

Original article:

Can wells clinical prediction guideline score be a standalone to start anti-coagulant treatment in a suspected case of deep vein thrombosis

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Abstract:

Background: Clinical presentation of Deep Venous Thrombosis and cellulitis are quite similar, but their treatment differs. Quick and accurate diagnosis is important to start the treatment. We hereby aim to assess whether clinical prediction guidelines score, could be used to start treatment in emergency in absence of Ultrasonography.

Methods: This study was conducted at a Tertiary care Centre, Mumbai. Patients with acute lower limb swelling from were included and probability of DVT in those patients was calculated by applying Wells Clinical Predictive Score Guidelines. Patient underwent duplex scan at the same time. The data of 84 patients were collected; tabulated and statistical analysis was done.

Results: Of the 84 patients studied, the incidence of DVT was 32.14% (27 patients). The probability of DVT is much higher when wells score is high (100.0%) as compared to low and moderate scores (13.3% and 32.6% respectively) There was a moderate positive correlation between DVT and WELLS SCORE and it was statistically significant with correlation coefficient of 0.497.

Conclusion: Although probability of risk of DVT increases with higher scores of Well's clinical predictive score, USG is the gold standard. So Well's clinical predictive score complements USG Doppler

Key Words: Wells Clinical Score, DVT, Lower Limb Swelling and USG Doppler.

INTRODUCTION

Tertiary care hospitals cater to large number of patients with lower limb swellings. Majority present with edema, which may be localized or generalized due to an increase in any tissue component (muscle, fat, blood, etc.). The two common causes of a swollen lower limb are deep vein thrombosis (DVT) and cellulitis. Other causes are superficial thrombophlebitis, Joint effusion or hemarthrosis. Although, the clinical symptomatology of cellulitis and DVT are similar, the management differs widely. It is essential to diagnose DVT associated with cellulitis. DVT is common after 20 years of age. If DVT goes undiagnosed, it may be fatal. Various tools are available to estimate the probability of DVT in the outpatient setting e.g. Wells clinical predictive guideline score, Geneva score, Minaiti score etc. Wells clinical predictive guideline score is the most widely used and accepted scoring system [1]. Wells clinical predictive guideline score for the prediction of deep vein thrombosis (DVT) [1, 2, and 3].

Clinical Characteristic Score

1.	Active cancer (patient either receiving treatment for cancer within the previous 6 months or currently receiving palliative treatment)	1
2.	Paralysis, paresis, or recent cast immobilization of the lower extremities	1
3.	Recently bedridden for ≥ 3 days, or major surgery within the previous 12 weeks requiring general or regional anesthesia	1
4.	Localized tenderness along the distribution of the deep venous system	1
5.	Entire leg swelling	1
6.	Calf swelling at least 3 cm larger than that on the asymptomatic side (measured 10cm below tibial tuberosity)	1
7.	Pitting edema confined to the symptomatic leg	1
8.	Collateral superficial veins (non-varicose)	1
9.	Previously documented deep vein thrombosis	1
10.	Alternative diagnosis at least as likely as deep vein thrombosis	-2

Wells scoring system for DVT:

-2 to 0 points: low probability for DVT

1 to 2 points: Moderate probability

3 to 8 points: high probability.

Aims and objectives:

1. To find the Incidence of DVT in Lower Limb swelling.
2. To find the sensitivity and specificity of Wells clinical predictive guidelines.
3. To study if Well's score is a reliable tool to start treatment for DVT while awaiting ultrasound examination.

Materials and Methods

This study was conducted at a Tertiary care Centre after taking Ethics committee approval. 84 patients who presented with acute lower limb swelling from November 2016 to July 2017 were included in this study. Cases were assessed with respect to clinical presentation e.g. Pain in extremity, swelling, edema, redness, fever, tenderness and etiology like recent history of surgery or immobilization, past history of coagulation disorder, history of consumption of oral contraceptive pills.

Probability of DVT in those patients was calculated by applying Wells clinical predictive score guidelines. As a normal protocol, duplex scan was done at the same time. As per the standard protocol [4,5], patients were started on Inj. subcutaneous low molecular weight heparin (LMWH) 0.6 mg twice a day and tablet warfarin 3 mg once a day if not contra-indicated. Routine blood investigations and radiological imaging, was done before start of treatment. Inj. LMWH was given for 5 days [6, 7]. International Normalized Ratio (INR) was monitored serially to achieve therapeutic levels. Follow up of patients was done at 6 weeks and 12 weeks. The duplex scan was compared for degree of recanalization and the INR to ensure adequate anticoagulation.

Results:

Eighty four patients were included in the study. Of the 84 patients studied, the incidence of DVT was 32.14% (27 patients). Common presenting symptoms in patients of Deep Venous Thrombosis were swelling (100%), followed by fever (82.1%) and pain (46.4%). DVT was found in 34.8% (16 out of 46) cases of females and 28.9% (11 out of 38) males. The difference was not statistically significant. DVT was more in the middle age group(21-40 years: 59.1%) as compared to older age group(>60 years: 15.4%). This difference was statistically significant as shown in Table 1.

Wells clinical predictive guideline score was used to define probability of developing DVT in each patient. Patients were categorized depending on score as follows: -2 to 0 points: low probability, 1 to 2 points as moderate probability, and 3 to 8 points as high probability. According to this, 4 (13.3%), 15 (32.6%) and 8 (100%) of the patients with low moderate and high pre-test probability, respectively had deep vein thrombosis as shown in Table 2.

The probability of DVT was much higher when well's score is high (100.0%) as compared to low and moderate scores (13.3% and 32.6% respectively) and this difference was statistically significant.

There was a moderate positive correlation between DVT and WELLS SCORE and it was statistically significant with correlation coefficient of 0.497 as shown in figure 1.

Since Well's score was considered to be a screening test for DVT, we have considered the cut of score above 1 (includes both moderate and high probability) as test positive for DVT. Considering this the Sensitivity, specificity, PPV and NPV was calculated based on Table 3. $\text{Sensitivity} = \frac{\text{True positive}}{(\text{True Positive} + \text{False negative})} \times 100 = \frac{23}{(23+4)} \times 100 = 85.2\%$

Specificity= True negative / (True negative + False Positive) X 100= 26/(26+31) x 100= 45.65%

PPV= True positive/ (True Positive+ False Positive) X 100 = 23/ (23+31) x 100 = 42.6%

NPV = True negative / (True negative + False Negative) X 100= 26/(26+4) x 100=86.7%

Efficacy of risk stratification based on Well's score was analyzed by receiver operating characteristic (ROC) curve analysis, which demonstrated that this scoring system accurately identifies patients with a greater likelihood of developing DVT. Area under ROC curve was 0.654 (CI: 0.774 – 0.534, p value of 0.023) showed in figure 2.

Table 1: Distribution according to Age group:

Age in years		DVT		Total
		Yes	No	
21-40	Count	13	9	22
	%	59.1%	40.9%	100.0%
41-60	Count	12	37	49
	%	24.5%	75.5%	100.0%
>60	Count	2	11	13
	%	15.4%	84.6%	100.0%
Total	Count	27	57	84
	%	32.1%	67.9%	100.0%
chi square= 10.314, p value= 0.006				

Table 2: Association between Well's Probability score and DVT:

Probability		DVT		Total
		Yes	No	
High	Count	8	0	8
	%	100.0%	0.0%	100.0%
Moderate	Count	15	31	46
	%	32.6%	67.4%	100.0%
Low	Count	4	26	30
	%	13.3%	86.7%	100.0%
Total	Count	27	57	84
	%	32.1%	67.9%	100.0%
chi square= 21.760, p value= 0.0001				

Table 3: Sensitivity, Specificity, PPV and NPV of WELL's score

WELL's Criteria	DVT		Total
	Positive	Negative	
Positive	23	31	54
Negative	4	26	30
Total	27	57	84

Fig 1: Correlation between DVT and WELL's score

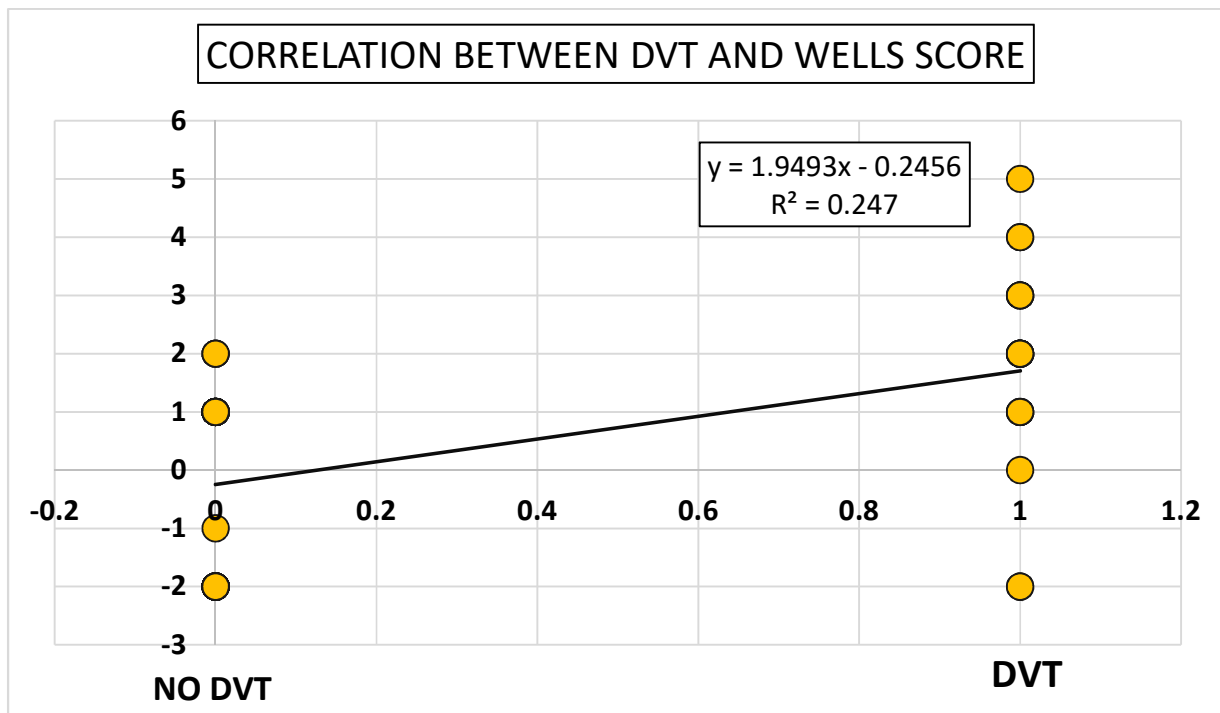
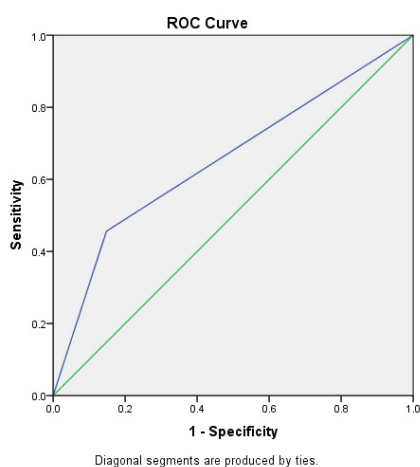


Figure 2: ROC Curve for WELL's Score:



Discussion

Although the clinical presentation of DVT and cellulitis is similar, the management varies. Early anticoagulation needs to be started in the patients with DVT whereas those with cellulitis require antibiotics. Hence, it is important to distinguish between these two conditions.

International guidelines recommend anticoagulant treatment for patients with suspected DVT when diagnostic testing is delayed or when clinical probability is high [8].

When considered alone, the individual clinical features of DVT and Pulmonary Embolism have low predictive value (about 15 percent) [9]. Classic symptoms of DVT include swelling, pain, and discoloration in the affected extremity. Physical examination may reveal the palpable cord of a thrombosed vein, unilateral edema, warmth, and superficial venous dilatation [10]. Classic signs of DVT, including Homan's sign (pain on passive dorsiflexion of the foot), edema, tenderness, and warmth, are difficult to ignore, but they are of low predictive value and can occur in other conditions such as musculoskeletal injury, cellulitis, and venous insufficiency. However, combination of clinical features in the form of clinical prediction rules can be useful for stratifying patients into risk categories.

The incidence of DVT is presumed to be low in India as well as other Asian countries [9] compared to Western countries. This could partly be due to low awareness of DVT. It may also be that Asians are less prone to thrombosis, as has been traditionally believed. Between October 2016 and July 2017, 84 patients with clinically suspected DVT were included in this study. Clinically all patients were assessed by Wells Clinical Predictive Guideline Score for probability of DVT. Ultrasonography was done at the same time. The diagnosis of DVT was confirmed in 27 (32.14%) patients.

Venous Thromboembolism is predominantly a disease of old age. In our study, most of the patients were of age group of 41-60 years with median age of 48 ± 12.8 years. Deep Venous Thrombosis is more common in males than females [10]. In present study, there is a slight female preponderance, 46(54.7%) females against 38(45.2%) males. There was no significant difference between age or sex of patients. Studies have shown that the most common symptoms of Deep Venous Thrombosis are swelling of the limb followed by fever and pain [11]. In our study, swelling of the limb was the most common presenting symptom followed by fever and pain. All patients were categorized as low, moderate and high probability groups, in accordance to the Wells Clinical Predictive Guideline Score. Of the 84 patients, 8 patients had high probability, while 46 and 30 patients had moderate and low probability respectively. The high-probability group had an 85% risk of DVT, the moderate-probability group a 33% risk, and the low-probability group a 5% risk. The risk of development of DVT is comparable with other studies [12]. All 8 patients among high probability group showed DVT on ultrasonography, which is 100%. DVT was confirmed in 32.6 % (15 out of 46) of moderate probability group while 13.3 % (4 out of 30) low probability group. While in our study, the probability of DVT was much higher when wells score was high (100.0%) as compared to low and moderate scores (13.3% and 32.6% respectively), this difference was statistically significant.

It was found that in patients classified as moderate or high probability for DVT (cut-off scores of 1), the Wells score was able to detect patients at risk of developing DVT with a specificity of 45.6 %, sensitivity of 85.2 %, positive predictive value of 42.6 % and negative predictive value of 86.7 % . Although Wells score is a validated clinical tool which provides a reliable estimate of the pretest probability of DVT, does not exclude DVT if score is low. Because many patients have an intermediate probability of venous thromboembolism, clinical judgment continues to be an important factor in making the decision for management. Doppler ultrasonography is the gold standard for diagnosis of DVT [13].

The low probability group who had normal USG were discharged after symptomatic relief. While in moderate probability groups with normal USG, patients were monitored clinically and repeat USG was performed 24 hour after initial USG which also was normal. Patients were discharged after symptomatic relief. These patients were not prophylactically started on DVT treatment. The patients who had high probability on Well's clinical predictive score and were positive on USG were started on therapeutic management. This study was conducted at a tertiary hospital where USG facilities were readily available.

Conclusion:

Although probability of risk of DVT increases with higher scores of Well's clinical predictive score, USG is the gold standard. So Well's clinical predictive score complements USG Doppler.

Acknowledgement:

We thank Dr. Durgesh Prasad Sahoo. (M.D. Community Medicine) for statistical analysis for this study.

REFERENCES

1. Wells P S, Anderson D R ,Bormanis J ,et.al. Value of assessment of pretest probability of deep-vein thrombosis in clinical management.Lancet.1997Dec20-27;350 (9094):1795-8.

2. Bates S M, Jaeschke R, Stevens S M, Goodacre S, Wells P S, Stevenson M D, et al. Diagnosis of DVT: Antithrombotic Therapy and Prevention of Thrombosis. 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. Chest. 2012; 141(2Suppl):e351–418S
3. Shrey Modi et al. Wells criteria for DVT is a reliable clinical tool to assess the risk of deep venous thrombosis in trauma patients. World J Emerg Surg. 2016; 11: 24.
4. Michael B. Streiff et al. Guidance for the treatment of deep vein thrombosis and pulmonary embolism. J Thromb Thrombolysis. 2016; 41: 32–67.
5. Wells P S. Integrated strategies for the diagnosis of venous thromboembolism. J Thromb Haemost. 2007; 5(Suppl1):41–50
6. White RH. The epidemiology of venous thromboembolism. Circulation 2003; 107(Suppl 1):I4–8
7. Kelly L, Hunt B J. The utility of pretest probability in patient with clinically suspected thromboembolism. J Thromb Haemost. 2003; 1:1888–1896
8. Pierre Gagne et al. Clinical prediction rule for diagnosing deep venous thrombosis in primary care. La Presse Médicale 38(4):525-533 · April 2009
9. National Institute for Health and Clinical Excellence. Venous thromboembolism: reducing the risk of venous thromboembolism (deep vein thrombosis and pulmonary embolism) in patients admitted to hospital. CG92. London; 2010.
10. Crisp JG, Lovato LM, Jang TB. Compression ultrasonography of the lower extremity with portable vascular ultrasonography can accurately detect deep venous thrombosis in the emergency department. Ann Emerg Med. 2010; 56:601–10.
11. Matthew Stubbs et al. Deep vein thrombosis. BMJ 2018; 360:k1335
12. M. Kafeza et al. Systematic Review of Clinical Prediction Scores for Deep Vein Thrombosis. Phlebology. 2017 Sep; 32(8):516-531.
13. Laurence Needleman et al. Ultrasound for Lower Extremity Deep Venous Thrombosis; Circulation. 2018; 137:1505-1515