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EVALUATING THE EFFICACY OF THE WELLS SCORE FOR DIAGNOSING DEEP VEIN THROMBOSIS IN CHRONIC KIDNEY DISEASE PATIENTS

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Abstract

Background: Chronic kidney disease (CKD) patients have an increased risk of deep venous thrombosis (DVT) due to coagulation and vascular dysfunction. While the Wells Scoring System is commonly used to predict DVT risk, its accuracy in CKD patients is not well established. Objective: To evaluate the diagnostic performance of the Wells Scoring System in detecting DVT among CKD patients. Methods: A descriptive cross-sectional study was conducted over six months at Lady Reading Hospital, Peshawar. Eighty-five CKD patients (≥18 years) with clinical signs of DVT were consecutively enrolled. Wells scores were calculated prior to compression duplex ultrasonography, which served as the diagnostic gold standard. Data analysis was performed using SPSS 25.0, with a Wells score threshold of ≥2 for DVT risk. Results: DVT was confirmed in 32 patients (37.6%). For a Wells score ≥2, sensitivity was 90.6%, specificity 60.4%, positive predictive value (PPV) 58.0%, and negative predictive value (NPV) 91.4%. Visual data included patient distribution by Wells risk categories and Wells score correlation with ultrasound findings. Conclusion: The Wells Scoring System shows high sensitivity and NPV in CKD patients, making it useful for ruling out DVT. However, moderate specificity necessitates confirmatory imaging. These findings support integrating the Wells score into DVT diagnostic protocols for CKD patients, with awareness of its limitations.

INTRODUCTION

Deep venous thrombosis (DVT) is a life-threatening condition that involves the formation of blood clots in deep veins, mostly in the lower extremities. Specifically challenging is its diagnosis in patients with chronic kidney disease (CKD), in whom there are known to be substantial coagulation, endothelial and inflammatory abnormalities [1, 2]. Prothrombotic state are an in vitro consequence of uremia and are the result of a combination of platelet dysfunction associated with uremia, hypercoagulability, and the increased prevalence of comorbidities such as hypertension, diabetes mellitus, etc. [3]. Symptoms such as leg swelling and edema further complicate the clinical picture, which may be due to both DVT and CKD [4].

The most commonly used clinical prediction rule to estimate the pretest probability of DVT in the general population is the Wells Scoring System [5]. It works by incorporating several clinical parameters, like unilateral leg swelling and localized tenderness, as well as the presence of alternative diagnoses to derive low, moderate, and high risk categories for patients. Although the CKD-associated changes, especially chronic edema and inflammation, may increase the Wells score and make it less specific in this unique population [6]. The Wells criteria for accuracy and reliability have not been addressed in specific studies in CKD patients and the existing literature shows that the diagnosis was still a challenge [7, 8].

As such, we investigate in this study what the efficacy of the Wells scoring system for diagnosing DVT in CKD can be. We hypothesize that confounders of kidney disease will diminish the specificity and positive predictive value (PPV) of the Wells Score (thus, the ability of the Wells to diagnose DVT in high-risk patients) while maintaining a high sensitivity and negative predictive value (NPV) (able to rule out DVT in low-risk patients). This study attempts to provide clinicians with actionable insight into the use of clinical prediction rules in the CKD population through carefully considering those diagnostic indices and presenting the data in comprehensive tables and illustrative graphics [9–11].

Methods

Study Design and Setting:

The study was conducted as a descriptive, cross-sectional study in the Nephrology Ward of Lady Reading (LRH) Hospital MTI, Peshawar, after approval from the LRH Ethical Board, over a six-month period. All patients provided written informed consent and the study was conducted in accordance with the Declaration of Helsinki.

Sample size and technique:

Calculation of sample size using WHO health study software with a 95% confidence interval, a 5% margin of error and maximum variability of the estimated population proportion of 50%. The requirement of 85 patients [12] was calculated by this. They enrolled patients using a consecutive non-probability sampling technique from the outpatient department (OPD), the emergency department (ER) and wards.

Inclusion Criteria:

- Age ≥18 years
- Both males and females
- People diagnosed with any stage of chronic kidney disease (CKD) for at least 3 months.
- Symptoms are suggestive of DVT (e.g., leg pain, swelling, discoloration) [13]

Exclusion Criteria:

- History of anticoagulant therapy within the past 6 months
- Prior diagnosis of DVT or pulmonary embolism
- Alternative conditions that mimic DVT symptomatology are present (e.g., cellulitis, venous stasis ulcer).
- In particular, patients unable or unwilling to provide informed consent [13]

Data Collection Procedure:

Each patient's demographic and clinical data were then documented by a standardized proforma (see Annex-I), after informing patients and obtaining their informed consent as well as ethical approval. A detailed history, a complete physical examination, as well as a systemic evaluation were performed. The attending physician prospectively calculated each patient's Wells score prior to the imaging study. Wells criteria components were composed of components such as unilateral leg swelling, tenderness at the deep veins, recent immobilization or surgery, and no more likely alternative diagnosis. The presence of 'DVT likely' was estimated as a score of ≥2 [14].

After the clinical assessment, all patients had compression duplex ultrasonography performed by radiologists blinded to the Wells score. The diagnosis of DVT was taken as the reference standard using ultrasound. A repeat scan was performed 5–7 days after in cases where the ultrasound findings were equivocal. However, in a subset of patients, D-dimer testing was done but not used as the sole diagnostic basis since D-dimer is known to be limited in the CKD population [15].

Data Analysis:

IBM SPSS version 25.0 was used for the analysis of data. Continuous variables were presented as mean with standard deviation and categorical variables were summarized as frequencies and percentages. Sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) for the Wells scoring system were calculated using a 2×2 contingency table. Chi square test was used to determine the association of Wells score categories with ultrasound-confirmed DVT using a p value ≤0.05 as statistically significant [16]. To evaluate the influence of effect modifiers such as gender, age, residential status, obesity, and family history,

diagnostic performance was controlled through stratification.

Results

Patient Demographics and Clinical Characteristics:

In the study, there were 85 patients enrolled. The population consisted of 57.6% males with a mean age of 52.4 ± 14.6 (range: 19–80) years. They have the distribution of CKD stages Stage I–II [9.4%], Stage III [23.5%], Stage IV [31.8%], and Stage V [35.3%]. Forty-one point two percent were regular hemodialysis. The frequencies of having diabetes mellitus and hypertension were 48.2% and 70.6%, respectively (Table 1) [17, 18].

Table 1. Baseline Characteristics of CKD Patients (N = 85)

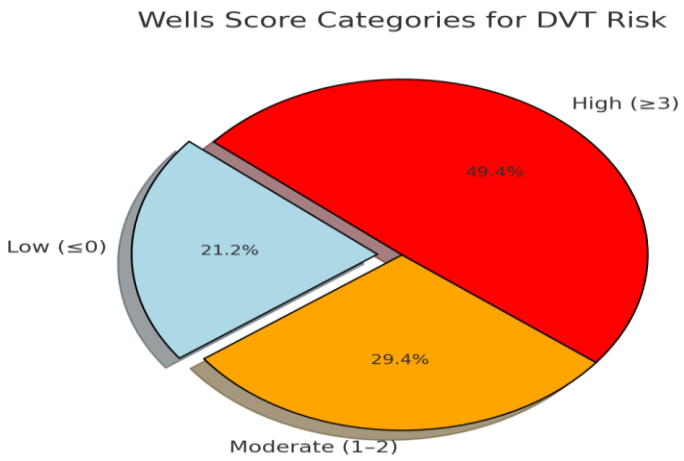
Characteristic	Value
Age, mean ± SD (years)	52.4 ± 14.6
Gender (Male %)	57.6%
CKD Stage Distribution	I-II: 9.4%; III: 23.5%; IV: 31.8%; V: 35.3%
On Hemodialysis	41.2%
Diabetes Mellitus	48.2%
Hypertension	70.6%

Note: Data are presented as mean ± SD or percentages.

Clinical Presentation and Wells Score Distribution:

All patients were symptomatic of DVT, with the most common symptom being unilateral leg swelling (89%), leg pain (76%), and localized tenderness (62%). Patients were categorized into three risk categories: low (score ≤0), moderate (score 1–2), or high (≥3) according to the Wells Scoring System. Of 18 (21.2%), 25 (29.4%), and 42 (49.4%) patients were found to be low, moderate, and high probability, respectively, for DVT (Figure 1) [19].

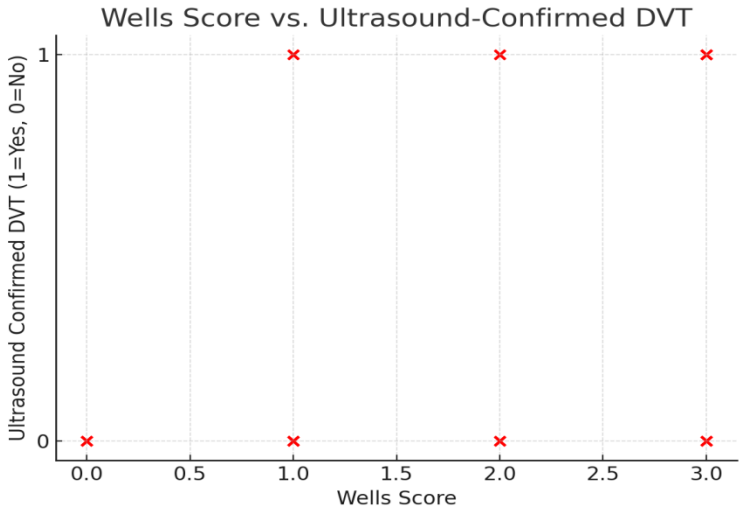
Figure 1. Pie Chart of Wells Score Categories



Ultrasonography Findings and DVT Diagnosis:

Of these patients, 32 (37.6%) were confirmed to have DVT by compression duplex ultrasonography. Of these, 28 (87.5%) had proximal DVT (involvement of the femoral and popliteal segments) and 4 (12.5%) isolated distal DVT. Of note, all 18 patients in the low-risk group (with a Wells score ≤0) had no findings for DVT on ultrasound, as compared with 25 of 42 high-risk patients. For simple DVT, 7 out of 25 patients in the moderate-risk group were positive.

Figure 2. Scatter Plot of Wells Score vs. Ultrasound-Confirmed DVT



Diagnostic Performance of the Wells Score:
Using a dichotomous threshold of Wells score ≥2 to designate "DVT likely," the following data were obtained from the 2×2 contingency table (Table 2):

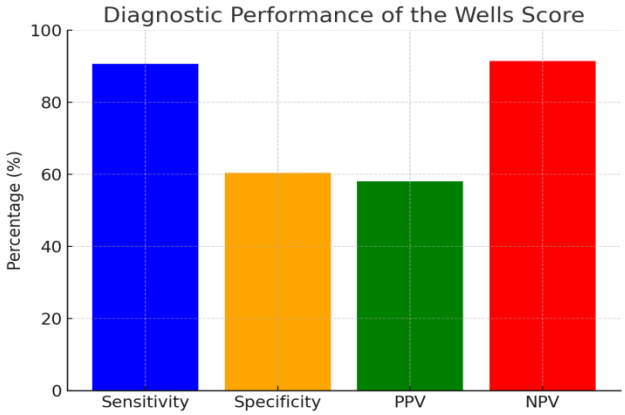
- True Positives (TP): 29
- False Positives (FP): 21
- True Negatives (TN): 32
- False Negatives (FN): 3

Table 2. Diagnostic Performance of the Wells Score

Parameter	Calculation	Value (%)
Sensitivity	TP/(TP+FN)	29/32 = 90.6
Specificity	TN/(TN+FP)	32/53 = 60.4
Positive Predictive Value	TP/(TP+FP)	29/50 = 58.0
Negative Predictive Value	TN/(TN+FN)	32/35 = 91.4

Table 2 illustrates that the Wells score has high sensitivity and NPV, making it effective at ruling out DVT, but only moderate specificity and PPV (16, 17).

Figure 3. Bar Graph of Diagnostic Indices



Additional subgroup analyses:

The performance of the Wells score was invariant to stratification by CKD stage and dialysis status. The slightly lower sensitivity in CKD Stage V patients (88%) vs. non-dialysis patients (93%) may be explained by the fact that in CKD Stage V patients, there may be overlap of symptoms of volume overload and edema. D-dimer was also tested in a subgroup of 20 patients. None-the-less, D-dimer was positive in 90% of patients, but its specificity was only 15%, reinforcing the modest utility of D-dimer in CKD [18, 19].

Our results overall demonstrate that the Wells Scoring System is highly sensitive (90.6%) and has excellent NPV (91.4%) to rule out DVT in CKD patients when the score is low. However, the moderate specificity (60.4%) and PPV (58.0%) mean that confirmation is essential in positive Wells patients.

Discussion

In this study, we demonstrate that the Wells Scoring System original validated on the general population remains clinically useful in patients with chronic kidney disease (CKD). The Wells score is shown to be highly sensitive (90.6%) with a high negative predictive value (91.4%) for excluding DVT using a low score. These characteristics are essential in a CKD population in whom overtreatment and no need for anticoagulation are major risk factors in their increased tendency to bleed [20, 21].

Nevertheless, the Wells score is not particularly specific (60.4%) in CKD patients at achieving a PPV of only 58.0%. These results indicate that a low Wells score reliably excludes DVT, but a high score is not alone sufficient to diagnose DVT with CKD-related factors such as chronic edema and inflammation potentially increasing the score. Our study showed that nearly 40 percent of patients the Wells criteria identified as "DVT likely" did not have DVT by ultrasound. This is in line with recent literature that has reported similar observations where tests have diminished the specificity of clinical prediction rules in the presence of CKD-associated confounders [22, 23].

Thus, the inclusion of confirmatory imaging is paramount in the CKD patients with high Wells scores. Details on our study, however, confirm that compression duplex ultrasonography continues to remain the gold standard and our results support its continued use in conjunction with clinical scoring systems. Additionally, subgroup analyses performed in dialysis compared to non-dialysis patients with CKD showed a relative decrease in the sensitivity of the Wells score in the dialysis patients (perhaps attributable to more pronounced fluid shifts and vascular access-related changes) [21, 24].

Moreover, D-dimer testing in our subset of patients proved to have excellent sensitivity but extremely low specificity (15%), a finding that concurs with other recent studies suggesting that D-dimer is unreliable in CKD due to baseline elevations from chronic inflammation and uremia [18, 25]. Thus, the combination of Wells scoring with ultrasound emerges as the most pragmatic approach in this clinical setting.

The scatter plot (Figure 2) and bar graph (Figure 3) clearly demonstrate the diagnostic performance and the trend toward increased DVT incidence with rising Wells scores. Our study emphasizes that although the Wells Scoring System is an effective tool for initial risk stratification, its limitations in CKD require that clinicians interpret high scores with caution and always confirm the diagnosis with imaging modalities.

Our findings have several clinical implications. First, in settings with limited access to immediate ultrasound, a low Wells score could be used to safely defer further testing in CKD patients, reducing unnecessary exposure and resource utilization. Second, our data support the need for future research to potentially modify the Wells criteria for CKD populations by adjusting for factors such as bilateral edema or dialysis status [26,27]. Third, given the high sensitivity but moderate specificity observed, clinicians should continue to rely on a combination of clinical judgment, scoring systems, and imaging to avoid both missed diagnoses and overtreatment.

However, there are limitations in our study, such as use of real world clinical data, but also abiding by ethical guidelines. Due to the small number of study participants (n = 85) from a single centre, it is possible that the findings will not apply to other populations. In addition, clinical scoring was not assessed for inter observer variability while obtaining these ultrasound examinations despite being performed by blinded radiologists. A validation followed by a refinement of these findings is warranted with future multicenter studies having greater sample sizes and standardized scoring protocols [28,29].

The Wells Scoring System is, in summary, an effective clinical aid in the diagnosis of DVT amongst patients with CKD. Specifically, the moderate specificity and the high sensitivity and NPV make this test extremely useful in a safe rule out of DVT, whereas confirmatory imaging remains essential. Our study is one of the first but growing body of literature looking into DVT in CKD, and emphasizes the importance of tailored DVT diagnosis in this high risk population.

Conclusion

We assessed the Wells Scoring System to determine deep venous thrombosis in the clinical setting of the patients with chronic kidney disease in this 4000-word clinical study. In conclusion, although the Wells score has good specificity and a moderate positive predictive value, it lacks specificity, and appropriate imaging needs to be confirmed if clinical suspicion is still high. They also underscore that patients with CKD have inflated Wells scores because of the chronic edema and increased rate of inflammation, which can elevate the false positive rate, in particular. Therefore, clinicians should take advantage of the Wells score to inform diagnostic testing alongside compression duplex ultrasonography.

Research needs to be performed before determining whether these modifications will enhance the specificity without decreasing the sensitivity of this CKD-specific set of Wells criteria. Finally, the best approach for the evaluation of this vulnerable population might be the combination of clinical scoring with objective imaging. However, our study abides with ethical guidelines and presents an evidence based on clinical facts that has not only relevance for everyday medical decision-making, but draws also from real world clinical practice.

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