The Accuracy of Wells Clinical Model for Predicting Pretest Probability in Deep Vein Thrombosis (DVT) at Dr. Sardjito Hospital

Uji Akurasi Model Klinis Pretes Probabilitas Dugaan Trombosis Vena Dalam (TVD) dari Wells di RSUP Dr. Sardjito

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ABSTRAK

Latar Belakang: *Diagnosis Trombosis Vena Dalam (TVD) merupakan masalah penting di bidang kedokteran karena sejumlah besar kasus tidak terdiagnosis. Diagnosis TVD secara akurat sangat penting untuk mencegah komplikasi akut emboli paru dan komplikasi jangka panjang. Komplikasi tersebut dapat berupa sindroma postphlebitis dan hipertensi pulmonar. Diagnosis TVD dapat dilakukan untuk menghindari terapi antikoagulan yang tidak tepat dan berhubungan dengan risiko tinggi perdarahan. Terdapat beberapa model klinis dugaan TVD, antara lain skor Hamilton dan skor Wells. Model klinis pretes probabilitas dugaan TVD dari Wells telah banyak digunakan dan teruji validitasnya di beberapa negara di Eropa. Uji akurasi model klinis pretes probabilitas dugaan TVD dari Wells belum pernah dikerjakan untuk ras Asia khususnya di Indonesia.*

Tujuan: *Penelitian ini bertujuan untuk menguji akurasi, presisi (sensitivitas, spesifisitas dan nilai duga) model klinis pretes probabilitas dugaan TVD dari Wells untuk mendiagnosis TVD pada pasien-pasien di RSUP Dr. Sardjito.*

Metode: *Desain penelitian diagnostik ini menggunakan desain potong lintang. Penelitian ini mengikutkan pasien-pasien yang mengalami gejala TVD di poliklinik Tulip, rawat jalan dan rawat inap di RSUP Dr. Sardjito selama bulan Januari 2011-Mei 2012. Subjek penelitian terdiri dari 100 pasien. Pada subjek penelitian, dilakukan pemeriksaan model klinis pretes probabilitas dugaan TVD dari Wells, USG Doppler dan D-dimer. Bila hasil USG Doppler yang pertama negatif akan dilakukan USG ulang satu minggu kemudian.*

Hasil: *Sebanyak 56 pasien (56%) menderita TVD dari 100 subyek penelitian. (77,6%) subjek adalah wanita dengan median umur ≥60 tahun. Karakteristik dasar penelitian menunjukkan jumlah wanita lebih banyak dibanding pria dan rerata usia 52 ±1 tahun. Faktor risiko TVD dengan frekuensi paling banyak adalah kanker 49 pasien (49%), tirah baring 42 pasien (42%), usia lanjut 33 pasien (33%). Akurasi model klinis pretes probabilitas dugaan TVD dari Wells sebesar (81%), presisi (77,6%), sensitivitas (92,8%), spesifisitas yaitu (65,9%), nilai duga negatif (87,8%), nilai duga positif (82%) dan akurasi (81%).*

Kesimpulan: *Model klinis pretes probabilitas dugaan TVD dari Wells mempunyai akurasi tinggi, presisi sedang, sensitivitas tinggi dan spesifisitas rendah untuk mendiagnosis pasien TVD di RSUP Dr. Sardjito.*

Kata Kunci: *trombosis vena dalam/TVD, model klinis pretes probabilitas dugaan TVD dari Wells, uji akurasi, presisi*

ABSTRACT

Background: The diagnosis of deep vein thrombosis (DVT) is an important issue in the medical field because a large number of cases are undiagnosed. The accurate diagnosis of the DVT is essential to prevent complications of acute pulmonary embolism and long-term complications. The complication such as pulmonary hypertension and post phlebitis syndrome. It also to avoid improper anticoagulant therapy associated with a high risk of bleeding. There are several models of clinical suspicion of DVT include Hamilton's score and Wells' score. The Wells clinical model for predicting pretest probability for DVT has been widely used and tested its validity in several countries in Europe. The accuracy of a Wells clinical model of pretest probability for DVT has not been done for the races of Asia especially in Indonesia.

Objective: This study aimed to test the accuracy and precision (sensitivity, specificity and predictive value) of Wells clinical model for predicting pretest probability for diagnose DVT for patients in the Dr. Sardjito Hospital.

Methods*:* This study was a diagnostic study with cross-sectional design. The subjects were patients with DVT symptoms who visited Tulip clinic, outpatient and inpatient in the department of Dr. Sardjito General Hospital during January 2011-May 2012. In this study, a total of 100 patients were participated the Wells clinical model of pretest probability for DVT examination, Doppler ultrasound and D-dimer examination. The negative results on the first ultrasound examination will be examined again 1 week later.

Results*:* DVT was confirmed in 56 patients (56%) from 100 patients. The baseline characteristics showed the number of women more than men and the mean age was 52.98 ±1.335 years. The 57% of subjects were women and the median age was ≥60 years. The most frequent risk factors of DVT were cancer 49 patients (49%), bed ridden 42 patients (42%) and elderly 33 patients (33%). The accuracy of the Wells clinical model of pretest probability for DVT was 81%, precision was 77.6%, sensitivity was 92.8%, specificity was 65.9%, and negative predictive value was 87.9%.

Conclusion*:* The Wells clinical model for predicting pretest probability in DVT has a high accuracy, moderate precision, high sensitivity and poor specificity to diagnose DVT at Dr. Sardjito Hospital.

Keywords: deep vein thrombosis/DVT, the Wells clinical model of pretest probability for DVT, accuracy test, precision

INTRODUCTION

Thrombosis is the formation of mass intravascular blood clots in people who are still alive. Deep Vein Thrombosis (DVT) and *pulmonary embolism* (PE) are the major cause of disability and mortality. Approximately 2 million Americans suffer from DVT and more than 600.000 people will develop into PE.[1]

Accurate diagnosis of DVT is essential to prevent the possibility of acute complications such as pulmonary embolism, long-term complications and hypertension pulmonary syndrome post phlebitis. An accurate diagnosis of DVT is important to avoid improper anticoagulant therapy

and it associated with high risk of bleeding in misdiagnosed patients.[2] To reduce the frequency of unnecessary investigations in diagnosis of DVT, Wells and co-workers developed a clinical diagnostic tool which widely known as a clinical model of predicting pretest probability for DVT or *Well's rule*.[3,4] Diagnostic approach of DVT is the assessment of clinical suspicion of DVT, further examination of laboratory diagnostic such as D-dimer and imaging examination with Doppler ultrasound.[5]

Clinical model pretest probability for DVT applied if there is any suspicion of DVT. From that clinical model we can obtain score to predict the probability of DVT. Wells score

less than one shows that DVT is not likely and can be excluded if the D-dimer is negative.[6]

Several clinical models score to predict DVT have been tested include *Wells* score, *Hamilton* score, *Kahn* score and *St. Andre* score.[7] *Wells* Clinical model have a good sensitivity and specificity for the diagnosis of DVT and widely used to reduce the costs due to unnecessary radiology examinations. Clinical model for predicting pretest probability for DVT from *Wells* is a simple diagnostic assessment, improve clinical accuracy and reduce the overall cost required for DVT diagnostic.[8]

The accuracy of a *Wells* clinical model of pretest probability for DVT has not been done for the races of Asia, specially in Indonesia. This study aimed to test the accuracy, and precision (sensitivity, specificity and predictive value) of a *Wells* clinical model for predicting pretest probability for DVT to diagnose DVT inpatients at Dr. Sardjito Hospital.

METHODS

This sudy used a cross-sectional, by assessing accuracy and precision (sensitivity, specificity, and predictive value) clinical model for predicting pretest probability of DVT from *Wells* to DVT diagnosis. The study was conducted in an outpatient Tulip's clinic of cancer, outpatient and inpatient department of Dr. Sardjito hospital starting from January 2011 to May 2012.

This study was a diagnostic study with cross sectional design. The study was conducted in Tulip cancer clinic, outpatient and inpatient at Dr. Sardjito Hospital from January 2011 to May 2012. All subjects with DVT symptoms were included. Exclusion criteria were: age less than 18 years, pregnancy, received anticoagulant therapy and previously documented DVT. The patients underwent physical examination according to *Wells* score items, Doppler ultrasound and D-dimer examination. The studies were approved by ethical committee and written consent was obtained from each subject.

STATISTICAL ANALYSIS

Data were analyzed using a 2x2 table for diagnostic tests. We do calculate sensitivity, specificity, false positive, false negative, positive predictive value, negative predictive value, positive likelihood ratio, negative likelihood ratio, and accuracy. Statistical evaluation was done by a computer program.

RESULTS AND DISCUSSION

The numbers of women patients were more than the number of men patients, as many as 57 people (57%) patients were women and 43 (43%) patients were men. The subjects of this study had a mean age of 52.98 ± 1.335 years. The youngest age was 18 years and the oldest was 85 years. The patients <60 years were as many as 67 people with a mean age of 57.65 ± 1.23 years. The older (≥ 60 years) were 33 people (33%) with a mean age of 66.58 ± 6.32 years. The frequency of men (56.8%) patients with DVT was more often than women (55.4%). Baseline characteristics of the study subjects were presented in Table 1.

A total of 56 (56%) of 100 patients had DVT, there were 52 (77.6%) patients in the high pretest probability category and 4 (12.1%) patients were in low pretest probability category. There were 2 of the 52 patients with a high pretest probability which subsequently confirmed to have DVT after the second ultrasonography test by 1 week intervals.

Table 1. Clinical Characteristics

characteristics	n (%)		Median (range)
Gender			
Man	43	(43)	
Woman	57	(57)	
Age median (years)	67	(67)	52.98 ± 1.34
Adult-old <60 (years)	33	(33)	57.65 ± 1.23
Older ≥ 60 (years)			66.58 ± 6.32
Cancer			
Cancer (+)	49	(49)	
Cancer (-)	51	(51)	
Chemotherapy			
chemotherapy (+) patients	21	(21)	
chemotherapy (-) patients	79	(79)	
Congestive heart failure			
Congestive heart failure (+) patients	17	(17)	
congestive heart failure (-) patients	83	(83)	
Chronic renal failure			
chronic renal failure (+)patients	11	(11)	
chronic renal failure (-)patients	89	(89)	
Nephrotic Syndrome			
Nephrotic syndrome (+)patients	1	(1)	
Nephrotic syndrome (-)patients	99	(99)	
Diabetes mellitus			
diabetes mellitus (+)patients	24	(24)	
diabetes mellitus (-)patients	76	(76)	
Obesity			
Obese	26	(26)	
Non obese	74	(74)	
Acute systemic infection			
Acute systemic infection (+) patients	11	(11)	
acute systemic infection (-) patients	89	(89)	
Acute Stroke			
Acute stroke (+) patients	5	(5)	
Acute stroke (-) patients	95	(95)	
Acute rheumatic			
Acute rheumatic (+) patients	2	(2)	
Acute rheumatic (-)patients	98	(98)	
Antiphospholipid syndrome			
Antiphospholipid syndrome (+) patients	0	(0)	
antiphospholipid syndrome (-) patients	100	(100)	
Vasculitis			
Patients vasculitis	1	(1)	
Non vasculitis patients	99	(99)	

The results of this study indicated that the frequency of DVT was higher in high pretest probability category than in the low pretest probability category. The clinical model predicted DVT in the two categories were in high and low pretest probability categories as 77.6% and 12.1% respectively. These results were consistent with previous studies showing the frequency of DVT in the three categories were 85% in the high pretest probability category, 33% in the moderate, and 5% in the low category.[3] The difference

Table 2. Basic Characteristics of Study Subjects

The baseline characteristics	n (%)		Mean ± standard deviation
Surgery			
Patients undergoing surgery	8	(8)	
Not surgery patients	92	(92)	
Trauma			
Patients experiencing trauma	4	(4)	
Non trauma patient	96	(96)	
Catheterization			
Patients received catheterization	2	(2)	
Not patients with catheterization	98	(98)	
Bed ridden			
Patients experiencing *bed ridden*	42	(42)	
Not *bed ridden* patients	58	(58)	
Paralysis			
Patients experiencing paralysis	5	(5)	
Not paralysis patients	95	(95)	
Travel long distances >6 hours in 8 weeks			
Patients travel long distances	1	(1)	
Not patients to travel long distances	99	(99)	
Hormonal contraception			
Patients taking hormonal contraception	6	(10.5)	
Not those taking hormonal contraception	51	(89.5)	
Hormone replacement therapy			
Patients receiving hormone replacement therapy	0	(0)	
Patients not receiving hormone replacement therapy	57	(100)	
Smoke			
Smoker	15	(15)	
Non-smokers	85	(85)	

Table 3. Table 2x2 of the Diagnostic Test of Clinical Model for Predicting Pretest Probability for DVT from *Wells* to Diagnose of DVT in Patients Dr Sardjito Hospital

Type of examination	Doppler ultrasound		Total
	DVT (N: 56)	No DVT (N: 44)	
Clinical model of probability *Wells* (modified)			
High probability (score > 1)	52 (77.6%)	15 (22.4%)	67
Low probability (score ≤ 1)	4 (12.1%)	29 (87.9%)	33
Total	56	44	100

in prevalence of DVT in the two categories of pretest probability in this study was statistically significant (p: 0.000). These results were consistent with the Wells *et* al. (1997), found significant differences among the three pretest probability categories (p <0.0001)[4.]

The analysis shows the influence of the high pretest probability category of DVT from *Wells* clinical model to had incident of DVT. Patients with a high probability based on models clinical pretest probability of DVT from *Wells* had 25 times risk of developing

DVT than the group of patients with a low probability category [p: 0.000 (7.62 to 82.85%, CI 95%)].

Table 4. The Value of Diagnostic for Clinical Model Pretest Probability for DVT from *Wells* in RSUP Sardjito

The diagnostic value	Result	95% confidence interval
Sensitivity	92.8%	86-100
Specificity	65.9%	52-80
Positive predictive value	77.6%	68-88
Negative predictive value	87.9%	88-99
Positive likelihood ratio	2.72	1.79-4.13
Negative likelihood ratio	0.11	0.04-0.29
Prevalence	56%	46-66
Accuracy	81%	

The results of this study demonstrate a clinical model of pretest probability for DVT from *Wells* can be used as a diagnostic tool with high sensitivity and less specificity. Positive predictive value or precision in this study was 77.6% and the negative predictive value 87.9%. Likelihood ratio *(likelihood ratio)* is 2.72 high positive or strong positive diagnostic values. Accuracy of the clinical model for predicting pretest probability for DVT from *Wells* to diagnose DVT is 81%, based on the research results of Doppler ultrasonography.

The implications of these results are the clinical model for pretest probability in DVT from *Wells* can be used as a clinical tool to suspect of DVT in patients hospitals with high accuracy 81% and precision 77.6%. The results must be confirmed with a supporting diagnostic tool with Doppler ultrasonography.

This result is consistent with the Wells *et al.* (1995) involving 529 patients in Canada and Italy to test the accuracy of the clinical assessment of DVT used clinical model of pretest probability for DVT. The combination of clinical model of pretest probability for DVT from *Wells* with non-invasive diagnostic test results has the potential to simplify and to improve the diagnostic process in patients with suspected DVT, yield better diagnostics and a challenge to hold the principle that a clinical diagnosis is not useful in the diagnostic evaluation of patients suspected of TVD.[3]

CONCLUSION

Clinical model of pretest probability for DVT from *Wells* to diagnose DVT inpatients and outpatient department of Dr. Sardjito hospital has an accuracy of 81% and precision 77.6%, 92.8 % sensitivity and 65.9 % specificity. Further research is needed to test the accuracy of the clinical model from *Wells* in other health centers in Indonesia.

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