Original Article Determining the diagnostic value of three clinical criteria Wells', YEARS and modified Geneva in pregnant women with suspected pulmonary thromboembolism

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Abstract: Background: Diagnosis of pulmonary thromboembolism (PTE) during pregnancy is a challenging medical issue due to complications of X-ray-based imaging studies such as Ct-angiography for neonates and pregnant women. Here we aimed to assess the predictive values of three clinical criteria for diagnosing PTE during pregnancy. Methods: This is a retrospective cohort study performed in 2018-2020 on 166 pregnant women suspected of PTE. We reviewed the documents of all patients referred to our medical center with suspected symptoms of PTE. The demographic characteristics of the patients, signs and clinical findings upon the arrival of patients as well as their laboratory tests including D-dimer with a history of abortion or delivery and leg symptoms were entered into the data collection form. Then, according to the information extracted from the patient's files, each patient was evaluated by all clinical PTE criteria, including Wells, YEARS and modified Geneva. For each patient according to clinical criteria and all three algorithms, clinical suspicion for PTE and treatment or non-treatment was determined were compared to the final MDCT result of patients. Results: The Well's criteria had 100% sensitivity, 6.47% specificity, a positive predictive value of 7.8% and a negative predictive value of 100%. In patients with Well's score of more than four, the sensitivity and specificity of PTE diagnosis were 100% and 6% respectively. The modified Geneva criteria had 100% sensitivity, 8.89% specificity, a positive predictive value of 8.21% and a negative predictive value of 100%. The modified Geneva criteria had 100% sensitivity, 7.74% specificity, positive predictive value of 8.44% and a negative predictive value of 100%. Conclusion: Wells, YEARS and modified Geneva criteria could significantly rule out PTE in pregnancy with 100% sensitivity.

Keywords: Thromboembolism, pregnancy, clinical criteria

Introduction

Pregnancy is a hypercoagulable condition that, similar to the Virshu triad, causes changes in coagulation, stasis, and vascular vulnerability [1]. The risk of venous thromboembolism (VTE) increases 4 to 5 times during pregnancy [2]. VTE is one of the leading causes of death and morbidity in pregnant women, accounting for one-third of all maternal mortality in the UK, and is twice as common as postpartum hemorrhage as the second most common cause of maternal mortality [3, 4]. Finally, VTE can lead to pulmonary thromboembolism (PTE), one of the most critical diseases in terms of mortality, especially during pregnancy [5]. Today, the gold standard for diagnosing PTE in patients is using pulmonary MDCT with PTE protocol or CT pulmonary angiography, which is performed in case of high clinical suspicion and positive laboratory tests, as well as using the clinical criteria [6, 7]. The use of these imaging methods in normal people is beneficial because it has a high specificity and specificity for diagnosing PTE.

On the other hand, it has been shown that CT scan due to the use of X-rays in imaging leads to complications, including an increased risk of various cancers, which is higher if the CT is used more than once [8]. Therefore, it is thought that the use of alternative methods and clinical

criteria or the use of imaging techniques that do not use radiation in pregnant women is doubly important because in addition to preventing radiation to the mother, exposure to the fetus is also contained [9, 10].

In recent years, studies have been conducted on the use of laboratory methods and clinical criteria in diagnosing PTE in pregnant women [10, 11]. The need for clinical methods in the diagnosis of PTE in pregnant women is because average values of laboratory tests such as D-Dimer are affected during pregnancy and, therefore cannot be relied on intermittently [12]. Different clinical criteria are used to diagnose PTE in non-pregnant people, each with its specificity and characteristics [13].

Predictive clinical models such as the Wells Scoring System are of particular value for various symptoms such as leg edema, tachycardia, bradycardia, and hemoptysis. The total score classifies patients in terms of pulmonary embolism risk into three groups: low, moderate and high risk [13, 14]. According to the studies, there is no valid scoring system during pregnancy, and clinical manifestations can be confused with the characteristics of a healthy pregnancy [14]. In the Wells criteria, items such as DVT symptoms, lack of better differential diagnosis to justify clinical symptoms, tachycardia, immobility for more than three days or recent surgery, previous history of DVT or PTE, presence of hemoptysis and presence of cancers are examined [15]. Each is given a score and according to the sum of the scores are classified into three groups: low, medium and high risk [16].

The YEARS clinical standard is another criterion used clinically by physicians to diagnose PTE [17]. The criterion, recently developed in a multicenter study in the Netherlands, uses three items of Wells's criteria for the clinical diagnosis of PTE. These criteria examine clinical signs of DVT, hemoptysis, and other differential diagnoses that explain the symptoms [18]. This criterion has been recognized in studies as a good clinical criterion and the algorithm for its use has been made available to subspecialty pulmonologists [19].

Other clinical criteria used in the diagnosis of PTE include modified Geneva. This clinical criterion, along with Wells' criteria, is one of the valid criteria in diagnosing PTE by lung specialists, during which patients' clinical signs are evaluated. According to scoring and determining the risk, patients are divided into three categories: low, medium and high risk for PTE, based on which it can be decided whether or not to start PTE treatment [20]. These criteria are highly valuable in people with suspected PTE, especially in cases where decision-making according to clinical criteria is important [21].

However, limited studies have been performed on clinical criteria for the diagnosis of PTE in pregnancy. According to approved medical sources, a specific clinical criterion for evaluating a pulmonary embolism in pregnant mothers has not yet been approved. Given the importance of minimizing imaging techniques for the diagnosis of pulmonary embolism due to its complications for the mother and fetus, the existence of such criteria can be beneficial. This study aimed to compare the diagnostic value of the three clinical criteria mentioned in combination with D-dimer in PTE in pregnant mothers.

Comparison between the negative predictive value and the sensitivity of these three methods can help reduce imaging techniques in PTE and thus reduce maternal and fetal complications. If the result is achieved, these criteria can be used as predictors of PTE.

Methods and material

Study design

This is a retrospective cohort study performed in 2018-2020 in Al-Zahra hospital affiliated to the Isfahan University of Medical Sciences. The current study was conducted on pregnant women suspected of PTE using easy sampling. The study protocol was approved by the Research Committee of Isfahan University of Medical Sciences and the Ethics committee has confirmed it (Ethics code: IR.MUI.MED. REC.1399.1007).

Patient's criteria

The inclusion criteria were definite pregnancy until six weeks after delivery or abortion, having clinical presentations of PTE including hypoxia, tachycardia and dyspnea, referring to our medical center, having MDCT with PTE protocol in their medical documents by the time of referral and signing the written informed consent to participate in this study. Patients with a history of anticoagulant treatments or any hypersensitivity to radiological contrast agents did not enter the study. The exclusion criteria were dissatisfaction with the diagnostic approach during the examination at any study stage (CT scan, blood test or diagnostic process).

The study population was selected based on the mentioned criteria and we reviewed the documents of all patients. In this study, due to the lack of agreed clinical criteria for ruling out PTE and pulmonary embolism, all patients who referred to our medical center with suspected symptoms of PTE, regardless of the clinical probability and D-dimer amounts and only based on clinical suspicion, underwent MDCT imaging with PTE protocol. According to the result of MDCT, it has been determined whether patients had PTE or not.

Patient's data

The demographic characteristics of the patients with a history of abortion or delivery were entered into the data collection form. The symptoms and clinical findings upon the arrival of patients as well as their laboratory tests including D-dimer were also recorded. These signs and symptoms include the following: history of DVT or PTE, history of surgery or lower limb fracture in recent months, active cancers, lower limb pain, and unilateral lower extremity edema, clinical signs of DVT, presence of another differential diagnosis that explain the symptoms and D-dimer level, tachycardia, immobility for more than three days or recent surgery, and the presence of hemoptysis.

Clinical criteria

Then, according to the information extracted from the patient's files, each patient was evaluated by all clinical PTE criteria, including Wells', YEARS and modified Geneva according to the symptoms and laboratory tests. The information and examinations were entered into the algorithms of these criteria.

Wells' criteria

The Wells' criteria evaluate the patient's clinical data regarding suspected DVT (3 points), an

altered diagnosis less likely than PE (3 points), heart rate more than 100 beats/min (1.5 points), immobilization or surgery in the previous four weeks (1.5 points), previous DVT (1.5 points), hemoptysis (1 point) and malignancy (1 point). The risks of PTE are then assessed according to the scores into low (0-2 points), moderate (3-6 points), and high (> 6 points) risks. We considered a score of four as a cut-off point for conducting CT-angiography.

YEARS criteria

Based on YEARS criteria, patients D-dimer and one of these three criteria are evaluated: clinical signs of DVT, hemoptysis and PTE as the most likely diagnosis. The patient then undergoes a CT pulmonary angiogram or exclusion of PTE. If \geq 1 YEARS criteria are met, a D-dimer < 500 ng/mL will rule out PE. In addition, PTE could be excluded in patients with zero scores based on YEARS item and D-dimer < 1000 ng/ mL.

Modified geneva

In modified Geneva, patients' characteristics, symptoms, and clinical data are assessed. In this clinical criteria, the following items are evaluated: patient age > 65 years (1 point), previous DVT or PTE (3 points), surgery in the past one month (2 points), active malignant condition (2 points), unilateral lower limb pain (3 points), hemoptysis (2 points), heart rate 75-94 beats/min (5 points) and pain on lower limb deep vein palpation and unilateral edema (4 points).

Then the probability of PTE is determined as: Low: if the patient is scored 0-3; Intermediate: if the patient is scored 4-10; High: when the patient is achieved more than 11.

PTE assessments

Each patient was scored separately according to the Wells' YEARS and modified Geneva criteria, and patients were divided into groups with different risk assessments. Then, based on generally accepted algorithms in non-pregnant patients and D-dimmer in lower-risk cases, the diagnostic value of each clinical criterion was calculated separately and compared with each other.

 Table 1. Results of Well's criteria for women suspected of

 PTE

Veriable		CT scan		Tatal
Variable		Positive	Negative	Total
Well's criteria	Positive	11 (7.3%)	130 (86.7%)	141 (94%)
	Negative	0	9 (6%)	9 (6%)
Total		11 (7.3%)	139 (92.7%)	150 (100%)

 Table 2. Results of modified Geneva criteria for women suspected of PTE

Variable		CT scan		Total
		Positive	Negative	Total
Modified Geneva	Positive	11 (7.5%)	123 (84.2%)	134 (91.8%)
	Negative	0	12 (8.2%)	12 (8.2%)
Total		11 (7.5%)	135 (92.5%)	146 (100%)

 Table 3. Results of YEARS criteria for women suspected of

 PTE

Variable		CT scan		Tatal
Variable		Positive	Negative	Total
YEARS criteria	Positive	13 (7.8%)	141 (84.9%)	154 (92.7%)
	Negative	0	12 (7.2%)	12 (7.2%)
Total		13 (7.8%)	153 (92.1%)	166 (100%)

For each patient, clinical suspicion for PTE and treatment or non-treatment was determined according to clinical criteria and all three algorithms. On the other hand, according to the final MDCT result of patients that showed the presence or absence of PTE at the time of admission, negative predictive value, positive predictive value, sensitivity, and specificity of each of these three criteria in pregnant patients were determined and compared with each other.

Statistical analysis

The data were entered into the Statistical Package for Social Sciences (SPSS) (version 24, SPSS Inc., Chicago, IL). The negative predictive value was considered the ratio of subjects truly diagnosed as negative to all those with negative test results. The positive predictive value was defined as the ratio of patients truly diagnosed as positive to all those who had positive test results. The sensitivity was considered the probability of the positive test, conditioned on truly having the condition. The specificity was the ability of the test to identify people without the disease correctly. *P*-value < 0.05 was considered as the significance threshold.

Results

Study population and Well's criteria

In the present study, we evaluated data of 166 pregnant women referred to our center with clinical suspicion of PTE. A retrograde evaluation of the patient's documents was conducted. Assessment of Well's criteria indicated true positive results for 11 patients (7.3%), false-positive results for 130 patients (86.7%), true negative results for nine patients (6%) and no falsenegative results (Table 1). Therefore, the Well's criteria had 100% sensitivity, 6.47% specificity, a positive predictive value of 7.8% and a negative predictive value of 100%. We also observed that in patients with Well's score of more than four, the sensitivity and specificity of PTE diagnosis were 100% and 6%, respectively.

Modified geneva

Evaluation of modified Geneva criteria showed true-positive results for 11 patients (7.5%), false positive results for 123 patients (84.2%), true negative results for 12 patients (8.2%) and no false-negative results (**Table 2**). Therefore, the modified Geneva criteria had 100% sensitivity, 8.89% specificity, a positive predictive value of 8.21% and a negative predictive value of 100%.

YEARS criteria

We also evaluated data of patients regarding YEARS criteria. Based on these data, 13 patients (7.8%) had true positive results, 141 patients (84.9%) had false-positive results, 12 patients (7.2%) had true negative results and no false-negative results were observed (**Table 3**). Therefore, the modified Geneva criteria had 100% sensitivity, 7.74% specificity, a positive predictive value of 8.44% and a negative predictive value of 100%.

Discussion

By evaluating data of 166 pregnant women referred to our center with clinical suspicion of

PTE, we observed that the use of the three clinical criteria for diagnosis of PTE was associated with significant results. Diagnosis of PTE in pregnant women is challenging because physicians could not easily use the standard clinical criteria and laboratory data, including d-dimer. Based on the latest data, the probability of PTE in pregnant women could be excluded even with a negative test result for d-dimer. The gold standard diagnostic test for PTE in pregnant women is pulmonary CT-angiography with PTE protocol and perfusion scan. Both methods are associated with high doses of radiation in mothers that could harm neonates. Therefore, much effort has been made to develop clinical criteria for diagnosing PTE.

In this retrospective study, we evaluated the data of the patients based on three primary clinical criteria. We assessed their sensitivity and specificity according to the final diagnosis with a CT scan. Our data indicated that all three clinical criteria had 100% sensitivity. Based on the results of our study, none of the cases with negative results based on the clinical criteria had PTE. This means a negative effect of clinical criteria could significantly rule out the possibility of PTE in pregnant mothers. On the other hand, the specificity of the criteria was not very high. The highest specificity was found for modified Geneva criteria (8.89%).

Previously, some studies have assessed using these criteria in patients with PTE. In a survey by Raji and colleagues in 2018, they assessed data of patients suspicious of PTE based on Wells and modified Geneva criteria. Among the evaluated cases, 31 patients were pregnant. Based on their results, the positive predictive value of the low clinical patients based on Wells' criteria and the revised Geneva score was 18.4% and 30.8%, respectively. In addition, positive predictive value for the high clinical probability of Wells' criteria and the revised Geneva score was 81.8% and 72.8% respectively [22]. This study highlighted the use of both Wells and modified Geneva criteria in PTE. By assessing the risks of patients with these criteria, the use of CT angiography and radiation could be significantly limited. Another study was performed by Cutts and colleagues in 2014. They assessed the Wells clinical prediction model and ventilation-perfusion scanning for PTE diagnosis in 183 pregnant women. Based on the results of this study, the sensitivity and negative predictive value of Wells criteria was 100% and they suggested using these criteria in pregnant women [23]. These results are in line with the findings of our study. We observed that the Wells, modified Geneva and YEARS criteria had 100% sensitivity in diagnosing PTE in pregnancy.

Therefore, it could be stated that these criteria could have high clinical importance for ruling out the PTE in pregnant women and preventing excessive radiation for mothers. In another study by Borsi and colleagues in 2020, data of 100 pregnant women were assessed to evaluate the use of d-dimer and Wells criteria for diagnosing PTE. Based on this study, concomitant use of D-dimer and Wells' criteria can help us to diagnose or rule out pulmonary thromboembolism and minimize the risk of pregnant women being exposed to X-rays. It was stated that the Wells criteria could significantly rule out the PTE in patients [24]. In another study by Langlois and others in 2019, the YEARS algorithm was used to exclude PTE during pregnancy in 371 women. It was reported that the failure rate of the YEARS algorithm in the pregnant women population was 0% [25]. Similar results were reported in the study of Van Der Pol and colleagues in 2019. They declared that PTE was safely ruled out by the pregnancyadapted YEARS diagnostic algorithm across all trimesters of pregnancy. CT pulmonary angiography was avoided in 32 to 65% of patients [26]. All these data associated with previous studies emphasize the use of Wells, YEARS and modified Geneva criteria in pregnant women with PTE [27-29].

The critical point of our study was that we compared the three main criteria while most previous reports have assessed two of these criteria. The results of our study were consistent with the findings of earlier reports showing the importance of Wells, YEARS and modified Geneva criteria. Here we had a retrospective evaluation of the patient's documents.

The limitations of this study were that this study could have unknown potential confounders, we used the data that was initially collected for these purposes, not all the relevant information, and we also had inferior level of evidence compared with prospective studies. We also had a restricted study population compared to some former studies, suggesting that more studies on larger populations should be performed.

Conclusion

Wells, YEARS and modified Geneva criteria could significantly rule out PTE in pregnancy with 100% sensitivity. These data indicate the importance of clinical criteria to avoid radiation exposure in pregnant women. We believe more attention should be given to the properties of these criteria during pregnancy.

Disclosure of conflict of interest

None.

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