Original Research Article

Study to determine Wells criteria as a reliable clinical tool in diagnosis of deep vein thrombosis: a one year cross-sectional single centric hospital based study

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ABSTRACT

Background: Venous thromboembolism which encompasses deep vein thrombosis (DVT) and pulmonary embolism (PE) is one of the major cardiovascular causes of death along with myocardial infarction and stroke. DVT is a common problem in non-ambulatory and hospitalized patients. It is a major cause of morbidity and mortality in these patients. Venous thromboembolism mimics other illnesses making its diagnosis difficult. In such circumstances clinical improvement often fails to occur despite standard medical treatment of the concomitant illness.
Methods: A prospective cross-sectional study was conducted at tertiary care hospital in which 40 patients with complaint of limb swelling were included. Risk was calculated according to the wells criteria and confirmed with color Doppler of the affected limb.
Results: Majority of people were more than 50 years with male preponderance and with history of smoking present. Subjects had leg swelling with edema and calf tenderness. Results were well established in favor of Wells criteria for making diagnosis of DVT. This criterion showed 100% sensitivity with a negative predictive value of 100% and an accuracy of 90%.
Conclusions: This criterion can help the clinicians to treat the disease before it takes a violent course and help the patients live a healthy life. The present study was done in a small proportion of patients. It is highly recommended that thorough studies and researches be conducted so that modern medicine can be highly efficacious, with newer techniques and procedures which can be beneficial for the patients.

Keywords: Deep vein thrombosis, Venous thrombosis, Pulmonary embolism

INTRODUCTION

The term thrombosis refers to the formation of an abnormal mass within the vascular system from constituents of blood. When it occurs in deep veins, it is known as DVT.[1] DVT and PE (comes under venous thromboembolism) are common pathologies that can affect both healthy individuals as well as medical or surgical patients and are preventable cause of mortality.[2,3] It can lead to complications such as post-phlebitic syndrome, PE, pulmonary hypertension and eventually death. Symptoms like breathlessness often seen with exertion are observed with chronic thromboembolic pulmonary hypertension.[4]

Some 2,00,000 cases of venous thromboembolism were seen each year. From these, around 30% patients died in 30 days and one fifth of these were due to pulmonary embolism, while 30% develop recurrent venous thromboembolism within 10 years. The mean incidence of first DVT in the general population was 5 per 10,000 person-years.[4] An annual incidence of DVT in general

population was 67 per 1,00,000.[5,6] Despite adequate therapy, 1-8% of patients in whom PE develops will die, whereas others will experience long-term complications such as post-phlebitic syndrome (40%) and chronic thromboembolic pulmonary hypertension (4%).[7-9]

The condition is predisposed by transient and reversible clinical risk factors such as surgery or oestrogen exposure or long term and permanent factors such as hemiparesis from stroke.[10] Clinical features are nonspecific, hence new strategies for diagnosing this condition have evolved.[1] In spite of adequate information on DVT and its fatal complications, decision as to when to start prophylaxis was always a challenge mainly in postoperative patients as profuse bleeding can occurred during the postoperative period.

As DVT is common in postoperative patients and during period of hospitalization, it leads to significant rise in the expense to the patient due to prolonged period of stay in the hospital and also loss of resources and manpower. The clinical diagnosis of DVT was not only challenging but may mimic other conditions as well, thereby making it risky to start empirical therapy with anticoagulants. Advanced imaging facilities such as Doppler venous ultrasound may not be always available in all peripheral hospitals. Due to delay in the diagnosis, the treatment also got delayed resulting in wastage of time and risk to patient's life.

A clinical scoring system had been developed namely Wells score which included various aspects in the history as well as various clinical signs which can help the clinician to arrive at a diagnosis of DVT. This helped to save time and money and avoid unnecessary investigations.

The aim of this study was to determine accuracy of Wells criteria as a predictive tool in diagnosis of DVT in suspected patients.

METHODS

The study was a prospective, observational study conducted during the period between January 2018 and December 2018 at the department of general surgery at Jawaharlal Nehru medical college. Approval was obtained from the local committee on research ethics and informed consent according to the tenets of the Declaration of Helsinki was obtained from all subjects. Patients were included in the analysis provided that they met the inclusion criteria.

Inclusion criteria

Patients aged >18 years and patients with lower limb swelling were included in the study.

Exclusion criteria

Patients that were excluded from the analysis were pregnant woman, previously diagnosed cases of DVT and patients with bleeding diathesis.

Forty patients who came with lower limb swelling were clinically examined and suspected to have DVT. Based on Wells criteria these patients were split up as low, intermediate and high-risk categories and diagnosis confirmed with color Doppler to estimate the efficacy of Wells tool.

Clinical assessment

Wells clinical prediction criteria for DVT. A score of +1 was assigned for active cancer (treatment ongoing or within the previous 6 months or palliative); paralysis, paresis or recent plaster immobilization of the lower extremities; recently bedridden for more than 3 days or major surgery within 4 weeks; localized tenderness along the distribution of the deep venous system; entire leg swollen; calf swelling more than 3 cm when compared to the asymptomatic leg (measured below tibial tuberosity); pitting edema (greater in the symptomatic leg); and collateral superficial veins (non-varicose).

Alternative diagnosis as likely or greater than that of DVT was assigned a score of -2.

A total score was calculated using all these parameters and the patients were categorized into risk groups as low risk ≤0 points, intermediate risk=1 or 2 points, high risk ≥3 points.

Subjects underwent color Doppler for confirmation so that efficiency of the test can be determined, that is, the correlation between Wells score and color Doppler.

Statistical analysis

For quantitative variable descriptive analytical method was applied with help of standard deviation and mean and for categorical variables with help of proportion and frequency. Percentage comparisons and cross tabulations used to explain connection between categorical outcomes and explanatory variable.

RESULTS

Wells score category had sensitivity of 100.00% (95% CI 89.42% to 100.00%) in predicting DVT, specificity was 42.86% (95% CI 9.90% to 81.59%), false positive rate was 57.14% (95% CI 18.41% to 90.10%), false negative rate was 0.00% (95% CI 0.00% to 10.58%), positive predictive value was 89.19% (95% CI 74.58% to 96.97%), negative predictive value was 100.00% (95% CI 29.24% to 100.00%) and the total diagnostic accuracy was 90.00% (95% CI 76.34% to 97.21%). From Kappa test it was observed that there was moderate agreement

was present between Well's score and DVT by color Doppler in classifying (Table 1).

Among the Wells criteria, paralysis, paresis or recent immobilization of the lower extremities was revealed in 97.5%, patients bedridden for >3 days in 82.5%. Collateral superficial veins could be demonstrably seen in 100% of subjects. Entire leg was swollen in just 2.5%. Localized tenderness along the deep venous system was seen in 5% and >3 cm calf swelling in comparison to asymptomatic leg in 12.5%. Pitting edema was seen more in the affected leg in 6 patients (15%) as compared to others. Differential diagnosis could not be thought for in 33 subjects (82.5%) (Table 2).

Table 1: Predictive validity of Wells score in predicting DVT (by color Doppler).

Parameters	Values	95% CI	
		Lower	Upper
Sensitivity (%)	100.0	89.42	100.0
Specificity (%)	42.86	9.90	81.59
False positive rate (%)	57.14	18.41	90.10
False negative rate (%)	0.00	0.00	10.58
Positive predictive value (%)	89.19	74.58	96.97
Negative predictive value (%)	100.00	29.24	100.00
Diagnostic accuracy (%)	90.00	76.34	97.21
Kappa coefficient	0.5531	0.1376	0.968

Table 2: Summary of Wells criteria in research section.

Wells criteria and score	Frequency	%
Active cancer (treatment ongoing or within the previous 6 months or palliative)		
0	40	100.00
Paralysis, paresis, or recent plaster immobilization of the lower extremities		
0	39	97.50
1	1	2.50
Recently bedridden for more than 3 days or major surgery within 4 weeks		
0	33	82.50
1	7	17.50
Localized tenderness along the distribution of the deep venous system		
0	2	5.00
1	38	95.00
Entire leg swollen		
0	1	2.50
1	39	97.50
Calf swelling by more than 3 cm when compared to the asymptomatic leg		
0	5	12.50
1	35	87.50
Pitting edema (greater in the symptomatic leg)		
0	6	15.00
1	34	85.00
Collateral superficial veins		
0	40	100.00%
Alternative diagnosis as likely or greater than that of DVT		
0	7	17.50
1	33	82.50

Table 3: Descriptive analysis of total score (out of 8) in the study population.

Total score (out of 8)	Frequency	%
0	3	7.50
1	3	7.50
2	1	2.50
3	4	10.00
4	23	57.50
5	5	12.50
6	1	2.50

Table 4: Descriptive analysis of DVT (by color Doppler) in research section.

DVT (by color Doppler)	Frequency	%
Yes	33	82.50
No	7	17.50

Out of 8 as total score, 23 participants had score as 4 (57.5%) with 0 score in 3 patients (7.5%) with maximum score in the surveillance came out to be 6 in one patient only (2.5%) (Table 3).

Thirty three (82.5%) subjects revealed DVT by color Doppler (Table 4).

Thirty three patients (82.5%) were in the high risk (>3) section according to Wells score criteria while 3 patients (7.5%) grouped in low risk (0) (Table 5).

Table 5: Descriptive analysis of Wells score criteria in research section.

Wells score criteria	Frequency	%
Low-risk (0)	3	7.50
Intermediate-risk (1-2)	4	10.00
High-risk (≥3)	33	82.50

Table 6: Demographic table.

Demographics	No. of patients (%) N (%)
Age (years)	
Mean (median, range) years	48.97 (50.50, 18-81)
Age distribution (in years)	
Upto 30	9 (22.50)
31-50	11 (27.50)
51-70	15 (37.50)
>70	5 (12.50)
Gender	
Male	33 (82.50)
Female	7 (17.50)
History of trauma	
Yes	8 (20.00)
No	32 (80.00)
Smoker	
Yes	23 (57.50)
No	17 (42.50)
Calf tenderness	
Yes	38 (95.00)
No	2 (5.00)
Wells score criteria	
Low risk (0)	3 (7.50)
Intermediate risk (1-2)	4 (10.00)
High risk (≥3)	33 (82.50)
DVT (b color Doppler)	
Yes	33 (82.50)
No	7 (17.50)

DISCUSSION

DVT remains one of the most important causes of morbidity and mortality especially among hospitalised patients.[11] Clinical features of DVT were not specific for the disease and hence there was a need to use objective tests in order to make the diagnosis.[12]

The revised index developed by Wells showed the strongest potential in estimation of probability of DVT in individual patients when used with additional diagnostic tests.[9] The pretest probability of detecting DVT using Wells score when combined along with non-invasive diagnosis reports was found to easier the diagnosis and cheaper.[13]

The Wells score was a reliable and robust method for pretest scoring irrespective of the assessor grade, as long as appropriate training has been carried out in terms of its use. A Wells score of >1 can authentically exclude incidence of DVT in injured making it an important pretest tool for risk stratification.[3]

In this study, Wells criteria was assessed as a predictive tool in confirmation of DVT. Observations were made based on duration of leg swelling, pain in the lower limb, history of trauma, presence of chest pain or dyspnea and ability to walk. Signs of calf tenderness, swelling, redness, local rise in temperature and peripheral pulsation were also seen.

Wells score had sensitivity of 100 percent in predicting DVT. Specificity was 42.86%. Our results showed that up to 33 of the 40 participants that had a significant score with Wells criteria were actually diagnosed with deep vein thrombosis. The remaining 7 patients with depressed Wells score also showed a nugatory diagnosis with Doppler scan.

A study conducted by Modi et al concluded that as the wells score increases the risk of DVT increased linearly with it proving it to be a reliable tool.[3] A study conducted by Dewar et al showed that Wells criteria was a good reliable criteria for the assessment of DVT in emergency department.[12] A study conducted by Wells et al concluded that the combination of pretest probability test with non-invasive test improved and simplified diagnosis of DVT.[13]

A study conducted by Kahn et al concluded that the index proposed by Wells et al was the strongest and most potential tool to be useful in diagnosis of DVT.[14]

Some studies also depicted the unreliability of the Wells criteria. The Wells score singly or conjunct with D-dimer testing will never accurately estimate the risk of DVT in prime concern subjects.[15]

Strengths

Well's criteria was a clinical tool that can be applied even in primary care centers with negligible radiological availability. Hence it can be an apt tool for diagnosis of poor patients in inaccessible areas. This can also ensure start of early prophylactic treatment.

Limitations

A higher number of patients could have provided a more reliable result and improved the statistical significance of the study. Also, Well's criteria was a predictive tool that required additional diagnostic tests for confirmation of the diagnosis. Furthermore, beginning prophylactic treatment could increase the risk of adverse effects.

CONCLUSION

In the research done on 40 patients to evaluate whether Wells criteria can be utilized as an important aid in the investigation of DVT, it was exhibited that it certainly helps the clinicians to arrive at disease and its process with its variables or parameters. This can benefit the patients in future to treat them earlier before it gets complicated and do not hamper their day-to-day activities improving their quality of life. Complications of DVT like PE, pulmonary hypertension and venous thromboembolism can prove fatal and hence it is more thoughtful for clinicians to detect the disease at the earliest and treat it effectively so that comorbidities can be reduced. The dreadfulness of the disease outcomes warrants study in depth for welfare of the patients. The present study was done in a small proportion of patients.

Recommendations

It is highly recommended that thorough studies and researches be conducted so that modern medicine can be highly efficacious, with newer techniques and procedures which can be beneficial for the patients.

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