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Validation of Modified wells Score in the Diagnosis of Deep Vein Thrombosis: A Prospective Observational Study

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Abstract

Deep vein thrombosis (DVT) is the presence of thrombus in deep venous system, commonly seen in lower extremities. Philip Steven Wells was one of the pioneers to diagnose DVT using a clinical prediction rule, i.e., Wells criterion for patient management, rather than relying on imaging modalities. To test the effectiveness of Modified Wells criteria in diagnosing DVT. To find the associated co-morbidities causing DVT. This is a prospective diagnostic efficacy study of the Modified Wells rule for DVT, comparing with the gold standard-Duplex Ultrasonography. All patients with clinical suspicion of DVT in lower extremities (new onset of pain, oedema) at our hospital between October 2019 and October 2020 were included in the study. Modified Wells score for each patient was calculated and the results were evaluated. Sixty-six suspected cases of DVT as per Modified Wells Score were subjected to the confirmatory test of venous duplex ultrasound. Amongst the total admitted cases, Modified Wells score was useful in predicting DVT in 60 of the cases, hence proving to be a potent diagnostic tool (91%). The average score among the various cases was 4/11. Higher the score more was the probability of having deep vein thrombosis. On evaluating the associated co-morbidities in the study group, it is clear that surgery (36.7%) was the significant contributing factor. Modified Wells score is an efficient clinical probability assessment indicator in diagnosing DVT and could be exercised with ease. Hence, establishing it as a valid diagnostic tool.

INTRODUCTION

Deep vein thrombosis (DVT) is the presence of thrombus in deep venous system, commonly seen in lower extremities. DVT in lower extremities is not only limb-threatening but also life-threatening due to chances of pulmonary embolism^[1]. Chronic venous insufficiency, a sequel of DVT, can limit person for performing regular activities and can impact economic burden to the society. It is a preventable condition that causes significant morbidity and mortality. Before easy availability of imaging modalities, this condition used to be diagnosed solely by history and examination. Philip Steven Wells was one of the pioneers to diagnose DVT using a clinical prediction rule, i.e., Wells criterion for patient management^[2]. Following the introduction of his criteria in 1995, it has been revised a few times. Currently, Modified Wells Criteria includes nine clinical characteristics with a score of 1 for each, one with a score of 2 and one with a score of 3 as shown in Table 1^[3]. The diagnosis of DVT based on clinical characteristics has been found useful to find the likelihood of DVT^[4].

Aim of the study is to test the effectiveness of Modified Wells criteria in diagnosing DVT and to find the associated co-morbidities causing DVT.

MATERIALS AND METHODS

This is a hospital based prospective study conducted between February 2020 and August 2023 at Sapthagiri Institute of Medical Sciences and Research Centre, Bengaluru with a sample size of sixty-six. All patients with clinical suspicion of DVT in lower extremities (new onset of pain, oedema) were included, with informed written consent. Patients with recurrent DVT and bleeding diathesis were excluded. All patients were examined and Wells score for each patient was calculated based on the parameters. Confirmation of the diagnosis was done by venous duplex ultrasound on the same day by a radiologist. Risk score interpretation (probability of DVT) was classified as low probability (5%) of DVT with score -2 to 0, moderate probability (17%) of DVT with score 1-2, high probability (17-53%) of DVT with score >2. Diagnostic efficacy of the Modified Wells Criteria for DVT compared with the gold standard Venous Duplex Ultrasonography. In every step of the study, patient's safety was given the highest priority.

Data collected, tabulated in Microsoft office access and was statistically analysed using SPSS version 24.0. SPSS Inc., IBM corporation, Chicago.

RESULTS AND DISCUSSIONS

Amongst the total patients of 66 in the study 29 cases were male and 37 cases were female. The Modified Wells score was applied to all patients with suspected DVT. Venous duplex ultrasound being

considered as gold standard confirmed the diagnosis of DVT in 91% of the cases, i.e., 60 out of 66 cases. Of the 60 cases, 25 cases (41.7%) were male and 35 cases (58.3%) were female. In our study, age group of 41-60 years (26 cases) were commonly affected, followed by 61-80 years (20 cases) and 20-40 years (14 cases). Mean age being 55.5 years (Range: 20-80 years). In 24 cases (40%) right side was affected, in 35 cases (58.3%) left side was affected and while in one case (1.7%) both the limbs were affected. Mean day of history at the time of presentation was 3 days (range 1-8 days, SD of 2.29).

Table 2 shows total number of cases in different clinical parameters of Modified Wells criteria. Pitting edema was present in 95% of our cases and was the commonest clinical characteristic in our patients with DVT. This was followed by swelling of the entire limb/leg (66.7%), localized tenderness along the distribution of deep venous system (present in 63.3%). Out of the total number of post op cases with DVT 83.3% of the cases with DVT were post caesarean section/ vaginal delivery followed by Orthopaedics (15%), General Surgery had the least frequent DVT cases (1.7%). This could possibly be due to early mobilization of the post-operative cases and passive flexion exercises advocated in the post-operative wards.

Out of total score of 11, Mean Modified Wells score was 3.5. In 35 cases (58.4%) Wells score was 4, in 14 cases (23.3%) score was 3, in 8 cases (13.3%) score was 5, in 3 cases (5%) score was 2. In terms of risk interpretation, there were 57 cases (95%) with Wells score 3-11 (high probability), while in 3 cases (5%) it was 1-2 (Moderate probability) and in 6 cases (10%) it was -2 to 1 (low probability).

Our study shows that DVT has female preponderance compared to male. In a study by Mohammad Mozafar *et al.*, of the 177 patients, 52.54% were female and 47.45% were male. DVT is almost equally common any of the side^[5]. Mean age of 55.5 years is similar to the study by Mohammad Mozafar^[5].

Pitting edema was present in 95% of cases which was the most common clinical characteristic in patients with DVT. This was followed by swelling of entire limb (present in 66.7%), localized tenderness along the distribution of deep venous system (present in 63.3%). In our study, the mean Modified Wells score was 3.5, and in about 90.1% of the total cases, Wells score successfully predicted DVT by being >2. In original Wells' study, DVT was present in only 3% of cases with low prediction score.

Modified Wells score has been extensively validated in both outpatient cases and admitted cases in hospitals in Canada, Europe and the United States, but such validation is scarce in South East Asian^[6,8].

Table 1: Modified Wells Criteria for pre-dicting DVT

Variable	Score
Lower limb trauma or surgery or immobilisation in a plaster cast	1
Bedridden for >3 days or surgery in last 4 weeks	1
Tenderness along the line of femoral or popliteal veins	1
Entire limb swollen	1
Calf >3 cm larger circumference than the other side (Measured 10cm below the tibial tuberosity)	1
Pitting oedema	1
Dilated collateral superficial veins (not varicose veins)	1
Malignancy (including treatment up to 6 months ago)	1
Intravenous drug abuse	3
Alternative diagnosis more likely than DVT	-2

Table 2: Different Clinical Characteristics of Modified Wells

Characteristics	Frequency 25	Percentage 41.67
Lower Limb Trauma/Surgery/Immobilization		
Bedridden More Than 3 Days	20	33.33
Tenderness	38	63.33
Entire Limb Swollen	40	66.67
Calf More Than 3 cm	36	60
Pitting Edema	57	95
Dilated Collateral Superficial Veins	7	11.67
Malignancy	1	1.67
IV Drug Abuse	1	1.67
Alternate Diagnosis	6	10

Amongst the post op cases with DVT 83.3% of the cases with DVT were post caesarean section/vaginal delivery. Pregnant women have a five-fold chance of having DVT compared to non-pregnant women^[9]. This again correlates with the statistics given by Office of the Surgeon General (US) and the National Heart, Lung, and Blood Institute (US)^[9].

Joel G Ray and co-workers' literature also suggests that dyslipidaemia has a role to play in DVT which could also be seen in some of our cases (10 cases)^[10]. Finally there was a single case of IV drug abuse who had tested positive for DVT, the link between DVT and intravenous drug abuse being already proved by V A Cooke in England^[11].

CONCLUSION

Among the 66 cases suspected with DVT, the Modified Wells score was able to predict DVT in 60 of the cases (90.1%) thus proving to be a very efficient diagnostic indicator. Of the various parameters, pitting edema, swelling of entire limb, and localized tenderness along the distribution of deep venous system are most often present.

Female preponderance was noted and considering the age distribution maximum cases were found to be between 4th-6th decade of life.

The most important co-morbid state for DVT is surgery especially caesarean section as seen in our study group as the patient is immobile as well as in a prothrombotic state.

This study concluded that the Modified Wells score is indeed an efficient clinical probability assessment indicator in diagnosing deep venous thrombosis and can be applied with ease as it requires only clinical assessment and thus avoids unnecessary delays thereby allowing us to initiate anticoagulation therapy at the earliest.

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