 0.6 are considered very poor; between 0.6 and 0.7, poor; between 0.7

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and 0.8, poor; 0.8 and 0.9, good; and >0.9 , excellent¹⁷; it was observed that the PROTECHT score presented the worst performance compared to the Khorana and Onkotev scores. The trends in the literature are mixed, with the Khorana scores presenting good performances in some studies, and very poor in others.

In a comparative study between CONKO, PROTECHT and Khorana¹⁸, a comparative performance was found for all, without superiority; however, all were considered poor because they presented AUCs between 0.6 and 0.7. In another study¹⁹, the performance of the Khorana score was considered very poor, as it was similar to this study, presenting an AUC of 0.565.

Another study that compared Khorana, PROTECHT and 5-SNP²⁰ observed that the performance of all three was considered poor (between 0.5 and 0.6), with PROTECHT performing relatively better among the three, but still delivering a poor performance.

Talking about Onkotev performance, a study that compared the Khorana, PROTECHT, Conko, Onkotev, Compass-CAT and CATS/MICA scores²¹, Onkotev presented the best performance among the three (0.68), as similar to the present study. However, this performance is still considered poor, considering that it was able to predict only 68% of VTE cases (therefore, less than 70%).

Another study²² showed that Onkotev's performance was also superior to Khorana's (0.71 and 0.66, respectively), suggesting better performance for individual VTE prophylaxis compared to Khorana. In another study²³, however, Onkotev's performance was similar (0.59) compared to Khorana (0.61), PROTECHT (0.61) and CONKO (0.60), with all presenting a very poor or poor performance in predicting VTE risk.

In this study, it was not possible to calculate the prevalence ratio for the development of VTE in relation to gynecological cancers in general, since this was a sample without a group without gynecological cancer or with other types of neoplasia for comparison. Since this was a cross-sectional study, it was not possible to establish causal relationships or define risk factors, since the patients were not followed over time, and only hypotheses were defined that can be explored in more appropriate studies, such as cohort studies.

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In addition, the analysis of data via electronic medical records limits the exploration of some variables, such as adverse events, where it would be necessary to monitor the patient in order to establish a more possible relationship between the medications and the observed event than a probable one. The use of anticoagulants is also a variable that is impacted by this limitation, since the system does not identify the timing of prescriptions, that is, it is not known whether those anticoagulants were actually administered to the patient or not.

5. CONCLUSION

The most prevalent age group was patients between 45 and 60 years old, with a mean age of approximately 53 years old, which accompanies the trends presented in other studies. Malignant neoplasm of the cervix was the most frequent, followed by malignant ovarian neoplasm and malignant endometrial neoplasm, in line with national and regional trends regarding cases of these neoplasms.

Although no statistically significant association was identified between the types of neoplasm and the development of VTE, malignant neoplasm of the cervix was the one with the highest frequency of this outcome compared to the other neoplasms in the study.

As it was seen above, Onkotev presented itself as the one with the best performance among the others, however, when it comes to classification, it's still seen as a poor performance, since it would be able to predict approximately 75% of the VTE cases that occurred. Nevertheless, it's visible how the utilization of more than one score on clinical practice is recommended, since neither of them isolated had a concise effect in this study.

This study is one of the first in Bahia to investigate the profile of anticoagulant use in this specific group of patients, aiming to fill gaps in the literature associated with this topic. However, as observed, further studies are needed to investigate the hypotheses raised.

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