Predictive value of different risk assessment models for deep vein thrombosis in patients with cancer

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Abstract. The present study sought to compare how well four established scoring tools, the Padua, Caprini, Wells deep venous thrombosis (DVT) and Autar models, identify DVT among patients with malignant tumors. Between January 2020 and March 2024, 180 patients with cancer who had DVT at Cangzhou Integrated Traditional Chinese and Western Medicine Hospital or Hengshui People's Hospital formed the thrombosis group and another 180 cancer patients treated over the same interval but without DVT served as the controls. The Padua, Caprini and Autar scores were available for all 360 patients. Given that 10 patients with DVT lacked pre-diagnostic documentation of one or more objective Wells clinical-sign items, the Wells analyses were restricted to 350 complete cases (170 patients with DVT and 180 controls), without retrospective reconstruction. The present study subsequently examined whether the four scores were associated with DVT occurrence using separate binary logistic regression models and constructed receiver operating characteristic curves to assess discrimination. Scores on the Padua, Caprini and Wells DVT tools were found to be significantly higher in the thrombosis group compared with the controls (all, P<0.001), whereas the Autar scores did not differ significantly between the groups (P=0.856). In the present logistic analysis, higher Padua, Caprini and Wells DVT scores tracked with greater odds of DVT; the area under the curve values were 0.899 for Padua and 0.723 for Caprini in the full cohort and 0.703 for Wells in the 350 complete cases. All three models therefore offer useful prediction of DVT in patients with cancer, with the Padua tool performing best; the Caprini and Wells models were less discriminative and did not differ significantly from each other.

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Introduction

Deep venous thrombosis (DVT) denotes abnormal clotting in the deep veins, which blocks venous return and compromises deep-vein function. As the pooled blood organizes into a thrombus, fragments may detach and embolize; among the resulting complications, pulmonary embolism can result in patient mortality without warning (1). Venous thromboembolism (VTE) is among the leading causes of preventable in-hospital death and a population-based cohort reported a 12-month cumulative VTE incidence of 2.3% after a cancer diagnosis, approximately ninefold higher compared with the general population (0.35%); this figure continues to rise (2). Individuals with malignant disease are particularly prone to DVT, as cancer engages all three components of Virchow's triad: The tumor drives a hypercoagulable state; long infusions and restricted movement slow venous flow (stasis); and invasive procedures (peripherally inserted central catheters, thoracocentesis and paracentesis), radiotherapy, chemotherapy and anti-angiogenic treatment directly damage the vascular endothelium (3,4). Once a patient with cancer develops DVT, hospitalization is prolonged and costs rise, as anticoagulation with in-hospital monitoring for bleeding is required, pulmonary embolism must be excluded and response documented by repeat imaging, and readmission is common; each VTE admission adds an estimated US $10,000 (US $17,000 for pulmonary embolism) in adjusted 2019 costs (5) and the risk of mortality is markedly elevated (6,7). The thrombus usually begins as a small, non-occlusive clot in the calf veins that does not impede venous return, so no swelling or pain is produced at this stage and early disease is frequently silent; consequently, DVT is often missed or diagnosed late (8,9). Indeed, in a nationwide autopsy series, 12.4% of patients with cancer exhibited pulmonary embolism at time of mortality, two-thirds of which was fatal and largely unrecognized during life (10). Therefore, detecting and preventing DVT early is a priority. Risk scoring has become a straightforward way to gauge this risk, as research regarding cancer-associated DVT has accumulated (11-13). Although such scoring has been increasingly studied in China, the published experience is still limited and largely draws on tools developed overseas (14-17). In the present study, the Padua, Caprini, Wells DVT and Autar models are compared in patients with malignant tumors, to guide the choice of a DVT scoring tool in day-to-day practice.

Materials and methods

Study subjects. The present study recruited patients with malignant tumors who were diagnosed with DVT at two Hebei Province hospitals, namely Cangzhou Integrated Traditional Chinese and Western Medicine Hospital (Cangzhou, China) and Hengshui People's Hospital (Hengshui, China), between January 2020 and March 2024. The thrombosis group comprised 180 patients. On a 1:1 basis, the present study randomly chose an additional 180 patients with malignant tumors but no DVT during the same period as controls. Basic clinical information (including age, sex and BMI) was recorded. The cohort comprised 223 male and 137 female patients, with a median age of 57 years (range: 33-79 years); the DVT group comprised 115 males and 65 females (median age: 57 years; range: 33-79 years) and the control group comprised 108 males and 72 females (median age: 57.5 years; range: 33-79 years). Of the 360 participants, 202 (101 DVT and 101 controls) were obtained from Cangzhou Integrated Traditional Chinese and Western Medicine Hospital and 158 (79 DVT and 79 controls) from Hengshui People's Hospital. For external validation, the larger center (Cangzhou Integrated Traditional Chinese and Western Medicine Hospital) was used as the derivation site and its cut-off values were then applied without adjustment at the second center (Hengshui People's Hospital). Given that the two groups were matched 1:1, DVT prevalence in the present sample was held at 50% and does not mirror the prevalence among hospitalized patients with cancer in routine practice. The present study was approved by the Ethics Committee of Cangzhou Integrated Traditional Chinese and Western Medicine Hospital (approval no. 2021-KY-062.1) and the Ethics Committee of Hengshui People's Hospital (approval no. 2022014039Z).

Inclusion criteria. Thrombosis group: i) Patients with a histologically or cytologically determined malignancy and a documented TNM stage; ii) diagnosis of DVT during hospitalization determined by Doppler ultrasonography and/or venography; and iii) sufficient core clinical data for cohort classification and data extraction. Control group: i) Patients with a histologically or cytologically determined malignancy and a TNM stage; ii) absence of DVT during hospitalization determined by Doppler ultrasonography and/or venography; and iii) sufficient core clinical data for cohort classification and data extraction.

Exclusion criteria. Thrombosis group: i) Patients with concomitant coagulation disorders or hematological diseases; ii) presence of thromboembolic disease prior to admission; and iii) insufficient data. The exclusion criteria for the control group were the same as for the thrombosis group.

Thrombosis risk assessment models

Padua model. The Padua tool was introduced in 2010 by Barbar *et al* (18) at the University of Padua (Padua, Italy) for rating venous thromboembolism (VTE) risk in medical inpatients. The tool contains 11 items (including active malignancy, prior VTE and thrombophilia) with individual items weighted from 1 to 3 points. A total <4 denotes 'low risk' and ≥4 denotes 'high risk'.

Caprini model. Caprini *et al* (19) first devised their model in 1991 in the United States. It lists 39 items, including age, BMI, surgery and cancer and weights each item at 1, 2, 3 or 5 points according to its effect on VTE risk. The summed score places patients into one of four bands: 'Low' (0-1), 'moderate' (2), 'high' (3-4) or 'very high' (≥5). Both the 2005 (20) and 2010 (21) editions are in use; the 2010 edition added items such as a history of superficial vein thrombosis and revised the weights of others, including BMI, duration of surgery, cancer history and central venous catheter. The 2010 edition was applied throughout the present study.

Wells DVT model. The Wells model was developed by Wells *et al* (22) in Canada, chiefly for outpatients. A total of nine positive clinical features (such as active cancer, previous DVT, leg swelling, edema and tenderness) each add one point, whereas the item 'an alternative diagnosis is at least as likely as DVT' removes two points; the total runs from -2 to 9 and is classed as 'low' (≤0), 'moderate' (1-2) or 'high' (≥3).

Autar model. Autar *et al* (23) produced their model in the UK in 1996. It spans seven dimensions (age, BMI, mobility, special risk, trauma, surgical intervention and high-risk diseases) and the items within them are scored from 1 to 7 points. Patients are grouped into three levels: 'Low' (≤10), 'moderate' (11-14) or 'high' (≥15) (23,24). Several items, including surgical intervention, trauma, reduced mobility and older age, directly reflect the risk of major orthopedic procedures (such as hip or knee arthroplasty and hip-fracture surgery), where prolonged immobilization and tissue injury confer a high DVT risk; the scale has therefore been validated chiefly in patients undergoing orthopedic surgery (25). As the present cohort comprised patients with cancer rather than orthopedic patients, these surgery- and trauma-oriented items may be less relevant, which may partly explain the limited performance of the Autar model in the present study.

Score calculation. The four scores were reconstructed retrospectively from the inpatient medical records (including admission and nursing notes, physician orders, medication records, and laboratory and imaging reports) at both participating hospitals (Cangzhou Integrated Traditional Chinese and Western Medicine Hospital and Hengshui People's Hospital), drawing only upon information available at the pre-diagnostic index time, within 24 h of admission and before any diagnostic Doppler ultrasonography or venography. The staff who assigned scores were blinded to imaging findings and nothing documented after DVT diagnosis was used. Every item on the published scales was retained only when it had been documented before the diagnostic work-up. During this process, the present study identified 10 patients in the DVT group for whom one or more objectively measured clinical-sign items of the Wells score (unilateral calf swelling of >3 cm relative to the contralateral leg, pitting edema confined to the symptomatic leg and/or collateral superficial non-variceal veins) had not been recorded in the pre-diagnostic charts. Given that these items were absent from the medical record at the predefined pre-diagnostic index time, they could not be scored without incorporating information documented after the diagnostic work-up, which would introduce outcome leakage. In accordance with a complete-case analysis and to avoid any

Table I. Comparison of general characteristics and essential clinical variables between the two groups.

Characteristic	DVT group (n=180)	Control group (n=180)	χ^2/t	P-value
Age, years	56.47±13.77	56.06±13.16	0.293	0.769
BMI, kg/m^2	22.98±4.11	23.18±4.33	-0.444	0.657
Sex				
Male	115 (63.9)	108 (60.0)	0.577	0.447
Female	65 (36.1)	72 (40.0)		
Cancer type				
Lung	55 (30.6)	48 (26.7)		
Colorectal	26 (14.4)	22 (12.2)		
Gastric	27 (15.0)	30 (16.7)	6.890	0.142
Gynecological	20 (11.1)	37 (20.6)		
Other	52 (28.9)	43 (23.9)		
Tumor stage				
Stage I	3 (1.7)	48 (26.7)		
Stage II	33 (18.3)	46 (25.6)		
Stage III	43 (23.9)	25 (13.9)	56.486	<0.001
Stage IV	101 (56.1)	61 (33.9)		
Length of stay, days	16.18±8.06	15.32±8.12	1.016	0.310
Pharmacological thromboprophylaxis	44 (24.4)	35 (19.4)	1.314	0.252
Mechanical thromboprophylaxis	46 (25.6)	40 (22.2)	0.550	0.458
Any thromboprophylaxis	81 (45.0)	70 (38.9)	1.380	0.240
Chemotherapy	88 (48.9)	74 (41.1)	2.200	0.138
Central venous catheter	58 (32.2)	37 (20.6)	6.306	0.012
Immobilization (bedridden ≥3 days)	89 (49.4)	34 (18.9)	37.357	<0.001
Previous VTE	0 (0.0)	0 (0.0)		

Data are presented as n (%) for categorical variables and as the mean ± SD for continuous variables. P-values were calculated using the χ^2 test (categorical variables) or an independent-samples t-test (continuous variables). The Mann-Whitney U test was used as a sensitivity analysis and yielded consistent results. Pharmacological and mechanical thromboprophylaxis were not mutually exclusive; 'any thromboprophylaxis' denotes their union. DVT, deep vein thrombosis; VTE, venous thromboembolism.

retrospective reconstruction, these 10 patients were excluded from all Wells analyses and no post-diagnostic information was substituted.

The other three models, which do not rely on these clinical-sign items, were complete for all 360 patients; the Wells analyses therefore comprised 350 patients (170 DVT and 180 controls). Accordingly, the denominators are model-specific: The Padua, Caprini and Autar analyses used all 360 patients, whereas all Wells analyses, including risk-category comparisons, logistic regression, receiver operating characteristic (ROC) analysis, DeLong comparisons and site-based validation, used only the 350 Wells complete cases. A second investigator independently re-rated a random 10% of charts to test reproducibility and the intraclass correlation coefficient for agreement was 0.97. Before the diagnostic work-up, the present study additionally extracted five key clinical variables from the same inpatient medical records at the two hospitals: i) Thromboprophylaxis (pharmacological and mechanical); ii) chemotherapy received within the preceding 3 months; iii) the presence of a central venous catheter (including a peripherally inserted central catheter or a totally implantable venous access port); iv) immobilization (being bedridden or having reduced mobility for at least 3 days, defined consistently with the Padua 'reduced mobility' item); and v) previous VTE. A number of these variables are themselves scored items of the risk models. Receipt of either pharmacological or mechanical prophylaxis was classified as any thromboprophylaxis; the two prophylaxis categories were not mutually exclusive. Each variable was retained only when documented at or before the pre-diagnostic index time and none were reconstructed from later records. No patient had a recorded history of previous VTE, as such patients were excluded by the aforementioned criteria. The group-level frequencies are reported in Table I.

Statistical analysis. The present study used SPSS statistics (version 27.0; IBM Corp.) for data processing. Continuous variables are reported as the mean ± SD and normality was determined using the Shapiro-Wilk test. Given that each group was large (n=180), an independent-samples (unpaired) t-test served as the primary comparison; with samples of this size, the central limit theorem ensures that the sampling distribution of the mean is approximately normal, so the test remains valid even when individual variables are not normally distributed.

Table II. Comparison of Padua model scores between the two groups.

Group	n	Low risk (<4)	High risk (≥4)	Score	Test statistic	P-value
Thrombosis	180	40	140	6.16±2.31		
Control	180	143	37	2.55±1.16		
χ^2 (risk level)					117.911	<0.001
t (score)					18.697	<0.001

Risk categories follow the Padua Prediction Score: Low risk, <4 points; high risk, ≥4 points. Scores are presented as the mean ± SD. P-values were calculated using the χ^2 test (risk category) and the independent-samples t-test (score).

The non-parametric Mann-Whitney U test was added as a sensitivity analysis and produced an identical pattern of significance, with the same variables remaining significant or non-significant.

To relate each model score to DVT occurrence, binary logistic regression was run; each score was entered in its own univariable model rather than all four together, since the scores are strongly correlated. Odds ratios (ORs) describe the change per 1-point increase and 95% CIs were derived from the coefficients and standard errors so that OR=exp(B). The present study further constructed ROC curves and obtained the AUC for each model. Paired ROC curves were compared with the DeLong test, allowing for the association between AUCs to be measured in the same cohort; pairwise DeLong P-values were calculated in R software (version 4.3.2; Posit Software, PBC) using the 'pROC' package (26). Calibration was assessed through a calibration slope.

At Cangzhou Integrated Traditional Chinese and Western Medicine Hospital, the Padua, Caprini and Wells scores were each entered into a univariable logistic model to derive the linear predictor, which was transported to Hengshui People's Hospital without coefficient updating. At Hengshui People's Hospital, a logistic recalibration model was fitted by regressing the observed DVT outcome on the transported linear predictor; the external intercept was freely estimated but not interpreted and the resulting slope was reported as the calibration slope. The derivation and validation samples comprised 202 and 158 patients for Padua and Caprini and 196 and 154 complete cases for Wells. A slope <1 indicates that the transported predictions are too extreme (high-risk predictions too high and low-risk predictions too low); although this pattern is compatible with overfitting at model derivation, it does not by itself establish overfitting, because it may also reflect differences in case mix between sites.

Given that the 1:1 case-control design fixed DVT prevalence at 50%, the calibration intercept, Brier score and absolute predicted probabilities were not interpreted for the general inpatient population. The Wells score was evaluated in the 350 complete cases. For pairwise DeLong comparisons involving Wells, the ROC curves for Padua, Caprini and Wells were regenerated in the same 350 common complete cases to ensure paired comparability. The Padua-Caprini comparison used the full 360-patient cohort as both scores were complete for all patients. The Padua-Wells and Caprini-Wells P-values therefore refer to the 350-case paired analyses, whereas the Padua-Caprini P-value refers to the full cohort. Risk-category comparisons for the Wells model likewise used the complete-case sample. P<0.05 was considered to indicate a statistically significant difference.

Results

General clinical characteristics are mostly similar between the groups. Results indicated that the two groups were similar in age, sex, BMI, length of hospital stay and cancer type distribution (Table I). Tumor stage, however, differed significantly (χ^2=56.486; P<0.001): Stage III or IV disease was present in 80.0% of the thrombosis group versus 47.8% of controls. The key clinical variables are compared in Table I. Before the diagnostic work-up, thromboprophylaxis (pharmacological or mechanical) had been used in 81 patients with DVT (45.0%) and 70 controls (38.9%; P=0.240), comprising pharmacological prophylaxis in 44 (24.4%) compared with 35 (19.4%) as well as mechanical prophylaxis in 46 (25.6%) compared with 40 (22.2%). Pharmacological and mechanical prophylaxis were not mutually exclusive and 'any thromboprophylaxis' denotes their union. A central venous catheter was present in 58 DVT patients (32.2%) compared with 37 controls (20.6%; P=0.012) and immobilization for at least 3 days was more frequent in the DVT group (89 patients; 49.4%) compared with controls (34 patients; 18.9%; P<0.001). Chemotherapy did not differ significantly between the groups (48.9 vs. 41.1%; P=0.138) and no patient in either group had a previous VTE, consistent with the exclusion criteria.

The Padua, Caprini and Wells scores are higher in the DVT group. Within the Padua, Caprini and Wells DVT models, both the scores and the share of patients rated high risk were higher in the thrombosis group compared with in controls (all, P<0.001; Tables II-IV). For the Wells model, the complete-case analysis comprised 170 DVT patients and 180 controls; the Wells score was 4.16±2.52 in the DVT group compared with 2.38±1.67 in controls (t=7.813; P<0.001). For the Autar model, neither the scores nor the risk-category distribution differed significantly (P=0.856 and P=0.754, respectively; Table V).

Higher Padua, Caprini and Wells scores are associated with DVT. In separate univariable models, higher Padua, Caprini and Wells DVT scores were significantly associated with DVT

Table III. Comparison of Caprini model scores between the two groups.

Group	n	Low + moderate	High + very high	Score	Test statistic	P-value
Thrombosis	180	57	123	4.91±2.62		
Control	180	115	65	2.78±1.96		
χ^2 (risk level)					37.452	<0.001
t (score)					8.737	<0.001

Risk categories follow the 2010 Caprini model: Low risk, 0-1 points; moderate risk, 2 points; high risk, 3-4 points; very high risk, ≥5 points. Scores are presented as the mean ± SD. P-values were calculated using the χ^2 test and the independent-samples t-test.

Table IV. Comparison of Wells DVT model scores between the two groups.

Group	n	Low + Moderate	High	Score	Test statistic	P-value
Thrombosis	170	51	119	4.16±2.52		
Control	180	119	61	2.38±1.67		
χ^2 (risk level)					45.640	<0.001
t (score)					7.813	<0.001

Risk categories follow the Wells DVT score: Low risk, ≤0 points; moderate risk, 1-2 points; high risk, ≥3 points. Scores are presented as the mean ± standard deviation. P-values were calculated using the χ^2 test and the independent-samples t-test. The Wells complete-case analysis excluded 10 patients with DVT whose pre-diagnostic charts lacked one or more objective clinical-sign items; the control group was complete (n=180). DVT, deep vein thrombosis.

Table V. Comparison of Autar model scores between the two groups.

Group	n	Low (≤10)	Moderate (11-14)	High (≥15)	Score	Test statistic	P-value
Thrombosis	180	62	18	100	15.79±8.85		
Control	180	57	16	107	15.63±8.56		
χ^2 (risk level)						0.564	0.754
t (score)						0.182	0.856

Risk categories follow the Autar deep vein thrombosis scale: Low risk, ≤10 points; moderate risk, 11-14 points; high risk, ≥15 points. Scores are presented as the mean ± SD.

[OR per 1-point increase: 2.809 (95% CI: 2.266-3.481), 1.456 (1.320-1.607) and 1.491 (1.326-1.677); all, <0.001), while the Autar score was not (OR: 1.002; P=0.855; Table VI).

Padua exhibits the highest discriminative value. The AUCs were 0.899 (95% CI: 0.866-0.932) for Padua and 0.723 (0.671-0.776) for Caprini in the full cohort (n=360), whereas the Wells AUC was 0.703 (0.651-0.755) in the 350 complete cases (all, P<0.001; Table VII; Fig. 1). The best cut-off values were 5, 4 and 3 points, with sensitivity and specificity of 74.4 and 93.3% (Padua), 67.8 and 71.1% (Caprini), and 70.0 and 66.1% (Wells). Pairwise DeLong testing showed that Padua exhibited a higher AUC compared with Caprini in the full cohort (P<0.001) and a higher AUC compared with Wells in the 350 common complete cases (P<0.001). The Caprini-Wells comparison in the same 350 complete cases did not reach statistical significance (P=0.073; Table VII); therefore, the pooled numerical ordering of Caprini above Wells is reported as an observed trend rather than a statistically established difference.

Discrimination is maintained at the external site, but Caprini and Wells are miscalibrated. At Hengshui People's Hospital, the AUCs were 0.903, 0.718 and 0.746 for Padua, Caprini and Wells (the Wells value is based on 154 complete cases: 75 DVT and 79 controls; the other two models used all 158 cases). Applying the Cangzhou Integrated Traditional Chinese and Western Medicine Hospital-derived cut-offs (5, 4 and 3) at Hengshui People's Hospital exhibited sensitivity and specificity values of 73.4 and 94.9% (Padua), 62.0 and 75.9% (Caprini) and 68.0 and 73.4% (Wells; Table VIII). At the derivation site, the corresponding Wells AUC among 196 complete cases (95 DVT and 101 controls) was 0.665. At the external site, the calibration slope was close to 1 for Padua (1.110), indicating that its slope was largely preserved. The slopes for Caprini (0.367) and Wells (0.504) were <1, indicating that

Table VI. Association between the four model scores and deep vein thrombosis occurrence (univariable binary logistic regression).

Score	B	SE	OR	95% CI	P-value
Padua	1.033	0.109	2.809	2.266-3.481	<0.001
Caprini	0.376	0.050	1.456	1.320-1.607	<0.001
Wells	0.400	0.060	1.491	1.326-1.677	<0.001
Autar	0.002	0.012	1.002	0.979-1.026	0.855

Results are from separate univariable binary logistic regression analyses, with each model score entered individually (the four scores were not entered simultaneously). The Wells model was based on 350 complete cases. ORs are expressed per 1-point increase. OR, odds ratio; B, regression coefficient; SE, standard error.

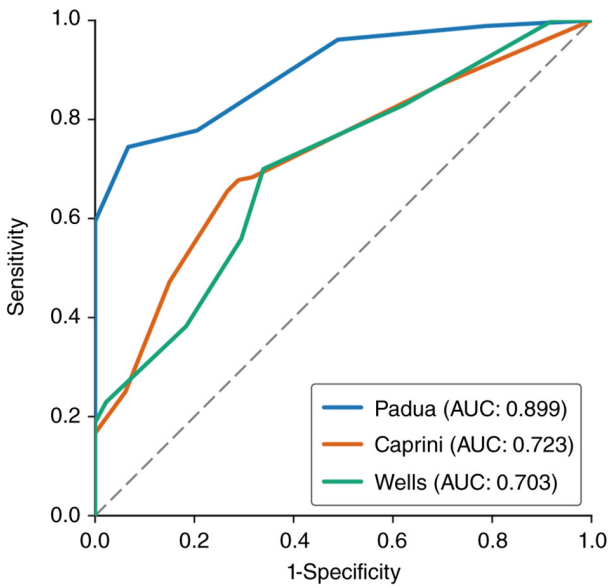


Figure 1. Receiver operating characteristic curves of the Padua, Caprini and Wells DVT models for predicting DVT in patients with malignant tumors. The AUC was 0.899 for Padua and 0.723 for Caprini in the full cohort (both, n=360) and 0.703 for Wells in the 350 complete cases (170 patients with DVT and 180 controls). AUC, area under the curve; DVT, deep venous thrombosis.

the transported predictions were too extreme at Hengshui People's Hospital. This pattern is compatible with overfitting at derivation but could also reflect between-site differences in case mix; it therefore suggests, rather than establishes, a need for recalibration and formal prospective evaluation remains necessary.

Discussion

DVT imposes a notable clinical and economic burden on patients with cancer, prolonging hospitalization and increasing mortality (5). In the present cohort, patients with DVT remained in hospital for 16.2 days on average (Table I); yet recognizing and preventing DVT early could ease this burden and limit disruption to anticancer treatment. Raising the standardized prevention rate for VTE was among the national healthcare quality and safety improvement goals for 2022 (27). Risk scoring that flags high-risk cancer patients is therefore key to the standardizing of DVT prevention (24,28). A number of DVT scoring tools have been described both in China and globally, the most widely used being the Caprini, Autar and Padua models (28,29). These tools differ in content and intended setting and do not perform uniformly across clinical situations, so each needs to be evaluated in the context where it will be used.

Currently, to the best of our knowledge, no DVT scoring tool has been built specifically for hospitalized patients with cancer, either in China or abroad, so models developed for other groups have to be adapted. The present study sought to identify suitable models by comparing four well-established tools, the Padua, Caprini, Wells DVT and Autar models, and applying them to two patient groups. Scores and the proportion of patients rated high risk or above on the Padua, Caprini and Wells DVT tools were higher in the thrombosis group (P<0.05), while the Autar scores and high-risk proportion did not differ significantly (P>0.05). This is plausible as the Autar scale was primarily constructed for DVT in patients with orthopedic conditions (25) and may fit patients with cancer less effectively. Klen *et al* (30) applied the Caprini and Padua tools to 223 patients who had undergone abdominal surgery and reported that Caprini predicted well in patients undergoing surgery, whereas the Padua tool is aimed at medical inpatients. Chen *et al* (31) found the Padua and Caprini models comparable in hospitalized patients with cancer (P<0.05), with Padua showing greater specificity. In 298 medical inpatients, Rafizadeh *et al* (32) found the Padua model predicted thrombosis strongly. The Wells DVT tool is designed mainly for outpatients, although some reports support its use in inpatients; Wang *et al* (33) reported that it outperformed the Khorana and Caprini models in gynecological malignancy. The present logistic regression demonstrated that higher Padua, Caprini and Wells DVT scores were significantly associated with DVT in patients with cancer, so that a higher score signals greater risk, whereas no such association appeared for the Autar score (P=0.855).

The Wells DVT score began as a diagnostic rule for outpatients with suspected DVT, not as a prophylaxis-oriented risk model and some of its items are clinical signs of a thrombus that is already present. Even so, the model exhibited moderate discrimination in the present cohort of hospitalized patients with cancer. The overlap may be partly explained by the items 'active cancer', 'paralysis or immobilization', 'recent bed rest or major surgery' and 'previous DVT', which are recognized VTE risk factors in their own right; the score thus captures some of the same risk information that drives the prophylaxis-oriented tools. When these signs were documented at the pre-diagnostic index time, they represented the pre-test clinical presentation rather than retrospective confirmation; patients with undocumented objective Wells items were excluded from the Wells complete-case analysis. Moderate discrimination was observed for Wells at both sites, although the point estimates differed (Cangzhou AUC 0.665; Hengshui AUC 0.746), results that should be interpreted cautiously. Despite this, its use in hospital has limits. The scale is meant to guide the diagnostic work-up of symptomatic outpatients, whereas numerous hospitalized

Table VII. Receiver operating characteristic analysis of the three models for predicting DVT.

Model	AUC	SE	P-value	95% CI	Youden's index	Sensitivity (%)	Specificity (%)	Cut-off
Padua	0.899	0.017	<0.001	0.866-0.932	0.678	74.4	93.3	5
Caprini	0.723	0.027	<0.001	0.671-0.776	0.389	67.8	71.1	4
Wells	0.703	0.028	<0.001	0.651-0.755	0.361	70.0	66.1	3

AUCs are reported with SE and 95% CIs. Padua and Caprini analyses used all 360 patients, whereas Wells used 350 complete cases (170 patients with DVT and 180 controls). DeLong comparisons involving Wells were performed in the same 350 complete cases, while the Padua-Caprini comparison used all 360 patients. Pairwise DeLong P-values were as follows: Padua vs. Caprini, P<0.001 (full cohort); Padua vs. Wells, P<0.001; and Caprini vs. Wells, P=0.073 (350 complete cases). Optimal cut-offs were selected by the maximum Youden index. AUC, area under the curve; SE, standard error; DVT, deep vein thrombosis.

Table VIII. Site-based external validation: AUC at each site and performance of the Cangzhou Integrated Traditional Chinese and Western Medicine Hospital-derived cut-offs at Hengshui People's Hospital.

Model	C-AUC (n=202)	H-AUC (n=158)	C-derived cut-off	Sensitivity (%)	Specificity (%)	Youden index	Calibration slope
Padua	0.897	0.903	5	73.4	94.9	0.684	1.110
Caprini	0.729	0.718	4	62.0	75.9	0.380	0.367
Wells	0.665 (n=196)	0.746 (n=154)	3	68.0	73.4	0.414	0.504
Autar	0.488	0.530					

Sensitivity, specificity and the Youden index represent the performance of the Cangzhou Integrated Traditional Chinese and Western Medicine Hospital-derived cut-offs when applied at Hengshui People's Hospital. Calibration slopes were estimated by fitting the observed Hengshui People's Hospital outcome against the unchanged linear predictor derived at Cangzhou Integrated Traditional Chinese and Western Medicine Hospital; the external intercept was freely estimated but not interpreted. Wells used n=196 at Cangzhou Integrated Traditional Chinese and Western Medicine Hospital and n=154 at Hengshui People's Hospital; the other models used n=202 and n=158. The Brier score and absolute predicted probabilities were not interpreted as the case-control prevalence did not represent the clinical population. The Autar model was not transported. AUC, area under the curve. C-AUC, Cangzhou Integrated Traditional Chinese and Western Medicine Hospital-derived AUC; H-AUC, Hengshui People's Hospital-derived AUC; C-derived cut-off; Cangzhou Integrated Traditional Chinese and Western Medicine Hospital-derived cut-off.

patients with cancer have no symptoms, which restricts its value for screening. The item 'an alternative diagnosis is at least as likely' is subjective and rater-dependent and may not behave the same way in a complex inpatient setting. The score also leaves out a number of cancer-specific and treatment-related items (including chemotherapy, central venous catheter and thrombophilia) that the Padua and Caprini models include. For these reasons, the Wells score is best treated as a complementary diagnostic aid rather than a stand-alone tool for prophylaxis stratification in hospital and its results should be read with these limits in mind.

With respect to the key clinical variables, immobilization and central venous catheterization were significantly more frequent in the DVT group, in keeping with their established role as VTE risk factors and with their inclusion as scored items in the risk models. Thromboprophylaxis was numerically (but not significantly) more common in the DVT group (45.0 vs. 38.9%); this is most consistent with confounding by indication, in which patients judged to be at higher risk were preferentially prescribed prophylaxis and it should not be interpreted as evidence that prophylaxis is ineffective. Chemotherapy rates did not differ between the groups and no patient exhibited a previous VTE because of the exclusion criteria.

The case-control sampling also warrants attention. Since DVT-positive and DVT-negative patients were enrolled in equal numbers, the 50% sample prevalence does not match the real-world incidence of DVT in hospitalized patients with cancer. Discrimination measures are relatively insensitive to prevalence and remain useful for comparing models within this sample, but positive and negative predictive values, decision thresholds and clinical utility depend on prevalence. ROC-derived cut-offs are also susceptible to differences in case mix and disease spectrum and therefore cannot be carried directly into routine care without prospective validation. The present study therefore transported the cut-offs to an independent site (Table VIII), although they should ultimately be further determined in a prospective cohort that reflects the true frequency of disease.

The present study went on to compare the three models in cancer patients, using ROC curves and their AUCs to judge their relative value. The AUCs were 0.899 for Padua, 0.723 for Caprini and 0.703 for Wells, with optimal cut-offs of 5, 4 and 3 points. These ROC-derived cut-offs were near, but not the same as, the published high-risk thresholds (≥4 for Padua and ≥3 for Wells; Caprini sets high risk at 3-4 and very high risk at ≥5). The corresponding sensitivity and specificity were

74.4 and 93.3% for Padua, 67.8 and 71.1% for Caprini and 70.0 and 66.1% for Wells. Padua was thus clearly more specific compared with other two models, while sensitivity was limited for all three, perhaps because none of these models were designed specifically for patients with cancer and each may miss cancer-specific factors. On this basis, Padua offered the greatest predictive value and was statistically superior to both other models; Caprini and Wells performed less well, with Caprini showing a numerically higher AUC compared with Wells, although this difference did not reach statistical significance and should be regarded as an observed trend.

The reasons for this may be as follows: Padua is primarily intended for medical inpatients; in the present cohort, 80.0% of the thrombosis group had stage III or higher disease versus 47.8% of controls, demonstrating an association between more advanced stage and greater DVT risk. Patients with advanced cancer often cannot undergo surgery and instead receive radiotherapy, chemotherapy or supportive care, placing them closer to the population for which Padua was built. The Caprini model covers a broad set of surgical and non-surgical factors, which makes it more elaborate and potentially less targeted than Padua in this setting, while the Wells model is aimed at outpatients and, in the pooled complete-case analysis, appeared less effective compared with Padua and numerically lower than Caprini; the site-specific point estimates at Hengshui were in the opposite order and should therefore be interpreted cautiously. The discrimination point estimates were broadly maintained at the independent site, although the pooled and site-specific ordering of Caprini and Wells was not identical: Caprini had a numerically higher pooled AUC than Wells, whereas Wells had a higher point estimate than Caprini at Hengshui. This further supports treating the Caprini-Wells ordering as an observed trend. The discrimination findings do not remove the need for formal calibration, because the Caprini and Wells slopes were <1 at the external site. In addition, 10 patients with DVT lacked pre-diagnostic documentation for one or more objective Wells clinical-sign items and were excluded from the Wells analyses by complete-case analysis rather than reconstructed retrospectively; this conservative approach may have slightly reduced the available Wells sample but safeguarded against outcome leakage.

The present study exhibits a number of limitations. First, although contrast venography is the reference standard for DVT (34), it is invasive and has narrow indications, so it is seldom used; the majority of the present cases were diagnosed by Doppler ultrasonography, which may introduce some bias in diagnostic choice. Second, despite recruitment from two hospitals, 56.1% of patients came from one center and the retrospective case-control design with a relatively small sample limits representativeness; all the models were also developed abroad and may not fit the local setting. Larger multicenter prospective studies with dedicated calibration and external validation are therefore needed. Third, given that the 1:1 case-control design holds DVT prevalence at 50%, the calibration intercept, absolute predicted risk and other prevalence-dependent measures could not be estimated and the cut-offs cannot be generalized directly; a prospective cohort reflecting real-world prevalence is required to establish calibration and clinical utility before these models guide prophylaxis. In addition, calibration slopes below 1 for the Caprini and Wells models at the external site indicate that the transported predictions were too extreme, but the present retrospective case-control design cannot determine whether this reflects overfitting at derivation or between-site case-mix differences; recalibration and formal assessment of both calibration slope and intercept (absolute calibration) in a prospective cohort are therefore warranted.

In summary, the Padua, Caprini and Wells DVT models all help predict DVT in patients with malignant tumors, with Padua showing the greatest and statistically superior value; the Caprini and Wells models offered moderate discrimination and did not differ significantly from one another. The Autar model, by contrast, does not appear suitable for assessing DVT risk in these patients.

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Availability of data and materials

The data generated in the present study may be requested from the corresponding author.

Authors' contributions

XH designed the present study, performed the data analysis and drafted the manuscript. As the principal investigator of the Hengshui People's Hospital site, XH was responsible for the organization, authorization, quality control and verification of the 158 associated cases; under the inter-hospital collaboration and with her authorization and supervision, the on-site extraction of these cases was performed jointly by personnel under her supervision and by investigators from the Cangzhou Integrated Traditional Chinese and Western Medicine Hospital site and XH takes responsibility for the authenticity and integrity of this data. JZ conceived and supervised the research and guided the revision of the manuscript. YS contributed to the present study design and provided key data analysis support. YL, QD and ZS were responsible for the enrollment and acquisition of the Cangzhou Integrated Traditional Chinese and Western Medicine Hospital cases and, under the cooperation and authorization of both hospitals and the supervision of the principal investigator, also participated in the on-site extraction of these cases; they contributed to the acquisition and interpretation of the data. XH and JZ confirm the authenticity of all the raw data. All authors read and approved the final version of the manuscript.

Ethics approval and consent to participate

The present study was performed in accordance with the Declaration of Helsinki and approved by the Ethics Committees of Cangzhou Integrated Traditional Chinese and

Western Medicine Hospital (approval no. 2021-KY-062.1) and Hengshui People's Hospital (approval no. 2022014039Z). The requirement for informed consent to participate in this retrospective study was waived by the ethics committee.

Patient consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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