Diagnostic performance of YEARS criteria combined with point-of-care lung and venous ultrasound in suspected pulmonary embolism

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Abstract

Clinical prediction rules and bedside lung and venous ultrasound are frequently used in the diagnostic workup of suspected Pulmonary Embolism (PE). The possibility of improving the YEARS criteria (YEARSc) by integrating ultrasound has never been investigated. We analyzed data from a previous study involving a total of 446 outpatients with suspected PE. Signs of Deep Vein Thrombosis (DVT) on venous ultrasound and signs of pulmonary infarctions or alternative diagnoses on lung ultrasound were used to recalculate two items of the YEARSc: signs and symptoms of DVT and alternative diagnosis less likely than PE. Diagnostic performance of ultrasound-enhanced YEARS criteria (US-YEARSc) and YEARSc were compared after final diagnosis. 446 patients were included, PE was confirmed in 125 (28%). US-YEARSc performed significantly better than YEARSc (sensitivity 82.4% vs 64.8%, p=0.001; specificity 81% vs 48.6%, p < 0.001). US-YEARSc plus negative d-dimer compared to YEARSc and negative d-dimer showed an inferior failure rate (5.9% vs 8.9%, p=0.25) and a superior efficiency (51.8% vs 48.2%, p=0.31), without reaching statistical significance. US-YEARSc perform better than YEARSc in the diagnosis of PE.

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Introduction

Clinical prediction rules are recommended to guide the diagnostic process for many acute conditions. For suspected Pulmonary Embolism (PE), the international guidelines recommend the use of a combination of d-dimer with clinical scores such as the Geneva score, the Wells score (Ws) and more recently the YEARS criteria (YEARSc) to optimize the diagnostic process and the use of Computed Tomography Pulmonary Angiography (CTPA) for final confirmation.[1-6]

Ultrasound is a safe, rapid, and powerful diagnostic tool and the integration of the clinical assessment with point-of-care ultrasound is increasingly being considered in the evaluation of acute patients.[7] Moreover, with the advent of portable devices, ultrasound is being used exponentially by the clinical care teams in the early evaluation of patients presenting with dyspnea, chest pain, syncope and shock, all conditions in which PE is in the differential diagnosis. Several authors have evaluated its diagnostic performance in patients with suspected PE.[8-17] However, apart from the intrinsic diagnostic power of ultrasound in the definitive diagnosis of a complex disease, only one non validated study as far as we know has investigated the possibility of improving Ws by integrating clinical data with lung and venous Ultrasound (US-Ws).[13] The primary aim of this study is to compare the diagnostic performance of the YEARSc with that of the YEARSc combined with lung and venous ultrasound (US-YEARSc), substituting the subjective evaluation of clinical signs of DVT and estimation of clinical probability of PE with direct data obtained from point-of-care ultrasound.

In addition, as a secondary outcome, we compare the diagnostic performance of the algorithm based on YEARSc plus d-dimer and US-YEARSc plus d-dimer.

Materials and Methods

Study design and protocol

We used previous data from a multicenter observational cohort diagnostic accuracy study of outpatients with suspected PE.[13] This study was designed to compare the diagnostic performance of the Ws with that of the Ws combined with lung and venous ultrasound (US-Ws). Study patients were recruited from July 2014 to April 2015 in the Emergency Departments (EDs) of four Italian university hospitals (Careggi University Hospital, Firenze; San Luigi Gonzaga University Hospital, Torino; San Paolo University Hospital, Milano; University Hospital of Perugia). The local ethics committee approved the study and publications (n. 2014/13852). Written informed consent was obtained for inclusion in the study. The study was registered on ClinicalTrials.gov (NCT02190110).

Hemodynamically stable consecutive patients, older than 18 years, presenting with dyspnea, chest pain, syncope, and palpitations with suspected acute PE were considered eligible for the study. The suspicion of PE was subjectively established by the attending physician after the initial standard evaluation, which included medical history, physical examination, and electrocardiogram in all patients and arterial blood gas analysis and chest X-ray when requested for clinical reasons. The attending physician adjudicated the score of the Ws item and gave notification to the sonographer investigator. Patients who did not undergo ultrasound examination within 3 hours from enrollment were excluded. The attending physician, blinded to ultrasound results, ordered a multidetector CTPA, or scintigraphy in alternative, independently from the patient's enrollment and in accordance to the standard of care recommended by international guidelines. High-sensitive D-dimer was part of the routine evaluation of patients suspected of PE.

Lung and venous ultrasound were performed according to predefined protocols. The lungs were examined by longitudinal and oblique scans in the anterior-lateral and posterior thoracic regions with convex or linear probes, depending on investigator convenience. The anterior-lateral examination was performed with the patient in the supine or near-supine position. When feasible, dorsal areas were scanned in the sitting position or by turning the patient in the lateral decubitus on both sides in the case of forced supine position. The examination was targeted to the detection of pulmonary infarcts. Pulmonary infarcts were defined as pleural-based, well-demarcated and echo-poor triangular or rounded consolidations with a main diameter of at least 0.5 cm.[10,17] Other predefined findings consistent with alternative diagnoses that could explain the symptoms of presentation, were pulmonary consolidations suggestive of pneumonia, pleural effusion, and diffuse interstitial syndrome. All of the above findings were defined and diagnosed according to international recommendations for point-of-care lung ultrasound.[14] Pleural effusion, when not associated with pulmonary infarctions, was never considered diagnostic for PE. Rather, a large isolated pleural effusion in a dyspneic patient or an effusion associated with a large consolidation or with a mixed ultrasound pattern typical of infection were considered alternative diagnoses. Leg vein ultrasound was performed with a linear probe. The femoral veins and the popliteal veins were visualized and compressed in the short-axis. Deep Venous Thrombosis (DVT) was defined by the absence of complete vein collapse during compression. Ultrasound examination was performed by one of twenty sonographer investigators: eight senior specialists in internal medicine or pulmonology, and twelve residents in internal medicine, emergency medicine, or pulmonology, with at least 6 months' experience in lung and venous ultrasound produced on their own. This practical personal experience was always preceded by a teaching course in emergency ultrasound, continued by a period of training assisted by an expert including a minimum of 30 lung and 30 venous ultrasound examinations. Multidetector CTPA ≥64 row detectors was the primary second-level diagnostic imaging test used at all enrolling centers. If CTPA was contraindicated due to contrast medium allergy or severe renal insufficiency (eGFR < 30 ml/min/1,73 m^2), lung scintigraphy was scheduled. After completion of this initial diagnostic procedure, patients entered a three-month follow-up period. All enrolled patients were asked to contact the ED, in the event of new, worsening, or recurrent symptoms after discharge from the hospital.

A diagnosis of PE was made only if confirmed by a second-level imaging test performed in the ED or during the time course of the follow-up. In patients who died before the diagnostic completion, PE was considered the cause of death only if confirmed at autopsy or if the cause remained unexplained, and PE could not be confidently excluded. At each center, the final diagnosis was made by a physician expert in PE diagnosis who was blinded to the study results and who reviewed all the clinical and imaging data obtained in the ED, during hospitalization, and during follow-up.

YEARS and ultrasound-enhanced YEARS criteria and algorithms

Two YEARSc items were re-calculated based on ultrasound signs detected by the sonographer: "Signs and symptoms of DVT" was replaced by "Venous ultrasound positive for DVT", and "Alternative diagnosis less likely than PE" was replaced by "Alternative diagnosis less likely than PE after lung ultrasound" (Table 1). The latter item was considered positive and scored one point if at least one pulmonary infarct was visualized on lung ultrasound, whereas it was scored zero if no infarct was visualized and if another ultrasound finding compatible with an alternative pulmonary diagnosis was detected. If the lung ultrasound was normal, the points assigned remained those considered in the YEARSc. The diagnosis of PE was considered "unlikely" for a score of 0 in both YEARSc and US-YEARSc.

We subsequently incorporated to the YEARSc and US-YEARSc a d-dimer cutoff of 500 ng/mL for a score ≥ 1 and of 1000 ng/mL for a score = 0 as indicated in the original YEARS algorithm (Figure 1).[5,6] Besides, we compared YEARS and US-YEARS algorithms with US-Ws algorithm considering a fixed d-dimer cut-off of 500 ng/mL, as indicated in international guidelines.[1]

Table 1. Items of the YEARS criteria and YEARS-US criteria.

YEARS criteria	YEARS-US criteria	Points
Signs and symptoms of DVT	Venous ultrasound positive for DVT	+ 1
Alternative diagnosis less likely than PE	Alternative diagnosis less likely than PE after lung ultrasound	+ 1
Haemoptysis		+ 1

DVT, deep venous thrombosis, PE, pulmonary embolism.

Data analysis

Data are expressed as mean ± standard deviation. Unpaired Student's t-test was used to compare normally distributed data. Fisher's exact test was used to compare non-continuous variables expressed as proportions. P value <0.05 indicates statistical significance. All p values are two-tailed. The extended McNemar test and the McNemar test were used to assess whether the sensitivities and specificities of YEARSc and US-YEARSc were significantly different.[18] The contribution of each ultrasound element was examined by plotting the Receiver Operating Characteristic (ROC) curves of YEARSc, YEARSc plus venous ultrasound, YEARSc plus lung ultrasound, and US-YEARSc as a whole.[19] To evaluate a diagnostic strategy to exclude PE, the failure rate, and the efficiency of d-dimer in patients with US-YEARSc unlikely was compared with YEARSc and US-Ws. Failure rate (false-negative rate) was calculated as the number of patients with a negative d-dimer and a final diagnosis of PE divided by all patients with negative d-dimer in the unlikely groups. Efficiency was defined as the proportion of patients with negative d-dimer combined with the study scored "unlikely" among study patients. Calculations were performed using SPSS statistical package (version 25.0, SPSS Inc., Chicago, Illinois). The study had no funding source.

Results

Study population

Of the 491 patients eligible for the study, 446 patients were included in the final analysis (Figure 1 shows exclusion reasons). CTPA was performed in 297 patients (66.6%) and lung scintigraphy in nine patients (2%). PE was confirmed in 125 patients (28%) (Table 2). The diagnosis of PE was established by CTPA in 119 patients, by lung scintigraphy in five patients, and by autopsy in one patient. The characteristics of patients with and without PE are shown in Table 3.

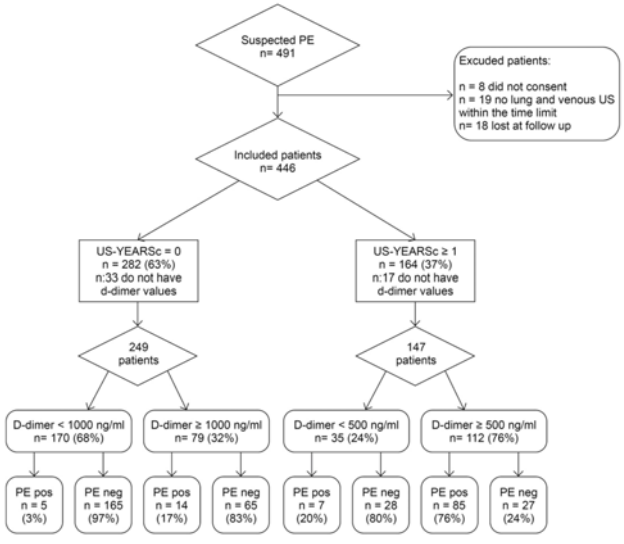

Figure 1. Flow diagram of the study and main results. PE, Pulmonary embolism; US, Ultrasound; % refers to the box above.

US-YEARS criteria *vs* YEARS criteria

US-YEARSc showed a 17.5% increase in sensitivity and a 32.4% increase in specificity when compared to YEARSc (p <0.01 for both) (Table 4). The number of patients classified as "unlikely" with the YEARSc was 200 (44.8%) vs 282 (63.2%) with US-YEARSc (p<0.01). In these "unlikely" groups, 44 (22%) in the YEARSc group and 22 (7.8%) in the US-YEARSc group were subsequently diagnosed with PE (false negatives) (p<0.001). ROC curve analysis showed that the AUC of YEARSc combined with venous ultrasound only (70.3%, 95% CI 64.2-76.3%) was superior to YEARSc alone (61%, 95% CI 54.9-67.1%, p=0.023), while YEARSc combined with lung ultrasound only (62.5%, 95% CI

Table 2. Final diagnosis in the study patients.

Final Diagnosis	n (%)
Pulmonary embolism	125 (28)
DVT	85 (19.1)
Pneumonia	73 (16.4)
Heart failure	52 (11.7)
Muscolo-skeletal chest pain	47 (10.5)
COPD / pulmonary fibrosis	46 (10.3)
Pleural effusion	20 (4.5)
Syncope	16 (3.6)
Tachyarrhythmia	15 (3.4)
Acute coronary syndrome	13 (2.9)
Lung cancer	11 (2.5)
Psychogenic dyspnea	10 (2.2)
Miscellaneous	18 (4)

Table 3. Characteristics of the study population according to final diagnosis.

		PE negative (n=321)	PE positive (n=125)
Mean age ± SD		69.5±16.7	68.9±18.5
Women		167 (52%)	70 (56%)
Symptoms of presentation			
Cardiac Arrest		2 (0,6%)	2 (1,6%)
Dyspnea		187 (58.3%)	91 (72.8%)
Chest pain	total	137 (43%)	38 (30%)
	pleuritic	105 (32.7%)	29 (23.2%)
Syncope		33 (10.3%)	15 (12%)
Palpitations		28 (8.7%)	11 (8.8%)
Shock/Hypotension		18 (6%)	8 (6%)
YEARS criteria			
Signs and symptoms of DVT		53 (16.5%)	44 (35.2%)
Alternative diagnosis less likely than PE		127 (39.6%)	68 (54.4%)
Hemoptysis	12 (3.8%)	4 (3.2%)	
Diagnostic evaluation			
CT scan		119 (95%)	178 (55%)
Scintigraphy		5	4
Polmunary Angiography		1	1

Data are presented as No. (%) or mean±Standard Deviation (SD); DVT, deep venous thrombosis, PE, Pulmonary Embolism.

56.3-68.7%) was not significantly better than the AUC of YEARSc alone (p=0.73). The AUC of the US-YEARSc (84.8%, 95% CI 80.4-89.3%) was superior to all three (p<0.01) (Figure 2). We also compared the US-YEARSc results with the US-Ws data from the same population and it showed a better sensitivity (difference +12.8%, p<0.01), a lower specificity (difference -7.2%, p<0.01) and a similar overall accuracy (difference -1.6%, p=0.65) (Table 4).

Diagnostic algorithm based on ultrasound, clinical scores and D-dimer

For the evaluation of the diagnostic algorithm, we considered 396 patients with available d-dimer. The diagnostic variables of different strategies to exclude PE, including clinical and ultrasound data without d-dimer and YEARSc or US-YEARSc with d-dimer, are shown in Table 5. PE was diagnosed in 22 of 282 (7.8%) patients with a US-YEARSc = 0, and out of 167 patients with lung ultrasound evidence of a possible alternative diagnosis, no infarcts and no evidence of DVT on venous ultrasound, PE was still diagnosed in 12 (7.2%) (p=0.81). The failure rate of US-YEARSc plus negative d-dimer (5.9%) was lower than the failure rate of YEARSc and negative d-dimer (8.9%), but the difference of -3% is not statistically significant (p=0.25). The efficiency of US-YEARSc plus d-dimer (US-YEARSc algorithm) (51.8%) was superior (+3.6%) to that of YEARSc plus d-dimer (YEARSc algorithm) (48.2%), but not statistically significant (p=0.31).

Compared to the US-Ws plus d-dimer, the US-YEARSc algorithm showed inferior sensitivity (difference -9.9%; p<0.01) and superior specificity (+23.1%; p < 0.01), which was confirmed by the lower failure rate in the US-WS group (Table 5).

Discussion

This retrospective study demonstrated that integration of lung and leg vein ultrasound improves the accuracy of a pretest probability score in the bedside diagnosis of PE, reducing the subjectivity in evaluation of two items of the YEARSc. The accuracy of YEARSc was significantly increased when the item "signs and symptoms of DVT" was replaced with "venous ultrasound positive for DVT", and when the item "alternative

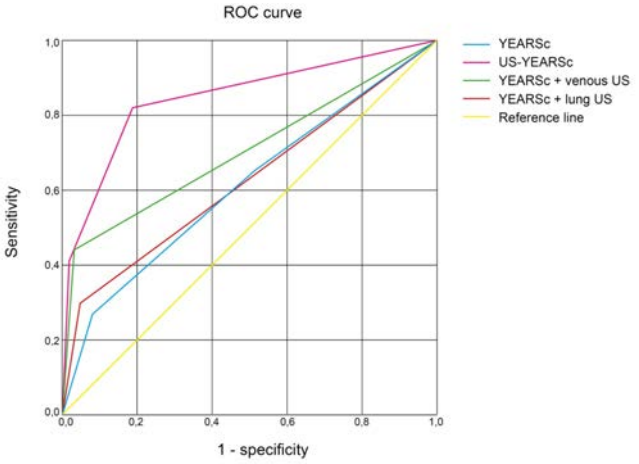

Figure 2. ROC curve for YEARS criteria, YEARS criteria plus lung or venous US and YEARS-US criteria. US, Ultrasound.

Table 4. Accuracy of the YEARS criteria, US-YEARS criteria and US-Ws for the diagnosis of PE.

	Sens % (95% CI)	Spec % (95% CI)	PPV % (95% CI)	NPV % (95% CI)	+LR (95% CI)	-LR (95% CI)	Accuracy
YEARS criteria ≥ 1	64.8 (55.8-73.1)	48.6 (43.0-54.2)	32.9 (29.3-36.7)	78.0 (73.2-82.2)	1.26 (1.07-1.49)	0.72 (0.56-0.94)	53.1 (48.4-57.9)
YEARS-US criteria ≥ 1	82.4 (74.6-88.6)	81.0 (76.3-85.1)	62.8 (57.1-68.2)	92.2 (89.0-94.6)	4.34 (3.41-5.51)	0.22 (0.15-0.32)	81.4 (77.5-84.9)
US-Ws > 4	69.6 (60.7-77.5)	88.2 (84.1-91.5)	69.6 (62.4-75.9)	88.2 (85.1-90.7)	5.88 (4.27-8.10)	0.34 (0.26-0.45)	83.0 (79.1-86.3)

YEARS-US criteria, Based on lung and veins ultrasound; PE, Pulmonary embolism. DVT, Deep vein thrombosis. Sens, Sensitivity; Spec, Specificity; PPV, Positive predictive value; NPV, Negative predictive value; +LR, Positive likelihood ratio; -LR, Negative likelihood ratio; 95% CI, 95% confidence interval.

Table 5. Diagnostic variables of four algorithm to rule out pulmonary embolism. YEARSc, US-YEARSc, Ws and US-Ws with negative d-dimer values.

	YEARSc and negative d-dimer†	US-YEARSc and negative d-dimer†	WS and negative d-dimer*	US-Ws and negative d-dimer*
Failure rate^ % (95% CI)	8.9 (8.76-9.04)	5.9 (5.71-5.99)	1.87 (1.68-2.06)	0.78 (0.61-0.95)
Efficiency+ % (95% CI)	48.2 (22.8-31.6)	51.8 (51.7-51.9)	27.0 (26.9-27.1)	32.3 (32.2-32.5)
Sensitivity % (95% CI)	84.7 (93.2-99.8)	89.2 (81.9-94.3)	98.2 (93.6-99.8)	99.1 (95.1-100.0)
Specificity % (95% CI)	61.1 (31.2-42.7)	67.7 (62.0-73.1)	36.8 (31.2-42.7)	44.6 (38.7-50.5)
PPV % (95% CI)	45.9 (32.1-43.6)	51.8 (44.5-59.1)	37.7 (32.1-43.6)	41.0 (35.1-47.2)
NPV % (95% CI)	91.1 (93.4-99.8)	94.2 (90.0-96.9)	98.1 (93.4-99.8)	99.2 (95.7-100.0)

US Wells score, Based on lung and venous ultrasound; PPV, Positive predictive value; NPV, Negative predictive value; 95% CI, 95% confidence interval. †, Calculated in 396 patients with available d-dimer, with d-dimer <1000 ng/ml if YEARSc/US-YEARSc = 0 and d-dimer <500 ng/ml if YEARSc/US-YEARSc ≥ 1 ; *, D-dimer cut-off < 1000 ng/ml ; ^, Calculated as the number of patients within the group with a final diagnosis of PE divided by all patients in the same group ; +, Calculated as the number of patients within the group divided by all included patients

diagnosis less likely than PE" was replaced with "alternative diagnosis less likely than PE after lung ultrasound", the accuracy was further increased. Venous ultrasound alone increased accuracy, but the best accuracy was obtained when both lung and venous ultrasound results were considered.

We used a point-of-care ultrasound technique that was easy to learn for operators, rapid, and low cost. All of these characteristics make this technique potentially suitable for widespread use as an adjunct to the physical examination in the acute care setting, as growing body of literature suggests.[7,14,30]

Two items of the YEARSc, the probability of PE and the clinical signs of DVT, are based on considerations that are strictly subjective and the risk of high variability when physicians with different experience and skills judge these two items is concrete.[20-30] In the proposed US-YEARSc, the two surrogate items supported by an early lung and venous ultrasound study represent the objective translation of the probability of PE (direct visualization of pulmonary infarctions or signs of alternative diagnoses) and DVT (definitive confirmation of the diagnosis).

The study was not powered to compare the diagnostic strategy when YEARSc and US-YEARSc were associated with d-dimer, and although US-YEARSc plus d-dimer seems to have a lower failure rate and a higher efficiency, a statistically significant difference was not found; to further investigate this, a prospective and adequately powered study is necessary.

US-YEARS algorithm showed inferior sensitivity compared to the US-WS plus d-dimer; when trying to rule-out a potentially life-threatening condition, maintaining a high sensitivity is of utmost importance to avoid missing a PE diagnosis. This result could be partly explained by the lower d-dimer cutoff used in the US-WS protocol (<500 ng/mL), and partly to the fact that the original study was specifically designed to evaluate US-WS protocol.

Limitations

The study is a retrospective analysis on data collected in a previous study not specifically designed for the evaluation of YEARS algorithm; given the intrinsic limitations of this type of study design, it should be considered a preliminary study for a future prospective one.

Although the technique used has been shown to be easy to learn and apply, there are still challenges and uncertainties associated with a rapid implementation and variability in accuracy between different institutions and medical personnel. Correct and effective skill acquisition and sufficient practice should always precede the use of lung and venous ultrasound in the diagnostic process of PE.

Since it was beyond the purpose of this study, we did not include echocardiography in the analysis; however, echocardiography is a powerful tool for emergency physician in patients with suspected PE. We excluded patients with haemodynamic instability, in which rapidly available US information can provide a significant advantage; this limitation could be evaluated in future studies on the subject.

The rate of PE in this study was high (28%), and it is not known how the performance of the US-YEARSc would be improved by the implementation of lung and venous ultrasound in a population with a lower incidence of PE. We investigated different strategies to rule out PE and whether these strategies could safely reduce the number of CTPAs performed in emergency (Table 5). All the analysed strategies have failure rates higher than 3%, although the use of ultrasound reduces them. These data could be explained by the fact that this is a retrospective study not designed to specifically evaluate these strategies.

Conclusions

In patients with suspected PE, point-of-care lung and venous ultrasound improves the accuracy of the conventional YEARS criteria. However, integration with the d-dimer is still needed. Further specifically designed studies are needed to evaluate whether a diagnostic strategy that integrates clinical information, lung and venous ultrasound, and d-dimer can improve the performance of YEARS and reduce the use of CTPA in the diagnostic approach to PE while maintaining an acceptable safety profile.

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