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ORIGINAL PAPER

Results of rotational thromboelastometry confirm venous thromboembolic risk prediction in urologic patients

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Summary ***Purpose: Venous thromboembolic (VTE) complications contribute substantially to perioperative morbidity and mortality. The decision for mechanical and/or chemo-prophylaxis is currently based on VTE risk assessment models since conventional laboratory assays of coagulation usually fail to detect changes indicating hypercoagulability. Rotational thromboelastometry is a novel assay of coagulation, that it could be potentially used in objectively selecting patients at risk for VTE, that should indisputably undergo prophylaxis. We evaluated the association of conventional and novel assays of coagulation and VTE risk.***

Methods: VTE risk was preoperatively assessed in 45 patients scheduled for endoscopic, open and laparoscopic urologic surgery, including transurethral resection of prostate, transurethral resection of bladder tumor, endoscopic vesical or ureteral stone lithotripsy, open prostatectomy, open cystectomy and urinary diversion, open or laparoscopic radical or partial nephrectomy, between March 2021 and October 2022, using three different risk assessment models (RAMs): the European Association of Urology (EAU) RAM, the American Urological Association (AUA) RAM, and the Caprini model. Patients under antiplatelet or anticoagulation agents were excluded. Patients' coagulation profile was determined by measuring PT, fibrinogen, aPTT, and rotational thromboelastometry analysis. For rotational thromboelastometry analysis extrinsic rotational thromboelastometry and fibrinogen rotational thromboelastometry were examined in every patient. Statistical analysis was performed with ANOVA test and χ^2 test.

Results: Mean values of all rotational thromboelastometry variables did not vary significantly among different EAU VTE categories. In extrinsic rotational thromboelastometry assessment a significant difference was observed in the mean values of the Clotting Time (CT) between the different risk groups based on AUA RAM. In the comparison between the risk groups defined based on the Caprini score, statistically significant differences were observed in the extrinsic rotational thromboelastometry Clot Formation Time (CFT). In fibrinogen rotational thromboelastometry analysis significant differences were identified in the clot amplitude after five minutes (A5) and Maximum Clot Firmness (MCF) indices between the AUA risk groups, along with significant difference in the mean Clot Formation Rate (CFR) value between the risk groups defined based on the Caprini score.

Conclusions: Rotational thromboelastometry can provide a detailed evaluation of the hemostatic status in patients undergoing urologic surgery that can be used as an adjunct to the VTE risk assessment models and thus, help to offer prophylaxis on a rather personalized basis. Future studies should assess the utility of thromboelastometry in identifying patients at high risk for VTE after major urological procedures.

KEY WORDS: *Venous thromboembolism; Urologic surgery; Rotational thromboelastometry; Hypercoagulability.*

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INTRODUCTION

Venous thromboembolic (VTE) complications contribute substantially to perioperative morbidity and mortality, as 1-5% of patients undergoing urologic surgery develop symptoms of VTE (1-3). Furthermore, pulmonary embolism seems to be the most common cause of postoperative death (4).

These data raise serious concerns regarding the necessity of administering prophylactic antithrombotic treatment to patients who will undergo, potentially hemorrhagic operations (5-8). In a systematic review and meta-analysis that included urological, gynecological, and general surgical procedures pharmacological thromboprophylaxis correlated with a decrease of approximately 50% on VTE risk, along with an increase of 50% on major bleeding (9). Interestingly, a large randomized series of patients undergoing open or robotic radical prostatectomy demonstrated that pharmacological prophylaxis did not confer a significant reduction on the VTE events (10).

The decision for mechanical and/or chemo-prophylaxis is currently based on VTE risk assessment models (RAMs) since conventional laboratory assays of coagulation such as *prothrombin time* (PT), fibrinogen levels and activated *partial thromboplastin time* (aPTT) usually fail to detect changes indicating hypercoagulability (11, 12). Currently the two major urological societies, *European Association of Urology* (EAU) and *American Urological Association* (AUA), propose their respective *risk assessment models* (RAMs) for postoperative VTE prevention, which are based on strong evidence (4, 13).

Rotational thromboelastometry (ROTEM®) (*ROTEM® delta, Pentapharm GmbH, Munich, Germany*) is a novel assay of

coagulation, which is based upon a modification of *thromboelastography* (TEG). ROTEM® analysis is frequently used to assess the visco-elastic properties of the clot formation during surgery as well as following trauma, and its results are reproducible and stable over time (14).

Hincker et al. (12) observed that preoperative ROTEM® may be able to identify patients that are at high risk for VTE after major non-cardiac surgery. Thus, it could be potentially used in subjectively selecting patients at risk for VTE that should indisputably undergo prophylaxis. Consequently, the decision for prophylaxis could be based more on the context of precision and personalized medicine, rather than that of the current risk-assessment prediction model.

The aim of our study is to evaluate the association between conventional (PT, fibrinogen and aPTT) laboratory assays of coagulation, ROTEM® analysis and VTE risk assessed by using EAU (15) and AUA (16) VTE *risk assessment models* (RAMs) and Caprini score (Figure 1) (17), in patients scheduled for urologic surgery.

Materials and methods

Study design and subjects

All patients undergoing urologic surgery in the *First Department of Urology, NKUA, Laikon Hospital* were eligible. Patients under antiplatelet or anticoagulation agents were excluded, as the ROTEM® delta test is not sensitive to the effect of these agents (18). The study was approved by the *Scientific and Ethics Committee of Laikon General Hospital of Athens*, and consent was obtained by all participants in this study. ROTEM® results were not known to the patients' physicians, and postoperative anticoagulation prophylaxis was used according to EAU Guidelines (15).

Data and sample collection

Patients' medical records were reviewed for demographics, comorbidities, and surgical procedure. VTE risk was preoperatively assessed in every patient using EAU (15) and AUA (16) VTE RAMs and Caprini score (17). The stratification proposed by each model is described in Table 1.

Patients' coagulation profile was also determined by measuring *prothrombin time* (PT), fibrinogen levels, *activated partial thromboplastin time* (aPTT),

ROTEM® analysis

Rotational thromboelastometry is a novel assay of coagulation that measures the viscoelastic properties in blood, during clot formation. Currently it is incorporated in the management of bleeding in trauma patients and those undergoing cardiac surgery. Other indications of blood coagulation profile assessment with the usage of ROTEM® include bleeding during complex procedures, such as liver transplantation, peri- and postpartum bleeding, and investigation of inherited and acquired bleeding disorders (18).

The ROTEM® system allows various activators and inhibitors to be added to the sample. This allows different

Figure 1.

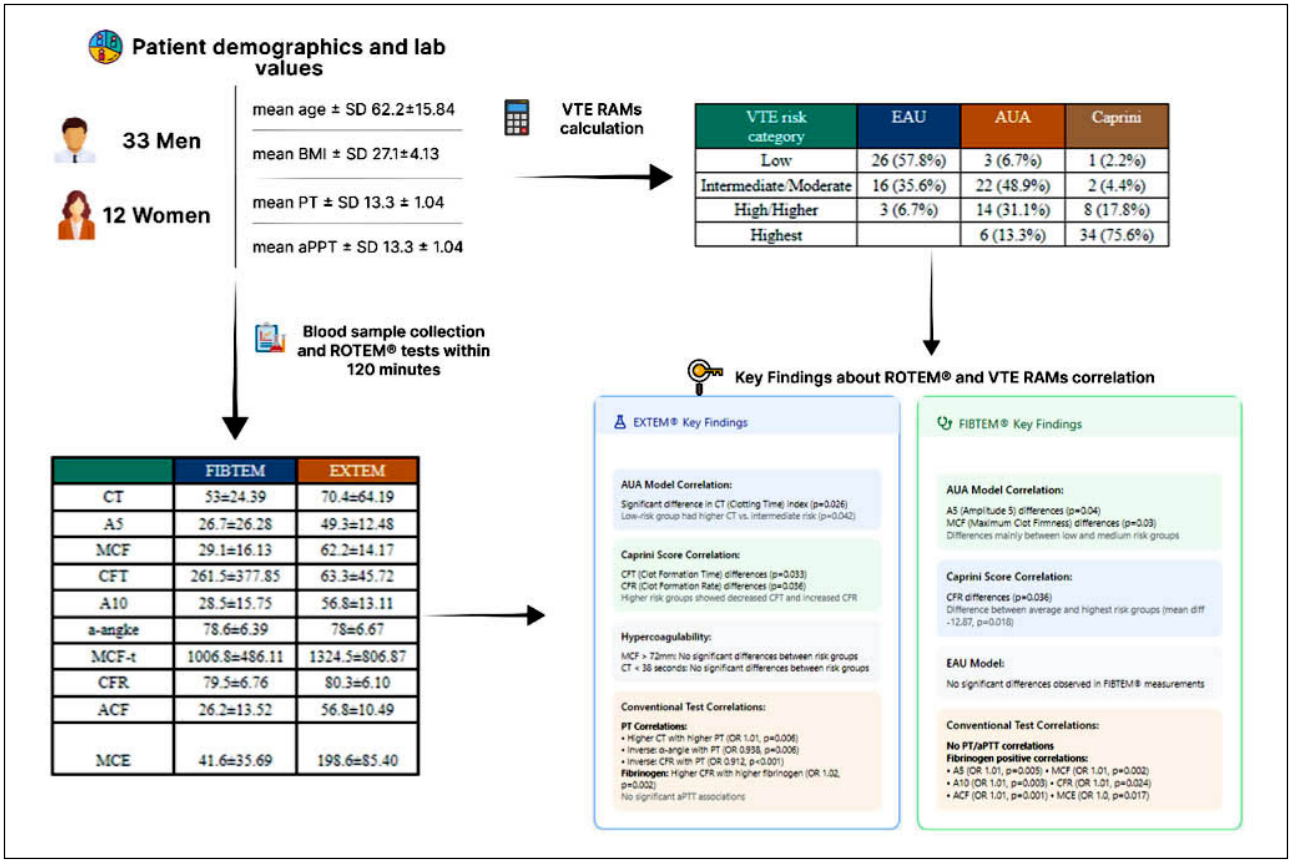

Table 1.
Description of risk groups proposed by EAU, AUA and Caprini models.

Risk Assessment Model	Stratification	Description
EAU	Low risk	No risk factors
	Medium risk	Any one of the following: age ≥ 75 years; BMI ≥ 35; VTE in first degree relative
	High risk	Prior VTE; Patients with any combination of two or more risk factors
AUA	Low risk	Minor surgery* in patients < 40 years with no risk factors**
	Moderate risk	Minor surgery in patients with risk factors Surgery in patients 40-60 years with no risk factors
	High risk	Surgery in patients > 60 years Surgery in patients 40-60 years with risk factors
	Highest risk	Surgery in patients with multiple risk factors
Caprini	Low risk	Total risk factor score*** 0-1
	Moderate risk	Total risk factor score 2
	Higher risk	Total risk factor score 3-4
	Highest risk	Total risk factor score 5 or more

** Minor surgery was defined as an operation with short operative time in which the patient was rapidly ambulatory.*
*** Surgery Trauma (major or lower extremity); Immobility, paresis; Malignancy; Cancer therapy (hormonal, chemotherapy, or radiotherapy); Previous Venous Thromboembolism; Increasing age; Pregnancy and the postpartum period; Estrogen-containing oral contraception or hormone replacement therapy; Selective estrogen receptor modulators; Acute medical illness; Heart or respiratory failure; Inflammatory bowel disease; Nephrotic syndrome; Myeloproliferative disorders; Paroxysmal nocturnal hemoglobinuria; Obesity; Smoking; Varicose veins; Central venous catheterization; Inherited or acquired thrombophilia.*
**** Total risk factor score was calculated through an extensive assessment of patient and surgery related risk factors. Caprini score assigns weighted points to clinical risk factors including age, duration and type of surgery, pregnancy or hormonal therapy, comorbidities, immobility, history of thrombosis, major trauma, presence of central venous catheter or PICC line or port (17).*

Table 2.
Available normal reference ranges for ROTEM measurements.

ROTEM variable	FIBTEM	EXTEM
Clotting time, s	43-69	42-74
Clot formation time, s	-	46-148
Alpha angle, degrees	-	63-81
Amplitude at 10/20 minutes	8-21	50-69
Maximum clot firmness, mm	9-25	49-71

processes of haemostasis to be assessed individually. In EXTEM® clot formation is activated by thromboplastin and the extrinsic clotting cascade is assessed. FIBTEM® assesses fibrin formation and polymerization, by blocking the thrombocytes with the addition of cytochalasin D. Other assays include INTEM®, which examines the intrinsic system, APTEM®, where fibrinolytic processes are inhibited in vitro, and HEPTEM®, which is sensitive for heparinized samples (19).

After the addition of proper clotting factors the blood sample was placed in a disposable cup heated at 37°C. Afterwards a constant rotational force was applied on the sample through a vibrating pin. The oscillating pin had a mirror attached where a light beam was directed. As the clot was forming the rotational force was gradually decreasing and alterations in light reflectance were detected by photo-sensors (18).

The ROTEM® delta analyzer was used by trained personnel to perform all ROTEM® tests. Every sample was analyzed on *extrinsic rotational thromboelastometry* (EXTEM®) and *fibrinogen rotational thromboelastometry* (FIBTEM®). The FIBTEM® and EXTEM® tests were performed on two parallel channels simultaneously, using programs specified by the manufacturer. The EXTEM® study evaluates the extrinsic mechanism of coagulation, while the formation of the thrombus is activated by thromboplastin. In the FIBTEM® test, coagulation activation is performed as in EXTEM®, with the difference that a platelet blocker is added. This results in functional assessment of fibrinogen levels and fibrin polymerization (19).

In patients included in the study, blood samples used for ROTEM® analysis were collected during insertion of peripheral venous catheter or during venipuncture for preoperative blood tests, not related to the study. This process was performed when patients came to the urology department for their preoperative check-up. The samples were stored in Vacutainer™ 3.5 mL (*Becton Dickinson, North Ryde, Australia*) collection tubes, containing 3.2% sodium citrate.

The analysis was performed within 120 minutes of blood collection, and the samples were stored at room temperature. The parameters offered after the completion of the analysis were *Clotting Time* (CT), clot amplitude *after five minutes* (A5), *Maximum Clot Firmness* (MCF), clot amplitude *after ten minutes* (A10), a-angle, *Maximum Clot Firmness time* (MCF-t), *Clot Formation Rate* (CFR), *Actual Clot Firmness* (ACF) and *Maximum Clot Elasticity* (MCE). All available rotational thromboelastometry reference ranges are shown on Table 2 (18).

Hincker et al. examined the association between thromboembolic events and rotational thromboelastometry in patients undergoing major non-cardiac surgery (12). In their analysis they found that a ROTEM® was defined as hypercoagulable when the value of the MCF index was > 97.5th percentile of the general population reference values for the EXTEM® test, (72 mm) or if the CT < 38 seconds. This is the only available literature on this subject that our search was able to find, so we used the same values to define hypercoagulability.

Statistical methods

Descriptive statistics were used to summarize the data. Categorical variables were summarized using frequencies and percentages, while continuous variables were summarized using the corresponding mean and *standard deviation* (SD). Normality was evaluated using the Shapiro-Wilk test, while homogeneity was assessed using the Levene's test. The ANOVA test was used to compare the mean values of continuous variables between different risk groups of VTE RAMs.

In case of finding a statistically significant difference, the post-hoc Tukey test was applied to find the specific groups whose mean values differed significantly. In case of violation of an assumption necessary for performing

ANOVA, the non-parametric Kruskal-Wallis test was used. In case of finding a statistically significant difference, the Dwass-Steel-Critchlow-Fligner test was applied to find the specific groups whose mean values differed significantly. A general linear model with a negative binomial distribution and a log link function was used to model the relationship between conventional laboratory coagulation examinations and ROTEM® measurements.
The frequency of hypercoagulability was compared between the different thromboembolic risk groups using the χ^2 test (12). In case of violation of a necessary assumption for the above test, Fisher's exact test was used alternatively. The statistical significance level was set at p-value < 0.05. Statistical analysis was performed using Jamovi software (20).

Results

The study included 45 patients, of whom 33 were men (73.3%) and 12 were women (26.7%). The mean age of the population and the mean *body mass index* (BMI) were 62.2 ± 15.84 and 27.1 ± 4.13, respectively. During preoperative testing, as part of the laboratory investigation of patients' blood coagulation, it is common practice in our department to measure prothrombin time (PT), activated partial thromboplastin time (aPTT) and fibrinogen levels. The mean values of these indices in the study population were 13.3 ± 1.04, 34.1 ± 5.71 and 383.6 ± 95.46, respectively. The above basic demographic and laboratory data are summarized in Table 3.
Patients' thromboembolic risk was assessed preoperatively using the VTE risk assessment models of the *European Association of Urology* (EAU), the *American Urological Association* (AUA), as well as by calculating the Caprini score.
Based on the EAU assessment model, 57.8%, 35.6% and 6.7% of the population were categorized as low, intermediate, and high risk for thromboembolic events, respectively. The respective percentages for low, intermediate, high, and very high risk groups based on the AUA model were 6.7%, 48.9%, 31.1% and 13.3%. The median Caprini score for the population was 6 (IQR 2.00) and 2.2%, 4.4%, 17.8% and 75.6% of the population were classified as low, intermediate, higher, and very high risk. Table 4 includes a summary of the division of patients into risk groups based on these three predictive models. In Figure 1 there is a summary of the study's population characteristics, the study's workflow, and its key findings.

Table 3.
Basic demographic data and values of conventional coagulation tests of the population.

	Patients (n = 45)
Gender, n(%)	
Male	33 (73.3%)
Female	12 (26.7%)
Age, mean value ± SD	62.2 ± 15.84
BMI, mean value ± SD	27.1 ± 4.13
Prothrombin time, mean value ± SD	13.3 ± 1.04
Activated partial thromboplastin time, mean value ± SD	34.1 ± 5.71
Fibrinogen, mean value ± SD	383.6 ± 95.46

SD: Standard deviation; BMI: Body Mass Index.

Table 4.
Distribution of the population into risk groups for thromboembolic events based on the predictive models.

	Risk assessment model		
VTE risk category	EAU	AUA	Caprini
Low	26 (57.8%)	3 (6.7%)	1 (2.2%)
Intermediate/Moderate	16 (35.6%)	22 (48.9%)	2 (4.4%)
High/Higher	3 (6.7%)	14 (31.1%)	8 (17.8%)
Highest		6 (13.3%)	34 (75.6%)

Comparison of the mean values of the EXTEM® test measurements between the different thromboembolic risk groups based on the EAU predictive models did not reveal statistically significant differences, A significant difference was observed in the mean values of the CT index (p = 0.026) in categories based on the AUA model categorization, with the low-risk group having a significantly higher CT compared to the intermediate risk group (p = 0.042).
In the comparison between the risk groups defined by the Caprini score, statistically significant differences were observed in the *Clot Formation Time* (CFT) index (p = 0.033), with the highest risk groups having lower CFT value (average risk 111.5 95% CI 47.3-175.7, highest risk 73.13 95% CI 41-105.2, very high risk 59.55 95% CI 43.3-75.8). In addition, a statistically significant difference was observed in the CFR index (p = 0.036), where an increase in the index was shown in higher risk groups (average risk 71.0 95% CI 62.9-79.1, higher risk 78.6 95% CI 74.6-82.7, very high risk 81.0 95% CI 78.9-83.1).
The mean values of the different EXTEM indices along with their respective standard deviation are provided in Table 5.
No significant differences were observed when comparing the mean values of FIBTEM® test measurements between the different thromboembolic risk groups based on the EAU predictive model.
Regarding the risk groups based on the AUA classification, significant differences were identified in the A5 (p = 0.04) and MCF (p = 0.03) indices. In both cases the difference depended from differences between the low and medium risk groups (A5 mean difference -19.47, p = 0.05, MCF mean difference -19.2, p = 0.05).
Finally, a statistically significant difference was identified in the mean CFR value between the risk groups defined by the Caprini score (p = 0.036), with the main difference found between the average and highest risk groups (mean difference -12.87, p = 0.018) (Figure 2) The mean values of the different FIBTEM indices along with their respective standard deviation are provided in Table 6.
Post-hoc pairwise comparisons along with their effect on coagulation are included in Table 7.
Defining hypercoagulability as MCF index value > 72mm in the EXTEM® study, no statistically significant difference was observed in the frequency of hypercoagulability between the different thromboembolic risk categories. Similarly, defining hypercoagulability as a CT value of

Table 5.
ANOVA test results for EXTEM parameters.

EXTEM parameter	EAU (Low, Intermediate, High-risk) (p-value)	AUA (Low, Moderate, High, Higher-risk) (p-value)	Caprini (Low, Moderate, Higher, Highest) (p-value)
CT, mean value ± SD	70.2 ± 57.63 62.2 ± 66.09 113.3 ± 111.51 (p = 0.362)	174.3 ± 127.75 50.2 ± 20.12 84.4 ± 78.93 49.7 ± 22.51 **(p = 0.026)**	127.00 ± NA 198.00 ± 171.12 58.38 ± 18.55 63.45 ± 57.40 (p = 0.078)
A5, mean value ± SD	49.8 ± 12.96 48.8 ± 11.17 47.3 ± 19.04 (p = 0.935)	46.0 ± 15.13 49.7 ± 11.12 49.4 ± 14.31 49.5 ± 13.95 (p = 0.975)	63.00 ± NA 37.50 ± 4.95 45.50 ± 9.84 50.63 ± 12.99 (p = 0.258)
MCF, mean value ± SD	62.3 ± 13.65 61.7 ± 15.4 64 ± 17.52 (p = 0.908)	63.3 ± 11.85 61.2 ± 15.06 61.6 ± 16.44 66.2 ± 6.82 (p = 0.993)	77.00 ± NA 56.50 ± 0.71 61.50 ± 13.84 62.23 ± 14.83 (p = 0.293)
CFT, mean value ± SD	55.1 ± 35.6 70.9 ± 55.57 90.3 ± 65.74 (p = 0.674)	75.7 ± 65.06 54.6 ± 30.82 65.4 ± 47.76 79.5 ± 73.42 (p = 0.921)	4.00 ± NA 111.50 ± 27.58 73.13 ± 24.12 59.55 ± 48.82 **(p = 0.033)**
A10, mean value ± SD	56.07 ± 13.05 57.1 ± 13.20 57 ± 18.52 (p = 0.996)	56.7 ± 13.43 56.7 ± 11.89 56.7 ± 15.22 57.5 ± 14.77 (p = 0.999)	72.00 ± NA 49.00 ± 2.83 53.25 ± 11.96 57.80 ± 13.62 (p = 0.203)
a-angle, mean value ± SD	79.3 ± 6.59 76.7 ± 5.77 73.3 ± 10.6 (p = 0.224)	75.0 ± 12.49 79.2 ± 5.00 77.7 ± 7.68 76.0 ± 6.54 (p = 0.631)	89.00 ± NA 68.00 ± 4.24 76.88 ± 3.48 78.52 ± 6.78 (p = 0.062)
MCF-t, mean value ± SD	1222.3 ± 768.25 1396 ± 926.85 1784.7 ± 253.99 (p = 0.116)	1378.7 ± 97.74 1263.9 ± 872.42 1226.3 ± 744.68 1718.7 ± 961.12 (p = 0.839)	1307.00 ± NA 1414.50 ± 106.77 1602.88 ± 926.66 1247.45 ± 813.43 (p = 0.784)
CFR, mean value ± SD	80.6 ± 6.38 80.9 ± 4.5 74.7 ± 10.07 (p = 0.258)	77.3 ± 11.37 81.2 ± 5.52 79.8 ± 6.90 80.2 ± 3.37 (p = 0.770)	90.00 ± NA 71.00 ± 4.24 78.63 ± 4.03 81.00 ± 6.03 **(p = 0.036)**
ACF, mean value ± SD	55.9 ±11.31 61 ± 7.55 48.5 ± 7.78 (p = 0.244)	52.0 ± 11.27 57.3 ± 8.46 56.1 ± 14.30 60.8 ± 5.12 (p = 0.753)	65.00 ± NA 45.50 ± 0.71 54.88 ± 11.64 58.18 ± 10.18 (p = 0.321)
MCE, mean value ± SD	195.9 ± 93.87 220.2 ± 62.76 131.5 ± 58.69 (p = 0.132)	199.7 ± 121.56 191.5 ± 64.29 197.0 ± 116.52 229.0 ± 43.60 (p = 0.802)	340.00 ± NA 129.50 ± 3.54 180.75 ± 73.56 204.95 ± 87.97 (p = 0.173)

less than 38 seconds, no statistically significant difference was observed in the percentage of hypercoagulability in the various risk groups according to predictive thromboembolic risk models.

Finally, conventional methods of assessing coagulation, prothrombin time, partial thromboplastin time and fibrinogen did not show statistically significant differences between risk groups based on predictive models.

Moreover, the investigation of the relationship between conventional laboratory tests and EXTEM indices indicat-

Table 6.
ANOVA test results for FIBTEM parameters.

FIBTEM parameter	EAU (Low, Intermediate, High-risk) (p-value)	AUA (Low, Moderate, High, Higher-risk) (p-value)	Caprini (Low, Moderate, Higher, Highest) (p-value)
CT, mean value ± SD	55.5 ± 25.21 47.6 ± 20.66 58.0 ± 39.00 (p = 0.580)	65.0 ± 5.20 51.1 ± 23.24 55.2 ± 30.31 48.8 ± 22.23 (p = 0.779)	59.0 ± NA 68.0 ± 0.00 65.3 ± 28.03 48.9 ± 23.60 (p = 0.293)
A5, mean value ± SD	27.0 ± 17.68 27.2 ± 13.88 21.0 ± 19.70 (p = 0.492)	11.7 ± 3.06 31.1 ± 17.94 25.6 ± 13.71 20.0 ± 13.87 (p = 0.04)	15.0 ± NA 10.0 ± 1.41 23.5 ± 8.02 28.8 ± 17.69 (p = 0.117)
MCF, mean value ± SD	29.3 ± 17.36 29.5 ± 14.10 26.0 ± 20.52 (p = 0.748)	14.7 ± 5.69 33.9 ± 17.37 27.6 ± 13.56 22.2 ± 15.11 (p = 0.03)	21.0 ± NA 11.5 ± 2.12 26.9 ± 8.22 31.0 ± 17.57 (p = 0.159)
CFT, mean value ± SD	360.3 ± 451.96 106.8 ± 88.26 42.0 ± NA (p = 0.689)	934.0 ± NA 175.5 ± 258.81 251.5 ± 495.06 526.8 ± 376.35 (p = 0.122)	934.0 ± NA NA 274.9 ± 355.83 232.0 ± 372.86 (p = 0.253)
A10, mean value ± SD	28.2 ± 17.18 30.4 ± 12.38 22.3 ± 20.98 (p = 0.267)	13.3 ± 4.16 32.5 ± 17.67 26.5 ± 13.17 25.2 ± 12.21 (p = 0.056)	18.0 ± NA 11.0 ± 1.41 25.1 ± 7.99 30.8 ± 17.04 (p = 0.092)
a-angle, mean value ± SD	78.1 ± 7.17 79.6 ± 5.09 77.0 ± 7.07 (p = 0.758)	74.5 ± 6.36 79.5 ± 7.07 78.4 ± 6.42 76.6 ± 2.70 (p = 0.640)	NA 74.5 ± 6.36 75.1 ± 6.74 79.6 ± 6.14 (p = 0.307)
MCF-t, mean value ± SD	996.8 ± 460.04 1044.5 ± 584.74 917.0 ± 266.78 (p = 0.910)	1195.3 ± 186.83 956.4 ± 451.58 983.9 ± 647.77 1174.6 ± 238.38 (p = 0.740)	1348.0 ± NA 1119.0 ± 186.68 1095.5 ± 449.61 966.9 ± 514.92 (p = 0.794)
CFR, mean value ± SD	78.7 ± 7.63 80.9 ± 5.04 79.0 ± 8.49 (p = 0.637)	68.0 ± 5.66 80.7 ± 6.87 79.8 ± 6.27 78.0 ± 4.06 (p = 0.075)	NA 68.0 ± 5.66 76.4 ± 6.40 80.9 ± 6.10 (p = 0.036)
ACF, mean value ± SD	26.5 ± 14.04 28.9 ± 11.71 10.5 ± 6.36 (p = 0.068)	14.0 ± 4.00 30.5 ± 14.61 25.4 ± 13.77 20.3 ± 1.89 (p = 0.06)	18.0 ± NA 12.0 ± 2.83 25.9 ± 7.59 27.9 ± 15.21 (p = 0.130)
MCE, mean value ± SD	43.2 ± 37.10 44.1 ± 35.09 12.5 ± 9.19 (p = 0.113)	17.3 ± 7.77 51.1 ± 42.00 40.2 ± 33.59 26.3 ± 1.89 (p = 0.130)	26.0 ± NA 13.0 ± 2.83 38.3 ± 15.71 46.0 ± 41.50 (p = 0.142)

ed that higher CT measurements were associated with higher PT values (OR 1.01 95%CI 1-1.01 p = 0.006), while an inverse relationship was observed between a-angle (OR 0.938 95% CI0.898-0.979 p= 0.006) and CFR (OR 0.912 95%CI 0.873-0.952 p = < 0.001) values with PT. No significant association was detected between aPTT and EXTEM measurements, whereas it was found that higher CFR (OR 1.02 95% CI 1.01-1.03 p = 0.002) measurements were associated with higher fibrinogen values (Figure 3).

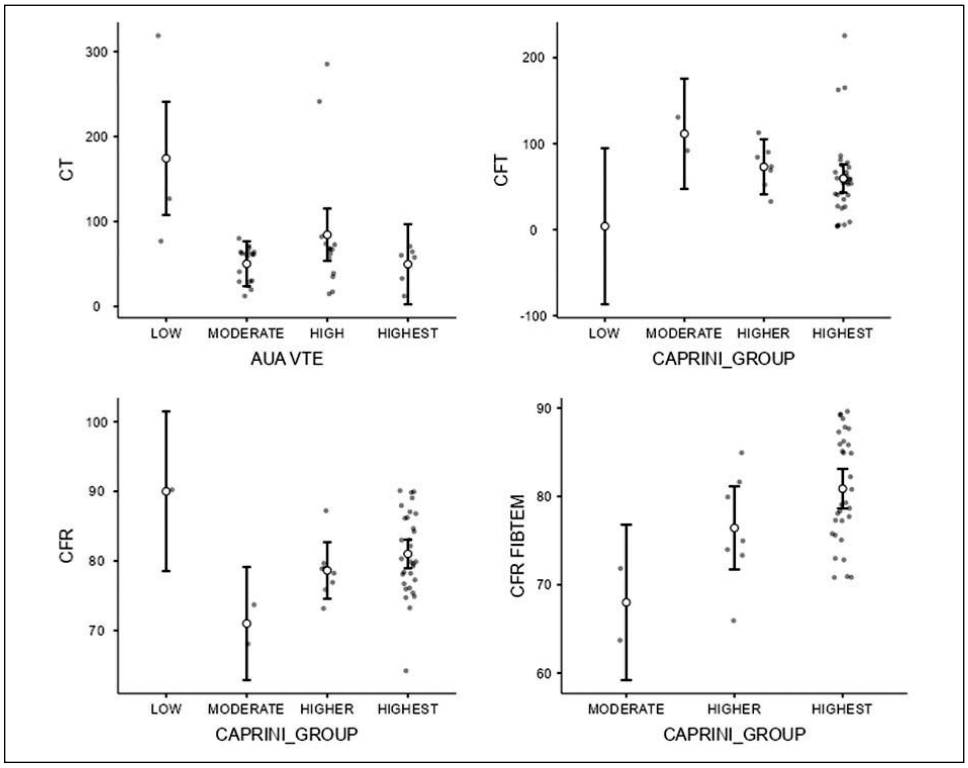

Figure 2.
Estimated marginal means (mean ± 95% confidence intervals) of EXTEM CT, EXTEM CFT, EXTEM CFR and FIBTEM CFR according to venous thromboembolic risk stratification.

Table 7.
Post-hoc pairwise comparisons in ROTEM variables with statistically significant differences in their mean value across different thromboembolic risk groups. CT EXTEM-AUA RAM, A5 FIBTEM - AUA RAM, MCF FIBTEM - AUA RAM and CFT EXTEM - CAPRINI analyzed through non-parametric ANOVA; CFR EXTEM-CAPRINI and CFR FIBTEM - CAPRINI analyzed through ANOVA. Post-hoc pairwise comparisons were performed using Tukey correction. MD: Mean Difference.

ROTEM variable - VTE RAM	Pairwise comparisons	Effect on Coagulation
CT EXTEM - AUA RAM	Low - Moderate p = 0.042	Lower CT value in Moderate AUA risk group reflects increased risk for hypercoagulation
A5 FIBTEM - AUA RAM	Low - Moderate p = 0.05	Higher A5 value in Moderate AUA risk group reflects increased risk for hypercoagulation
MCF FIBTEM - AUA RAM	Low - Moderate p = 0.05	Higher MCF value in Moderate AUA risk group reflects increased risk for hypercoagulation
CFT EXTEM - CAPRINI	Unable to detect any statistically significant pairwise differences	The gradual decrease in mean CFT values across Moderate-Higher-Highest Caprini risk groups reflects an increase in risk of hypercoagulation
CFR EXTEM - CAPRINI	Low - Moderate MD = 19, p = 0.045	Higher CFR value in Low Caprini risk group reflects increased risk for hypercoagulation
CFR FIBTEM - CAPRINI	Moderate – Highest MD = -12.87, p = 0.018	Higher CFR values in Highest Caprini risk group reflects increased risk for hypercoagulation

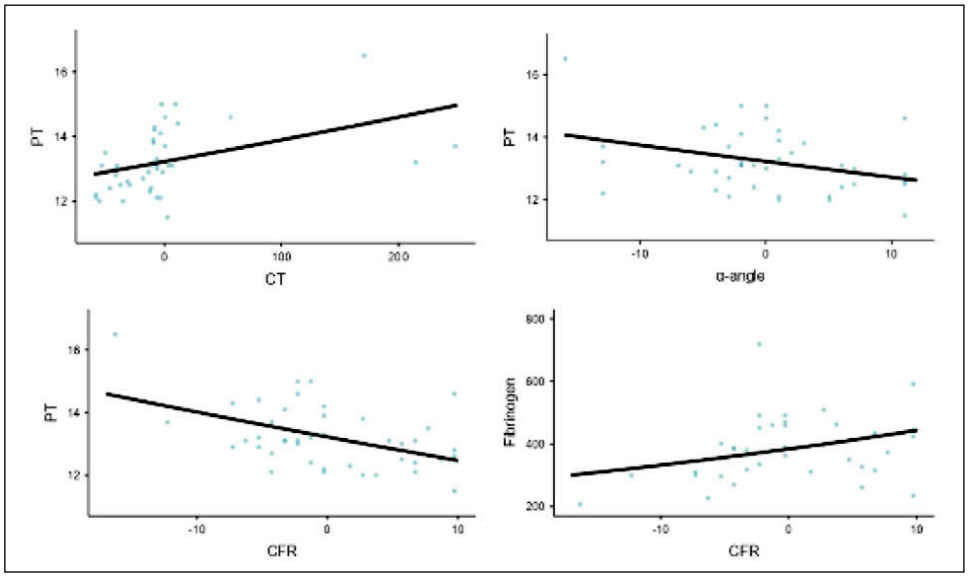

Figure 3.
General linear regression models plots about EXTEM indexes and conventional laboratory tests.

Figure 4.
General linear regression models plots about FIBTEM indexes and conventional laboratory tests.

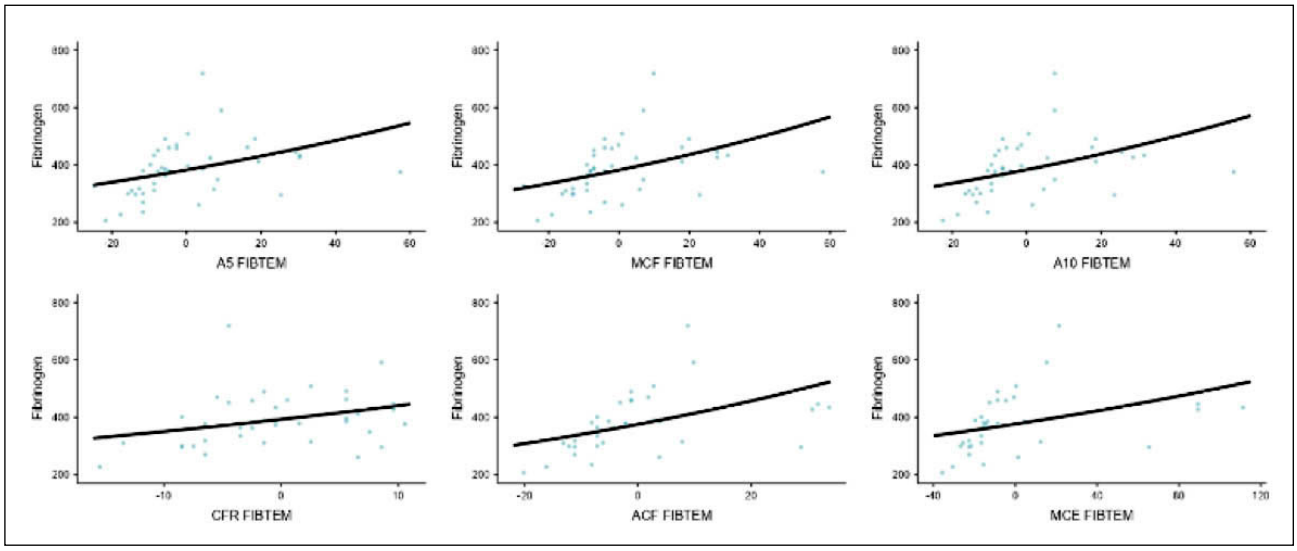

Table 8.
Mean values of standard coagulation tests in different thromboembolic risk groups and ANOVA test results.

Laboratory assay	EAU (Low, Intermediate, High-risk) (p-value)	AUA (Low, Moderate, High, Higher-risk) (p-value)	Caprini (Low, Moderate, Higher, Highest) (p-value)
Prothrombin time	13.3 ± 0.961 13.2 ± 0.866 13.5 ± 2.570 (p = 0.78)	13.8 ± 0.755 13.2 ± 0.892 13.3 ± 1.375 12.9 ± 0.887 (p = 0.706)	14.6 ± NA 13.4 ± 0.424 13.2 ± 0.779 13.2 ± 1.123 (p = 0.518)
Activated partial thromboplastin time	33.8 ± 5.531 34.4 ± 6.503 35.3 ± 5.339 (p = 0.721)	33.2 ± 0.231 33.2 ± 5.965 36.2 ± 5.994 33 ± 5.477 (p = 0.175)	32.9 ± NA 33.3 ± 0 31 ± 2.993 35 ± 6.255 (p = 0.304)
Fibrinogen	370.3 ± 82.115 418.3 ± 102.707 313 ± 132.827 (p = 0.183)	253.7 ± 39.463 397.5 ± 96.655 391.1 ± 95.535 379.8 ± 73.774 (p = 0.086)	235 ± NA 263 ± 50.912 427.3 ± 131.329 384.7 ± 79.988 (p = 0.057)

Subsequently, the corresponding relationship between FIBTEM indices and conventional coagulation tests revealed no significant correlation between either PT or aPTT and FIBTEM results. However, there was a positive linear relationship between A5 (OR 1.01 95%CI 1-1.02 p = 0.005), MCF (OR 1.01 95%CI 1-1.01 p = 0.002), A10 (OR 1.01 95%CI 1-1.01 p = 0.003), CFR (OR 1.01 95%CI 1-1.02 p = 0.024), ACF (OR1.01 95%CI 1-1.02 p = 0.001), MCE (OR 1 95%CI 1-1.01 p = 0.017) and fibrinogen levels (Figure 4).

Lastly, the mean values of the standard coagulation tests were compared within the different risk categories, although this comparison revealed no statistically significant differences among the risk groups defined by the three VTE RAMs. The mean values of the standard coagulation tests in each risk group are provided in Table 8.

Discussion

Analysis of the results of this study revealed some interesting findings. More specifically, to the best of our knowledge this is the first study to examine the correlation between rotational thromboelastometry, and the VTE risk assessment tools provided by the European and American Urological Associations.

Firstly, a poor relationship between the EAU RAM and the ROTEM indices was observed. The EAU RAM has been, recently, validated using data from the VISION study including patients undergoing urologic, general abdominal

and gynecological surgery demonstrating clinical applicability (21). However, taking into consideration that different studies in the literature have proven the ability of ROTEM in evaluating hypercoagulability in conjunction with the poor level of recommendation of thromboprophylaxis in the EAU clinical guidelines regarding specific procedures included in the different risk groups of EAU RAM, ROTEM could serve as a useful instrument for a more balanced approach to perioperative thromboprophylaxis (15, 22, 23).

Moreover, this study revealed statistically significant differences in the EXTEM CT, FIBTEM A5 and MCF values between the different risk groups for VTE according to the AUA RAM criteria. Significantly lower values of CT, higher values of A5 and MCF, that were detected mainly in patients of moderate risk compared to low-risk patients, indicate higher risk of hypercoagulation. AUA proposes the use of a VTE screening instrument developed by *Geerts et al.* and the accordance between the ROTEM results and the AUA risk groups offers an indirect validation of the tool (24). Consequently, it can be concluded that according to ROTEM findings, EAU cannot categorize the patients regarding their risk for thromboembolic events as reliably as the AUA model, in disagreement with our previously published study indicating similar efficacy of these VTE RAMs (25).

However, these results should be interpreted with caution in relation to both the small number of patients in each group and the lack of a consistent trend across the AUA risk classes for some parameters.

Other statistically significant findings related to EXTEM were the differences in CFT and CFR between risk groups of the Caprini score, while for FIBTEM a statistical significant difference was shown for the CFR index between the average and very high-risk groups for VTE.

It has to be underlined that, regarding EXTEM CFT, ANOVA detected an overall difference among groups, which can be, also, visible at Figure 2, but after Tukey correction no pairwise comparison reached statistical significance probably due to the global nature of the ANOVA test and the small sample size. Thus, this outcome reveals statistical caution, not inconsistency. Additionally, in respect of EXTEM CFR, although a trend of increasing mean values across moderate, higher and highest risk groups was present, the pairwise comparison identified as source of this significant difference the higher CFR mean value in low compared to moderate risk group indicating enhanced risk of hypercoagulation in the low-risk group. Lower CFT and higher CFR values correspond to enhanced risk of hypercoagulation.

Contradictory to previously published literature, where no differences were detected in thromboelastometry measurements among patients undergoing bariatric surgery stratified by their preoperative Caprini score (26). The inconsistency of the results might derive from the fact that by utilizing Caprini groupings most of the patients undergoing major abdominal or pelvic surgery are classified as high risk, in spite of being distributed across different risk of developing VTE, combined with the small number of patients included in this study (27).

Another area we analyzed was the correlation, in the EXTEM® test, between MCF and CT values, which *Hincker et al.* (12) found to be associated with hypercoagulability in patients undergoing non-cardiac surgery, and the risk groups based on the three VTE RAMs. There did not appear to be statistical significance in the percentage of patients who had MCF > 72 mm or CT < 38s between the various risk groups.

Additionally, the present study indicated that certain EXTEM indices, including CT, a-angle, and CFR, were linearly correlated with both PT and fibrinogen levels. However, only a poor correlation was detected, namely a unit of increase in CT value is expected to cause a 1% increase in PT count, while a unit of increase in CFR would increase fibrinogen levels by 2%. This comes to partial agreement with previously published literature concluding that due to the poor association between EXTEM CT and PT or aPTT, the results of these tests cannot be used interchangeably to assess hemostatic disorders intraoperatively (28). Also, a significant association was detected between FIBTEM measurements, including A5, A10 and MCF, and fibrinogen levels. This has been previously described indicating that fibrinogen constitutes a major contributor to clot firmness which is measured by ROTEM assays (29).

These results are added to a series of studies that have shown that ROTEM® may be able to predict hypercoagulability (12, 23, 30, 31). However, further studies should be conducted before considering to add thromboelastom-

Declarations

Ethical approval and consent for participate: *The study was approved by the Scientific and Ethics Committee of Laikon General Hospital of Athens (approval number 447/28-06-2021).*

Consent for publication: *Consent was obtained by all participants in this study.*

Availability of data and material: *The datasets used and/or analyzed during the current study are available upon reasonable request from the corresponding author.*

Competing interests: *The authors declare that they have no competing interests.*

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Authors' contributions: *KD: Ethics committee approval, Protocol/project development, Data collection, Manuscript original drafting; KK: Data analysis and interpretation, manuscript original drafting; NM: Data acquisition, Data analysis and interpretation, contribution to manuscript writing and editing; EF: Protocol/Project development, contribution to manuscript writing and editing; PS: Protocol/project development, Interpretation of data, Manuscript editing; IA: Interpretation of data, Manuscript editing; IA: Interpretation of data, Manuscript editing; KS: Interpretation of data, Manuscript editing; DM: Protocol/project development, Funding obtaining, Supervision, Manuscript editing; All the authors read and approved the final version of the manuscript and agreed to be accountable for all aspects of the work.*

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etry to the preoperative screening of patients for the decision-making process for thromboprophylaxis.
Finally, the limitations of this study should not be overlooked. One limitation is the limited sample of patients, when the sample required to draw conclusions with a low probability of statistical error need to be significantly increased. Another limitation is the fact that postoperative thromboembolic episodes were not evaluated. which would have made the results of this study stronger.

Conclusions

Rotational thromboelastometry can provide a detailed assessment of the hemostatic status in patients undergoing urological procedures, which can be used as a complement to thromboembolic risk assessment models and, therefore, help in deciding for prophylaxis on an individualized basis. Future studies should evaluate the utility of thromboelastometry in identifying patients at high risk for VTE after major urological procedures.

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