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Validation of Risk Assessment Models of Deep Vein Thrombosis Among Hospitalized Medical and Obstetrics Patients at Two Tertiary Referral Hospitals in Rwanda

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ABSTRACT

INTRODUCTION: Deep Vein Thrombosis (DVT) is a significant cause of morbidity and mortality for hospitalized patients and pregnant women. Different risk assessment models (RAMs) were developed to identify at-risk patients but not validated in either patients' settings.

Aim of the study: To evaluate and compare the performance of the Padua, Geneva, and Wells score in terms of risk stratification and pre-test clinical probability of DVT among hospitalized medical and obstetrics patients at two tertiary hospitals in Rwanda.

METHODS: We conducted cross-sectional, descriptive monthly surveys. We included all consenting patients that were admitted to medical and obstetrics wards during the study surveys. We collected demographics, risk factors, signs, and symptoms of DVT. The DVT risk was calculated using each one of the above scores, followed by DVT screening of both lower extremities by compression ultrasound scans.

RESULTS: Out of 807 participants; 571 (70.7%) were women, 43 (7.5%) were pregnant, and 173 (30.3%) were in postpartum period. DVT was detected in 46/807 (5.7%) patients and was statistically significantly more frequent in high versus low-risk categories when applying each score. By the Wells score, DVT was nearly twenty times greater among high versus low-risk patients (50%, vs. 2.6%, $p < 0.0001$), and six times by the Geneva score.

CONCLUSION: The Wells and Geneva scores were significant predictors of DVT among hospitalized medical and obstetrics patients in Rwanda. More studies are needed to validate these scores in different clinical settings.

Keywords: Deep Vein Thrombosis, Risk Assessment Model, Medical patients, Rwanda

INTRODUCTION

Deep vein thrombosis (DVT) is characterized by one or more blood clots forming in a deep vein, commonly in the leg or pelvis. DVT clots may migrate to the lungs, causing a pulmonary embolism (PE) [1,2]. Deep vein thrombosis and pulmonary embolism constitute venous thromboembolism (VTE), and they are the leading cause of preventable morbidity and mortality for inpatients worldwide [3]. The incidence of VTE varies from 5% to 30% among general medical patients [4]. The risk of VTE is higher in pregnant women compared to non-pregnant women of the same age [5], and it is also increased in the postpartum period [6].

In the United States, about eight million hospitalized patients are at a high risk of DVT each year [7]. Data from Canada showed that DVT incidence among pregnant women was 12.1 per 10 000 [8]. Admissions with acute infection are also associated with an increased risk for DVT [9,10]. The prevalence of asymptomatic DVT in general medical inpatients not on thromboprophylaxis is 15 %, detected by venography, and 5 to 7% using Doppler ultrasonography [11,12]. In a study conducted in France, the prevalence of asymptomatic DVT on hospital admission was 5.5%, and its incidence during hospital follow-up was 2.6 per 1,000 person-days [13].

Because DVT's signs and symptoms are often non-specific, the decision to order a lower extremity imaging study to rule out DVT has

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a low threshold [14,15]. A number of risk assessment models (RAM) and algorithms have been developed to help physicians identify those at high risk for DVT, but they lack generalizability. Worldwide, there is a problem to choose which RAM to use, as most of them have not been validated in other countries and different clinical settings [16,17].

In this study, we evaluated the Padua, Geneva, and Wells scores in hospitalized medical and obstetric patients in Rwanda. The Padua Prediction Score was developed at the University of Padua in Italy and modified the Kuchers model [18]. The Padua score contains additional items, and the assigned scores are modified to permit the identification of all conditions recommended for thromboprophylaxis (see appendix 3). It was validated among medical inpatients at the same university in a prospective cohort study. An increased risk of VTE was defined as a cumulative score of at least four [19]. The Geneva risk score was generated from consensus guidelines and recommendations from the American College of Chest Physicians. These were derived from a VTE prevention study [20] (see appendix 2). It was validated as a risk assessment tool for hospitalized medical patients at risk of VTE in a multicentre prospective study conducted in the university hospitals in Geneva, Switzerland. A predefined cut-off of three accurately distinguished low-risk from high-risk patients [21]. The Wells score was developed by combining experts' recommendations and available literature on DVT (see appendix 1). The Wells Score is a validated tool for diagnosing DVT that can be used in emergency, surgery, and outpatient settings [22]. The Wells scores' ability to stratify symptomatic patients with suspected DVT was tested in a prospective study conducted in Canada. A Wells score of 3 or more was associated with a high pre-test clinical probability of DVT [23,24].

There is no baseline data on DVT in Rwanda; however, different studies mention that it is the leading cause of preventable inpatient morbidity and mortality worldwide [3]. Currently, no work has been done to quantify or formally assess the risk of DVT with available RAMs in the Rwandese population. Although these tests have been validated in clinical settings in Europe and North America, their applicability in Rwandan settings is not known. It was therefore considered appropriate to conduct a study to assess their utility in hospitalized medical and obstetric patients in Rwanda, as there is currently no validated score that can be used to predict DVT in these settings.

Aim of the study

Evaluate and compare the performance of the Padua, Geneva, and Wells score in terms of risk stratification and pre-test clinical probability of DVT among medical and obstetrics inpatients at two tertiary referral hospitals in Rwanda.

Specific objectives

To evaluate and compare the performance of the Padua, Geneva, and Wells score in terms of risk stratification of DVT among medical and obstetrics inpatients at two tertiary referral hospitals in Rwanda.

To Evaluate and compare the performance of the Padua, Geneva, and Wells score in terms of pre-test clinical probability of DVT among medical and obstetrics inpatients at two tertiary referral hospitals in Rwanda.

METHODS

Study design

This was a cross-sectional, descriptive, multi-center study. It was conducted at the Kigali University Teaching Hospital (CHUK) and the Butare University Teaching Hospital (CHUB) in the departments of Internal Medicine and Obstetrics & Gynecology, over 12 months (from August 2015 to July 2016). The cross-sectional surveys were undertaken monthly in the last week of every month. The participants who were already recorded were not eligible for repeat study entry. CHUK and CHUB are both tertiary referral hospitals. CHUK is a 560-bed hospital located in the center of Kigali city and receives patients from all the country's corners via district and provincial hospitals. CHUB is a 325-bed national referral hospital located in the south of Rwanda, which serves the Southern and Western Provinces' population.

Study population

The study included all eligible and consenting patients admitted to the hospital wards of the departments listed above during the study surveys. Patients were eligible if they were over the age of 21 years, had been in the hospital for at least 72 hours, willing to participate, and provided a written consent form. Patients known to have DVT, surgical patients, pediatric patients, outpatients, and those not willing to participate were excluded from the study.

Sample size

The sample size was calculated as follows:

$$N = \frac{\alpha 2.\ P.Q}{E2}$$

N: Sample size P: Expected prevalence in the study population
α: 1.96 Q: 1-P E: Absolute standard error E= 0.01

Given the lack of prior local studies in the study population, the prevalence of symptomatic DVT was estimated based on a Sudanese study in an obstetric population with a DVT prevalence of 0.5% [27]. In several studies, the rate of asymptomatic DVT was approximately ten times higher than the symptomatic rate, giving an estimated 5% prevalence. A similar 5% figure for asymptomatic DVT was also obtained from a similar study conducted in a hospitalized population in France [13].

Based upon a large eligible population (hospitalized medical and obstetrics-gynecology patients), and assuming the estimated asymptomatic DVT prevalence is 5%, a sample size of 454 was calculated to achieve a 1% absolute standard error in the rate of DVT at a 95% confidence level. To ensure adequate power to analyze risk factors and prediction modeling, the target sample size was doubled. Nine hundred sixteen (916) medical and obstetrics patients were assessed for study participation at the two study sites during the study period. Still, only 807 patients with complete data were considered for analysis.

Data collection procedure

After consent was obtained, patients were enrolled in the study.

Data were collected on a pre-designed case report form (data collection tool), which were assigned a unique study code to assume anonymity. We collected baseline demographic data (patient hospital identification, sex, date of birth, hospital location), clinical features including vital signs (temperature, blood pressure, oxygen saturation, respiratory rate, heart rate, BMI), symptoms and signs of DVT (pain and/or tenderness of the lower limb(s), tenderness along the line of femoral or popliteal veins, increased calf circumference more than 3 cm, swelling of the entire lower limb, unilateral limb pitting edema, dilated superficial collateral (non-varicose) veins, the risk factors of DVT including a history of being immobilized (complete bed rest or inability to walk for >30 min per day) for more than three days, surgery within the last four weeks, lower limb trauma, recent travel >6 hours sited, congestive cardiac failure, respiratory failure, recent stroke (<3 months), acute infectious disease and a history of confirmed VTE or use of DVT prophylaxis. Other medical conditions associated with DVT were recorded, including inflammatory bowel disease, malignancy (presently or previously on active or palliative treatment within the last six months), myeloproliferative syndrome, nephrotic syndrome, and chronic venous insufficiency. The patient's clinical information related to pregnancy, puerperium, and oral contraceptive pills was also collected for women. These clinical features of DVT factors were previously employed in published and validated risk assessment models that we are testing (the Wells, Geneva, and Padua scores) (see appendix 1, 2, and 3, respectively).

Each patient was stratified as being at low or high risk for DVT according to each of these scores. Then they were screened both lower extremities for DVT by compression ultrasound scans completed with Doppler studies of iliac, femoral, and popliteal veins in both legs. Ultrasound scans were performed by senior medical residents that were trained and certified to undertake ultrasound scans with an emphasis on DVT. The ultrasound examination was performed using an L38xi/10-5 MHz linear transducer probe. For each patient, the doctor who performed the ultrasound scanning was not the one who completed the data collection form and was not aware of the patient's risk category. For each positive or suspected DVT case, the study team requested a local radiologist to review the scan for confirmation. The results were immediately communicated to patients and the treating team to start treatment. A study was considered positive in the case of the absence of complete venous compressibility at any location.

Ethical considerations

The study was approved by the University of Rwanda College of Medicine and Health Sciences IRB (Ref: CMHS/IRB/64/2015). After explaining the objectives, methodology, benefits, and outcomes, a signed form giving written consent were obtained from each participant or his surrogate before enrollment. The participant's information was kept under conditions of strict confidentiality. All collected data were rendered anonymous (only marked with a code) and can, therefore, not directly be traced back and not be made publicly available. The key record identifying the participant was kept confidential. Even after the publication of results, they will remain confidential. For each positive DVT case, the study team communicated the results directly to the patient and the treating team to start treatment.

Statistical analysis

Data were collected on case report forms and entered using EpiData software, version 3.1. Using standard statistical methods, descriptive analysis was performed with the Statistical Package for Social Sciences (SPSS) software, version 20. The RAMs' frequency was included, and chi-square analysis was performed on the outcome of DVT versus no DVT for each RAM. Cross tabs and chi-square analyses were then undertaken to see if previously validated cut-off points for the RAMs were significantly associated with DVT. Where they were, regression studies with baseline characteristics were performed. A Pearson chi-square statistical test was undertaken for categorical variables. P-values less than 0.05 were considered statistically significant. Data from patients with incomplete files and missing information for some variables were not deemed for analysis.

RESULTS

Out of 807 participants included in the analysis, 509 (63.07%) were from medical and 298 (36.93%) from the obstetrics and gynecology departments. They were drawn equally from CHUB and CHUK. The average age of participants was 41±16 years (range: 21-91). The majority: 571 (70.7%) were women, and 7.5% (43/571) women were pregnant, while 30.3% (173/571) were in the postpartum period (Table 1).

The frequency of DVT in the whole study population was 5.7% (46/807), and the frequency of thromboprophylaxis was 6.7% (54/807). Subgroup analyses of differences in the prevalence of DVT according to gender, BMI and pregnancy were not statistically significant; female 32/571 (5.6%) compared to male 14/236 (5.9%) P=0.855, patients with high BMI 6/68 (8.8 %) versus the ones with normal BMI 34/645 (5.27%) P=0.464, pregnant women 5/43 (11.6%) versus non-pregnant women 27/528 (5.1%) P=0.206 (Table 2).

The proportion of patients considered high risk versus low risk varied considerably between the scoring systems. There were 303 out of 807 (37.55%) patients classified as high risk according to the Padua score (> 4), 442 out of 807 (54.77%) according to the Geneva score (> 4), and 52 out of 807 (6.44%) according to the Wells score (> 3).

The rates of Deep Vein Thrombosis among patients categorized as high versus low risk was statistically significant when applying each one of these risk assessment models. For the Padua score it was (8.2% vs. 4.1%, p = 0.0154, Odds Ratio: 2, the 95% CI: [1.08 – 3.96]), for the Geneva score (9% vs. 1.6%, p < 0.0001, Odds Ratio: 5.9, the 95% CI: [2.46 – 17.35]) and for Wells score (50% vs. 2.6%, p < 0.0001, Odds Ratio: 36.7, the 95% CI: [17.11 – 78.61]) (Table 3).

A comparison of these three risk assessment models' test characteristics shows that the Geneva score was more sensitive (86.9%) and the Wells score more specific (96.5%). All the tests have a good negative predictive value (NPV), which is above 95%, but none has a good positive predictive value (PPV) (Table 4).

Table 1: Socio-demographic and clinical characteristics of study participants

	All patients N (%)	Medical patients N (%)	Obs. & Gyn. patients N (%)
Total Population	807 (100)	509 (63.07)	298 (36.93)
Gender			
Female	571 (70.76)	273 (53.63)	298 (100)
Male	236 (29.24)	236 (46.37)	0 (0)
Age			
Mean (+/- SD)	41±16	45±18	34±10
20-39	459 (57)	221 (43.4)	238 (82.2)
40-59	207 (25.6)	165 (32.5)	42 (12.7)
>60	141 (17.4)	123 (24)	18 (5.1)
BMI (kg/m^2)			
<18	94 (11.6)	77(15.2)	17 (3.7)
18-25	645 (79.9)	396 (77.8)	249(85.4)
25.1-30	57 (7.0)	28 (5.5)	29(9.6)
>30	11 (1.5)	8 (1.6)	3(5.5)
Hospital			
CHUK	391 (48.45)	246(48.33)	145(48.66)
CHUB	416 (51.55)	263 (51.67)	153(51.34)
Clinical variables			
Pregnancy (N=571)	43 (7.5)	0(0)	43(14.4)
Postpartum period (N=571)	173 (30.3)	2(0.4)	171(57.4)
Past History of VTE	5 (0.6)	1(0.2)	4(1.3)
Receiving DVT Prophylaxis	54 (6.7)	38 (7.5)	16 (5.3)

The receiver operating characteristic curves (ROCs) show the performance of the Padua, Geneva, and Wells score for pre-test clinical probability of DVT in this study population. The areas under the 3 RAMs curves were: 0.92 for the Wells, 0.84 for the Geneva, and 0.65 for the Padua score, compared with a true area of 0.5 predicted by the Null hypothesis. The Wells and Geneva scores were better tools for DVT prediction than the Padua score (Figure 1).

DISCUSSION

DVT rates and distribution

In this study, 5.7% of patients in general medical and obstetric wards in teaching hospitals in Rwanda hospitalized for other conditions were found to have a lower limb DVT when screened with Doppler ultrasound. This was very similar to a rate of 5.5% in a study of asymptomatic DVT on hospital admission in France [13]. Other previous studies had found that the rate of asymptomatic DVT among inpatients who are not on prophylaxis ranged from 5 to 7% when Doppler ultrasound scanning was used as the screening test [12,13].

Table 2: DVT rates and prophylaxis

N=807	DVT RATES Cases/Total (%)	P-VALUE	DVT PROPHYLAXIS Cases/Total (%)
Total population	46/807 (5.7)		54/807 (6.7)
AGE		0.817	
20-39	28/459(6.1)		5/459(1.1)
40-59	8/207 (3.8)		40/207(19.3)
≥60	10/141 (7)		9/141 (6.4)
Gender		0.855	
Male	14/236(5.93)		12/236(5.08
Female	32/571(5.6%)		42/571(7.36)
BMI		0.464	
Low (<18)	6/94(6.38)		4/94 (4.25)
Normal (18-25)	34/645(5.27)		42/645 (6.51)
Overweight (25.1-30)	4/57(7)		4/57 (7)
Obese (>30)	2/11(18.1)		4/11 (36.3)
Admitting Service		0.756	
Internal Medicine	30/807(5.89)		38/509(5.37)
Obstetrics &Gynecology	16/298(5.37)		16/298(7.47
Pregnancy (n =571)		0.206	
Yes	5/43(11.63)		5/43(11.63)
No	27/528(5.11)		37/528(7.01
Postpartum (n=571)		0.063	
Yes	5/173(2.89)		7/173(4.05)
No	27/398(6.78)		35/398(8.79)

**Chi-square test was used to produce the p-values*

Table 3: DVT Risk Stratification and Rates by Risk Score

	Sample size by risk category (%)	DVT Rates Cases/Total (%)	Odds Ratio [95% CI]	P-value
TOTAL (N=807)		46/807 (5.7)		
Padua Score				
Low Risk < 4	504 (62.55)	21/504 (4.17)	2.06 [1.08 – 3.96]	0.0154
High Risk ≥ 4	303 (37.55)	25/303 (8.25)		
Geneva Score				
Low Risk < 4	365 (45.23)	6/365 (1.64)	5.96 [2.46 –17.35]	<0.0001
High Risk ≥ 4	442 (54.77)	40/442 (9.05)		

** The reference category (low risk) was used for the calculation of the odds ratio*

Pre-test clinical probability of DVT

The performance of the three risk assessment tools employed in this study varied significantly in predicting the presence of DVT among hospitalized medical and obstetric patients. Among these examined tests, the Wells score had the best performance

Table 4: Characteristics of the studied risk assessment models (RAMs)

	Sample size by risk category (%)	DVT Rates Cases/ Total (%)	Odds Ratio [95% CI]	P-value
TOTAL (N=807)		46/807 (5.7)		
Padua Score				
Low Risk < 4	504 (62.55)	21/504 (4.17)	2.06 [1.08 – 3.96]	0.0154
High Risk ≥ 4	303 (37.55)	25/303 (8.25)		
Geneva Score				
Low Risk < 4	365 (45.23)	6/365 (1.64)	5.96 [2.46 –17.35]	<0.0001
High Risk ≥ 4	442 (54.77)	40/442 (9.05)		
Wells Score				
Low Risk < 3	755 (93.56)	20/755 (2.65)	36.75 [17.11-78.61]	<0.0001
High Risk ≥ 3	52 (6.44)	26/52 (50.00)		

**These figures were calculated using the results from Table 3*

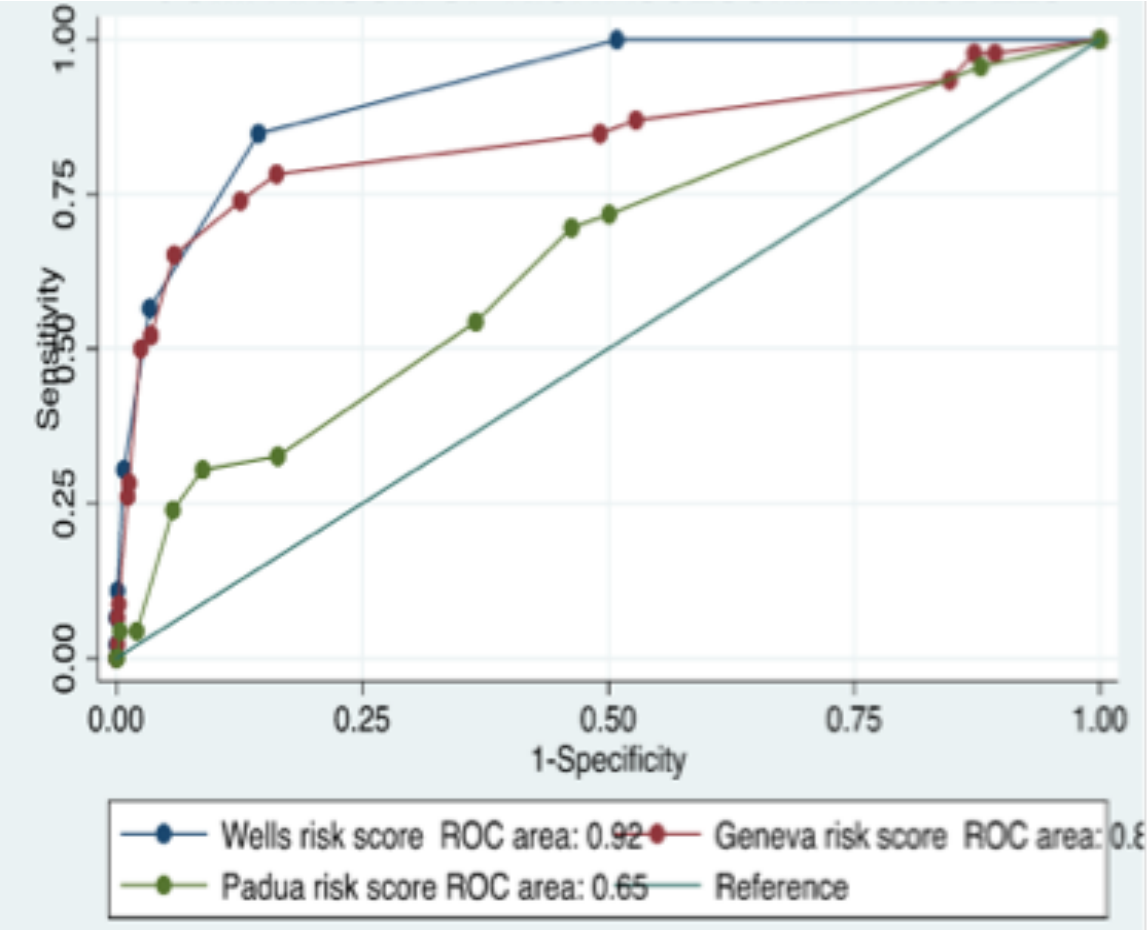

Figure 1: Receiver operating characteristics curves

in predicting DVT in this study population. Patients designated as high risk by the Wells score (Wells score≥3) were diagnosed with DVT nearly twenty times more often than patients defined as low risk.

The Padua and Geneva scores did not accurately predict DVT in low versus high-risk groups. Although these risk scores were initially developed for use in outpatient and surgical settings, it was considered worthwhile to test their utility in medical and obstetric inpatients. Possible reasons for the poor performance of the Padua score include the possibility of patient misclassification as two of the elements of this risk score; the presence of a known thrombophilic condition and acute rheumatic disease was not assessed in the present study. However, these conditions are not common in Rwanda.

With a cut-off of 4, the Geneva score is effective in distinguishing groups at low and high risk for DVT. The receiver operating char-

acteristics curves show that Geneva has a large and significant area under the curve. However, it should be used with caution as its goal is to predict pulmonary embolism and not DVT [25].

According to the Wells score, 52 patients (6.4%) were at high risk for DVT (score of 3 or more), and among 52 patients at high risk for DVT, 26 patients (50%) had DVT. Among 755 patients at low risk, only 20 patients (2.6%) had DVT. Referring to these findings, a Wells score of 3 or more is a significant predictor of DVT. These findings are similar to the results of one study conducted in Japan in 2005, exploring the possibility that a combination of D-dimer testing and a pre-test clinical score (Wells score) could reduce the use of venous duplex scanning in patients with suspected DVT. In total, 158 patients were enrolled. DVT was identified in 2.6% of patients from the low risk and 63% of patients from high-risk groups, respectively [26]. Another study conducted in the United States published in 2015 found that the Wells score performed only slightly better than chance in predicting DVT risk in hospitalized patients [10].

Study Limitations

Medical residents undertook the ultrasound screening for DVT. While they were not qualified radiologists, they were senior residents trained and certified to undertake ultrasound scans for the detection of DVT and had had previous experience in ultrasound screening for DVT in their routine clinical practice. Furthermore, repetition of the scans, the use of Doppler studies, and radiologists' involvement in verifying all positive scans made for a high likelihood of accurate DVT diagnosis.

This study combined Medical and Obstetric inpatients that may well have different risk profiles to get country-wide representative data on the performance of these scores in predicting DVT. To get country-wide representative data on these scores' performance in predicting DVT, future researchers should include patients with other conditions and patients from other centers in Rwanda.

It is also difficult to reach any conclusion about these RAMs' performance in pregnant women as the number of pregnant women was small.

Listwise deletion of missing data can introduce a systematic bias, but this is likely to have been minimal in this study as the number of patients with missing data was relatively small.

CONCLUSION

In hospitalized medical and obstetric patients in Rwanda, the Padua score for risk assessment is not a useful tool for predicting DVT. A score of 4 or more on the Geneva RAM is a significant predictor but should be used cautiously. However, the performance of the Wells score as a diagnostic tool for DVT in these patients is well supported. A Wells score > 3 identifies patients more likely to have DVT that should be further investigated. Further studies with these or new RAMs in different groups of patients and different patient settings should be undertaken to better predict DVT's risk in Rwanda.

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

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Authors' contributions

All authors contributed to the design and development of this study. EN, RM, and ER coordinated the data collection process. TDW, MPS, F,M and PLT reviewed and corrected the final work. KLL performed statistical analyses. All authors read and approved the final manuscript.

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