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ORIGINAL CONTRIBUTION

Evaluation of the "hemoptysis" item in clinical decision rules for the diagnosis of pulmonary embolism in the emergency department

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Abstract

Background: Hemoptysis is not common in pulmonary embolism (PE) and lacks specificity for its diagnosis. However, this item is present in different validated scores that estimate the clinical probability of PE. The relevance of this item in clinical decision rules (CDRs) is not clearly established.

Objective: The aim of this study was to evaluate the impact of removing the "hemoptysis" item from the PERC, YEARS, and PEGeD CDR in patients with low clinical probability of PE.

Design: This was a post hoc analysis of two European prospective cohorts, which included 2968 patients presenting to the ED with a low clinical probability of PE (PROPER and PERCEPIC) and a 3-month follow-up. The primary endpoint was the false-negative rate of a CDR score without the hemoptysis item. Secondary endpoints included the potential reduction of chest imaging if the item hemoptysis was to be removed and risk stratification of the Geneva and Wells scores without the hemoptysis item.

Results: Of 2968 patients included (mean ± SD age 46 ± 18 years, 53% female), 87 patients (3%) had a PE diagnosed at 3 months. A total of 2908 were followed-up at 3 months and analyzed. Using the PERC rule with and without the hemoptysis item, there were 13 and 14 missed cases of PE, respectively (failure rate 0.45% [95% CI 0.25%–0.78%] and 0.48% [95% CI 0.27%–0.82%]). Using the YEARS strategy, there were 11 missed PE cases with or without the hemoptysis item (false-negative rate 0.57% [95% CI 0.30%–1.05%]). With the PERC and YEARS rule, removing the hemoptysis item would have led to a 1% reduction in chest imaging. The PEGeD strategy was not modified by the removal of the hemoptysis item.

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Conclusions: The hemoptysis item could be safely removed from the PERC, YEARS, and PEGeD CDRs. However, there was no subsequent clinically relevant reduction of chest imaging.

KEYWORDS
computed tomography pulmonary angiography, D-dimer, emergency department, emergency medicine, hemoptysis, PEGeD, PERC, probability scores, pulmonary embolism, revised Geneva, Wells, YEARS

INTRODUCTION

Pulmonary embolism (PE) is frequently suspected in emergency department (ED) patients, which often leads to the prescription of irradiative chest imaging (computed tomographic pulmonary angiogram [CTPA] in most cases).[1,2] In the past few years, rationalizing the use of chest imaging in the ED has become a priority. Indeed, an increased use of CTPA has been reported without clear benefit in terms of prognosis.[3] This increased use is reportedly associated with potential overdiagnosis of PE, increased cost, length of ED stay, and side effects from both chest imaging and undue anticoagulant treatments.[3,4]

To reduce the number of CTPA procedures performed to rule out PE, different clinical decision rules (CDRs) have been derived and validated. Among them, the Wells and Geneva scores coupled with the D-dimer assay have shown a high negative predictive value (NPV), allowing the exclusion of the diagnosis of PE without the need of chest imaging.[5,6] The D-dimer assay is sensitive but not specific causing many false positives in low-risk patients with subsequent negative CT scans. This led to the development of a clinical rule, the PERC (Pulmonary Embolism Rule-out Criteria) rule, allowing PE to be ruled out on clinical criteria only.[7] The YEARS and PEGeD CDRs were recently developed, allowing the D-dimer threshold to be raised for ordering chest imaging to 1000 ng/mL upon absence of certain criteria (a YEARS score of 0 and a low Wells clinical probability, respectively).[8,9] These three CDRs and the two scores of clinical probability all include the "hemoptysis" item, which may change the diagnostic workup if present. The literature on PE and hemoptysis is poor, and it is reported that hemoptysis is neither sensitive nor specific to PE. Historically, hemoptysis was part of a triad considered specific to PE and necessary for its diagnosis, combining dyspnea, chest pain, and hemoptysis, but studies at the time reported much higher rates of hemoptysis in PE than recent studies (29% in a 1957 study, compared to 3% in 2004 in a study by Kline et al.[10]). The main etiologies of hemoptysis are respiratory infections, neoplasia, and bronchial dilatation.[11] Whether hemoptysis is a relevant clinical item to adapt the diagnostic workup for PE in the ED is unknown, especially considering that the real PE prevalence in ED patients with suspected PE has become significantly lower than in previous validation studies. Removing the hemoptysis item from these CDRs would simplify them and could increase the number of very-low-risk patients for whom additional tests could be dispensed with. The objective of this study was to assess whether the inclusion of the hemoptysis item in CDR is relevant for patients with low implicit clinical probability and to assess the impact of removing this clinical item from the different CDR on subsequent on the failure rate of these diagnostic algorithms.

METHODS

Study design

This study was a post hoc analysis of two European cohorts, which prospectively included patients presenting to the ED with a low implicit clinical probability of PE: PROPER and PERCEPIC. The PROPER study was a cluster randomized noninferiority trial that compared the PERC-based diagnostic strategy with the conventional strategy in patients with a low clinical probability of PE.[12] The PERCEPIC study was an observational, prospective, multicenter study that aimed to prospectively assess the NPV of the PERC rule in a European cohort of patients with a low clinical probability of PE.[13] In both studies, patients were followed up at 3 months through a telephone interview, and the presence of a thromboembolic event during follow-up was confirmed by an adjudication committee. When the patient could not be reached, the patient's general practitioner was contacted. For patients lost to follow-up, death records were queried. Any death during follow-up was analyzed by the adjudication committee and a sudden unexplained death was considered a thromboembolic event if it could not be excluded.

The protocols of both studies were approved by the ethics committees. As a secondary analysis on anonymized data, patient consent was waived for this study.

Population

A total of 2968 patients were included (Figure 1). The PROPER cohort included 1916 patients (from 14 EDs in France, between 2015 and 2016) presenting to the ED with a low pretest probability of PE empirically assessed by the physician's Gestalt. The PERCEPIC cohort included 1757 patients from 12 EDs in France and Belgium, between May 2015 and April 2016, including 1052 patients with low clinical probability of PE who were included in the present study;

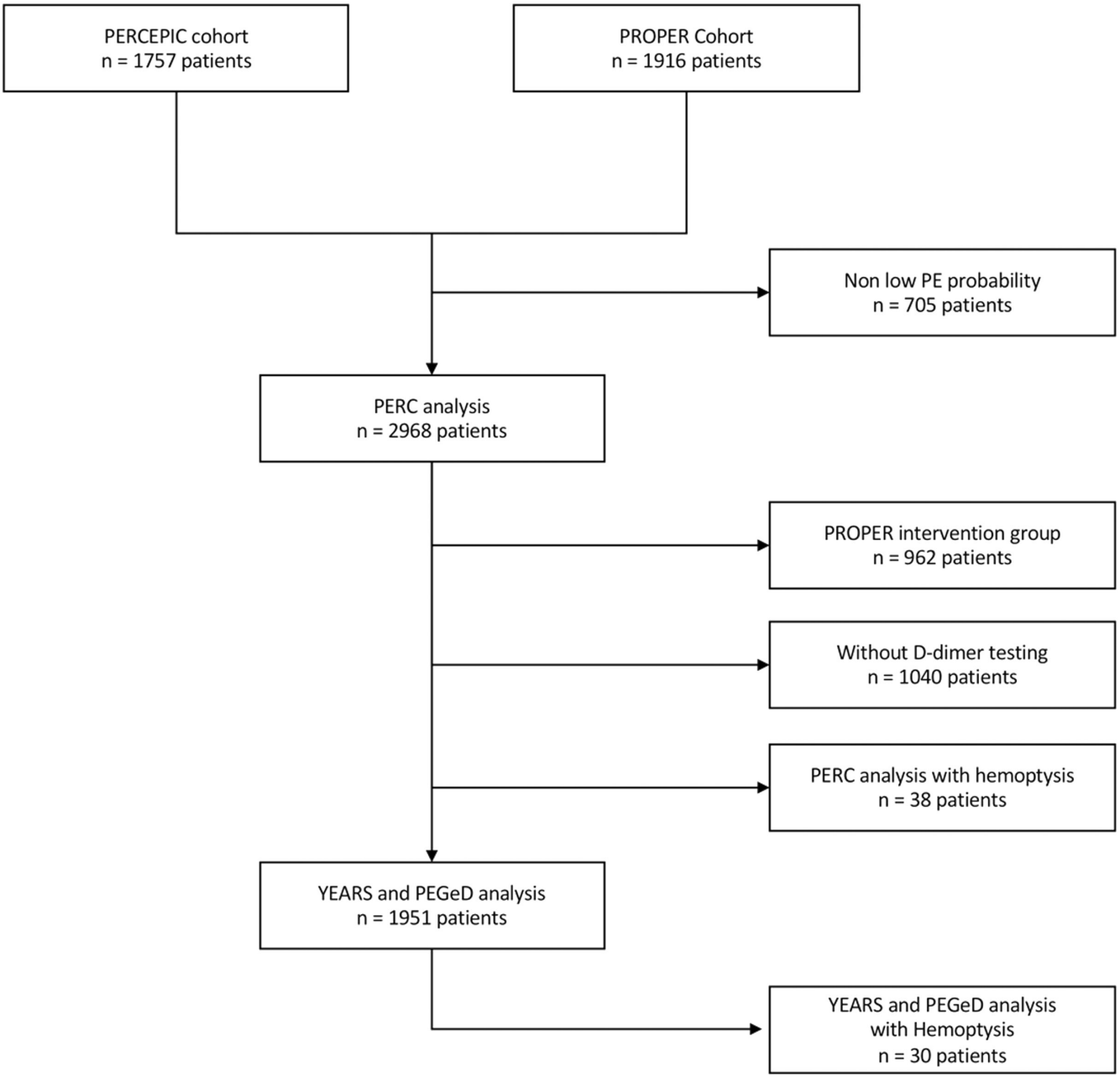

FIGURE 1 Flow chart. PE, pulmonary embolism PERC, Pulmonary Embolism Rule-out Criteria

705 patients were excluded from the PERCEPIC cohort for non–low probability of PE (558 with a moderate clinical probability, 147 with a high clinical probability of PE). In both studies, the low clinical probability was assessed by an unstructured physician's Gestalt evaluation of a risk of PE less than 15%.

Primary and secondary endpoints

The primary endpoint was the failure rate of the PERC, YEARS, and PEGeD based strategy without the hemoptysis item, when patients were followed up at 3 months. In the 60 (2%) patients lost to follow-up at 3 months in whom PE was ruled out at ED visit, we considered that they did not met the primary endpoint of PE at 3 months. The secondary endpoints included the potential reduction of CTPA if these CDR were applied without the hemoptysis item and the prevalence of PE according within the different classes of Geneva and Wells scores with and without hemoptysis item. A sensitivity analysis on PE diagnosed in the ED (and not at 3 months) was also performed.

Statistical analysis

Patient characteristics were expressed as number (percentage) for categorical variables, and as mean (standard deviation [SD]) or

median (interquartile range [IQR]) for quantitative variables, depending on their distribution. Confidence intervals (CIs) were calculated using Wilson's method with continuity correction. Recent recommendations suggested to adapt the acceptable failure rate to the prevalence of PE in the tested population. To validate the safety of a diagnostic strategy, the 2017 International Society of Thrombosis and Hemostasis recommendations of the Scientific and Standardization Committee were followed, according to which the maximum acceptable failure rate should be 1.82% + 0.0053% × prevalence.[14–16] In our population, the prevalence of PE was 3%. The upper bound of the 95% CI of our primary endpoint should then be less than 1.84% to respect these recommendations.

The analysis of the primary endpoint was performed on all patients analyzed at 3 months, i.e., 2908 patients. For the analyses performed to evaluate the YEARS and PEGeD strategy, in patients who received a conventional strategy, i.e., a D-dimer assay followed if necessary by CTPA, were included. We therefore excluded patients in the PROPER intervention group that did not undergo D-dimer testing. These analyses were thus performed on a total population of 1951 patients (Figure 1.) A sensitivity analysis that only considered PE diagnosed in the ED (and not at 3-month follow-up) was performed, which included 2968 patients.

In line with recent suggestions that the safety of a new strategy should be best evaluated among patients where the strategy was actually applied, post hoc analyses on the subgroup of patients that had a PERC, YEARS, and PEGeD score of zero, i.e., those in whom the strategy would have actually changed the workup strategy.[15,16]

RESULTS

A total of 2968 patients were included; 2908 were followed-up at 3 months and are included in the analysis. The mean (±SD) age was 46 (±18) years and 1584 (53%) were female. At 3 months, 87 PEs were diagnosed (prevalence of 3%) and seven (0.2%) patients died. Baseline characteristics are reported in Table 1. There were three (8.1%) PE cases in the 37 patients with hemoptysis and 84 (2.9%) PE cases in the 2871 patients with no hemoptysis (difference 5.2% [95% CI 0.0%–18%]].

TABLE 1 Baseline characteristics

	n	Population	
	2968		
Age (years), mean (±SD)		46	(±18)
Age > 50 years		1191	(40)
Gender			
Male		1384	(46)
Female		1584	(53)
HR (beats/min), mean (±SD)		83	(±17)
HR > 100 beats/min		457	(15)
SpO_2 (%), mean (IQR)		98	(97–100)
SpO_2 < 95%		217	(7)
Temperature (°C), mean (±SD)		36.7	(±1.8)
Risk factors for PE	2968		
Estrogen use		291	(10)
Signs of DVT		135	(5)
History of VTE		146	(5)
Recent immobilization		101	(3)
Hemoptysis		38	(1)
Active cancer		51	(2)
PE considered most likely diagnosis		242	(8)
D-dimer testing		2477	(84)
Positive D-dimer[a]	2477	704	(28)
D-dimer value (µg/L)	2477		
<500		1648	(67)
500–1000		471	(19)
>1000		358	(14)
Number of CTPA procedures	2968	649	(22)
PE diagnosed in the ED	2968	84	(3)
PE diagnosed at 3 months	2968	87	(3)
Death from any cause at 3 months	2968	7	(0.2)

Abbreviations: CTPA, computed tomography pulmonary angiogram; DVP, deep venous thrombosis; HR, heart rate; IQR, interquartile range; PE, pulmonary embolism; VTE, venous thromboembolism.

[a]Positive D-dimer if >500 µg/L in patients 50 years old and under and if >age x 10 µg/L in patients over 50 years old.

Primary endpoint

Among the 2908 patients included and followed up at 3 months, 1137 (39%) patients had a PERC score of 0 in whom 13 patients had a PE that was not diagnosed in the ED (failure rate 0.45% [95% CI 0.25%–0.78%]). After the hemoptysis item was removed, 1151 (40%) patients had a PERC score of 0 among whom 14 had a PE (failure rate 0.48% [95% CI 0.27%–0.82%]). One additional PE case was not diagnosed using the PERC rule without hemoptysis in a 34-year-old patient.

Among the 1925 patients included in the YEARS analysis and followed up at 3 months, 1651 (86%) patients had a YEARS score of 0 among whom 11 patients had a PE that was not diagnosed in the ED (failure rate 0.57% [95% CI 0.30%–1.05%]). After the hemoptysis item was removed, 1676 (87%) patients had a YEARS score of 0 among whom 11 had a PE (failure rate 0.57% [95% CI 0.30%–1.05%]).

Among the 1925 patients included in the PEGeD analysis and followed up at 3 months, 1237 (64%) patients had a Wells score of 0, and 11 had a PE (failure rate 0,57%% [95% CI 0.30% to 1.05%]). After the hemoptysis item was removed, 1257 (65%) patients had a Wells score of 0 and 12 patients had a PE (failure rate 0.62% [95% CI 0.34%–1.11%]).

Using the PERC rule, the removal of the hemoptysis item would have led to the reduction of six (1.0%) CTPA procedures (560 without hemoptysis item vs. 566 with hemoptysis item), and for the YEARS rule the reduction was seven (1.0%) CTPA procedures (344 without hemoptysis item vs. 351 with hemoptysis item). There was no CTPA reduction for the PEGeD rule. The results are summarized in Tables 2 and 3.

Sensitivity analysis

A sensitivity analysis was performed on the data during the ED visit. Among the 2968 patients included, 38 had hemoptysis in whom three had a PE at baseline, compared 81 in the 2830 patients without PE (7.9% vs. 2.8%. respectively; difference 5.1% [95% CI 0%–18%]).

The failure rates of the PERC rule with or without hemoptysis were 0.40% (95% CI 0.22%–0.72%) and 0.44% (95%CI 0.24%–0.77%) respectively. The failure rate of the YEARS rule with or without hemoptysis was 0.46% (95%CI 0.24%–0.87%) in both groups, and the failure rate of the PEGeD rule with or without hemoptysis was 0.62% (95% CI 0.33%–1.1%).

Revised Geneva, Wells, and simplified Wells scores

Performances of the revised Geneva, Wells, and simplified Wells scores with and without the hemoptysis item are reported in Table 4. The risk stratification remained very similar after this change.

TABLE 2 Failure rate according to the diagnostic strategy at 3 months

Diagnostic strategy	False negative (*n*)	Failure rate (% [95% CI])
PERC strategy (*n* = 2908)		
PERC	13	0.45 (0.25–0.78)
PERC without hemoptysis item	14	0.48 (0.27–0.82)
YEARS strategy (*n* = 1925)		
YEARS	9	0.57 (0.30–1.05)
YEARS without hemoptysis item	9	0.57 (0.30–1.05)
PEGeD strategy (*n* = 1925)		
PEGeD	11	0.57 (0.30–1.05)
PEGeD without hemoptysis item	12	0.62 (0.34–1.11)

Abbreviation: PERC, Pulmonary Embolism Rule-out Criteria.

Post hoc analyses

Analyses in the subgroup of patients in which the different scores were zero are reported in Table 5.

DISCUSSION

In this retrospective analysis of 2968 patients from two European cohorts, the failure rates of the PERC, YEARS, and PEGeD based

TABLE 3 Reduction of CTPA according to the diagnostic strategy

Diagnostic strategy	CTPA reduction, *n* (%)
PERC without hemoptysis item vs. PERC	6 (0.98)
YEARS without hemoptysis item vs. YEARS	7 (0.98)
PEGeD without hemoptysis item vs. PEGeD	0 (0)

Abbreviations: CTPA, computed tomography pulmonary angiogram; PERC, Pulmonary Embolism Rule-out Criteria.

TABLE 4 PE risk stratification based on Wells and revised Geneva scores

Clinical probability scores (%)	PE at 3 months	PE in the ED
Revised Geneva score		
Low risk (<2)	1.2	1.1
Intermediate risk (2–4)	5.4	5.1
High risk (>4)	19.4	18.8
Revised Geneva score without hemoptysis item		
Low risk (<2)	1.2	1.2
Intermediate risk (2–4)	5.4	5.1
High risk (>4)	20.7	20.0
Wells score		
Low risk (<2)	2.3	2.2
Intermediate risk (2–6)	7.1	6.7
High risk (>6)	17.6	17.6
Wells score without hemoptysis item		
Low risk (<2)	2.3	2.2
Intermediate risk (2–6)	7.2	6.7
High risk (>6)	15.4	15.4
Simplified Wells score		
PE unlikely (0–1)	2.5	2.4
PE probable (>1)	10.6	9.8
Simplified Wells score without hemoptysis item		
PE unlikely (0–1)	2.5	2.4
PE probable (>1)	10.5	9.7

Abbreviation: PE, pulmonary embolism.

TABLE 5 Post hoc analyses: false-negative rates among patients with negative CDR

Diagnostic strategy	Patients with negative CDR (*n*)	False negative, *n* (%)
PERC strategy		
PERC score = 0	1137	13 (1.14)
PERC score = 0 without hemoptysis item	1151	14 (1.20)
YEARS strategy		
YEARS score = 0	1651	11 (0.67)
YEARS score = 0 without hemoptysis item	1676	11 (0.66)
PEGeD strategy		
PEGeD	1605	11 (0.69)
PEGeD without hemoptysis item	1606	12 (0.75)

Abbreviation: CDR, clinical decision rule; PERC, Pulmonary Embolism Rule-out Criteria.

diagnostic strategies were below the acceptable threshold after removing the hemoptysis item. This change would have led to a slight potential reduction of chest imaging.

In this study, there was a nonsignificant association between hemoptysis and PE, with an absolute difference of 5.2% [95% CI 0.0%–18%], probably due to a lack of power as hemoptysis is reportedly associated with an increased risk of PE.[10] The prevalence of hemoptysis among patients with a low clinical probability of PE was very low; only 38 patients (1%) had hemoptysis and among them three patients (8.1%) had PE. In another recent study, similar results were found of low prevalence of hemoptysis in patients with low clinical probability of PE. Among 1414 patients with low clinical probability, 28 patients (2%) had hemoptysis and among them four patients (14.3%) had PE.[17]

The performance of the PERC score is not significantly reduced by the removal of the hemoptysis item. One PE is not diagnosed by applying the PERC strategy without hemoptysis, out of 15 patients with hemoptysis and no other PERC criteria. The prevalence of PE in patients with hemoptysis and no other PERC criteria is therefore 6.6%. Removing the hemoptysis item reduces the number of scans by only six (i.e., 1%). The performance of the YEARS and PEGeD rules are not altered by the removal of hemoptysis. A small reduction in the number of scans is achieved by applying the YEARS rule without hemoptysis. The risk stratification by the Geneva and Wells scores remains similar without the hemoptysis item.

Removing the hemoptysis item from the current CDR seems therefore safe, but this study does not provide enough argument to remove the hemoptysis item from the PERC score. The absence of modification in the YEARS and PEGeD strategies questions the interest of the hemoptysis item in these algorithms, but removing it would not lead to an important reduction of CT scans.

The main strength of this study is the large size of the cohort with a prospective recruitment in several EDs, with very few lost to follow-up. The overall prevalence of PE in this cohort was 3%, which is very different than the ones that were used for the derivation and validations of the tested CDRs and probability scores. This rate is consistent with what has been recently reported in low-risk population.[12,17,18]

However, in the Wells' score princeps article, the PE prevalence was 9.5%,[19] and this prevalence was 23% in the revised Geneva score publication.[20] Since it has been increasingly reported that the real PE prevalence in routine ED practice is below 10%, there was a need to reassess the relevance of including the chosen clinical items in real-life population. Furthermore, the interest of including hemoptysis item in the different CDR is of limited value for patients presenting with hemoptysis.

Indeed, CT scans are widely performed in these patients to localize the origin of the bleed as well as to establish the etiological diagnosis. The application of the different CDR may therefore not reduce the number of CT scans in these patients. The real benefit in terms of reducing the number of scans would be even lesser than that shown in this study. Moreover, the application of the PE diagnostic scores in patients presenting with hemoptysis systematically leads to the measurement of D-dimer levels, which delays the CT scan.[11] Therefore, it can be suggested that patients with hemoptysis should not follow usual diagnostic strategies for PE and should undergo chest CT that includes bronchial artery injection.

According to the post hoc analyses, both strategies appear to meet the requirements of the SSC 2017 guidelines even using the failure rate in the actual impacted population. All of these strategies appear to be within recommendations after applying a failure rate relative to the population actually impacted by the strategy, but a statistical analysis with determination of the 95% CI of the failure rate would be required to confirm this hypothesis.

LIMITATIONS

This study has some limitations. First, only patients with a low implicit probability of PE were included in this cohort. Although patients were included following an unstructured Gestalt estimation of <15%, the overall prevalence of PE was 3%. Hemoptysis

alone or in association with other symptoms may have changed the probability to not low. The data from this study may therefore not be applicable in patients with intermediate clinical probability of PE.

Second, there were only 38 patients (1%) with hemoptysis. This could have led to a lack of power to detect significant differences. However, the clinical impact would still be limited. Moreover, there was a small number of patients with hemoptysis in our cohorts, with subsequent wide CIs for estimating the prevalence of PE.

Third, some patients were lost to follow-up at 3 months and may have had a PE that was not diagnosed at ED visit, which could be a bias in the interpretation of the results. However, in the two included cohorts, the overall rate of missed diagnostic is approximately 0.1%. Therefore, it is likely that none of the patients lost to follow-up may have had a PE at 3 months.

Fourth, data regarding localization and severity of PEs were not collected. There may have been a difference in diagnosed PEs with or without hemoptysis. It was not possible to evaluate the association of PE severity with the presence of hemoptysis.

Fifth, the clinical characteristics of the hemoptysis were not collected, especially its estimated volume. Therefore, it was not possible to determine whether certain characteristics are more suggestive of PE than others.

CONCLUSIONS

In patients with low clinical probability of pulmonary embolism, the hemoptysis item could be safely removed from the PERC, YEARS, and PEGeD based strategies for pulmonary embolism, with a low risk of diagnostic failure. However, there was no subsequent clinically significant reduction in the rate of chest imaging.

AUTHORS CONTRIBUTIONS

Héloïse Bannelier and Yonathan Freund conceived the study. Héloïse Bannelier and Yonathan Freund developed the analysis plan. Yonathan Freund undertook the main analysis. Héloïse Bannelier and Melanie Roussel wrote the first draft of the paper. Judith Gorlicki, Andrea Penaloza, Delphine Douillet, and Pierre-Marie Roy made important critical revisions. All authors have read and approved the final version of the manuscript.

CONFLICT OF INTEREST

The authors declare no potential conflict of interest.

DATA AVAILABILITY STATEMENT

Please contact author for data requests.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The protocols of both studies (PROPER and PERCEPIC) were approved by the ethics committees.

CONSENT FOR PUBLICATION

Not applicable. As a secondary analysis on anonymized data, patient consent was waived for this study.

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