Performance of Helical Computed Tomography in Unselected Outpatients with Suspected Pulmonary Embolism

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Background: **Helical computed tomography (CT) is commonly used to diagnose pulmonary embolism, although its operating characteristics have been insufficiently evaluated.**

Objective: **To assess the sensitivity and specificity of helical CT in suspected pulmonary embolism.**

Design: **Observational study.**

Setting: **Emergency department of a teaching and community hospital.**

Patients: **299 patients with clinically suspected pulmonary embolism and a plasma D-dimer level greater than 500 μg/L.**

Intervention: **Pulmonary embolism was established by using a validated algorithm that included clinical assessment, lower-limb compression ultrasonography, lung scanning, and pulmonary angiography.**

Measurements: **Sensitivity, specificity, and likelihood ratios of helical CT and interobserver agreement. Helical CT scans were withheld from clinicians and were read 3 months after acquisition by radiologists blinded to all clinical data.**

Results: **118 patients (39%) had pulmonary embolism. In 12 patients (4%), 2 of whom had pulmonary embolism, results of helical CT were inconclusive. For patients with conclusive results, sensitivity of helical CT was 70% (95% CI, 62% to 78%) and specificity was 91% (CI, 86% to 95%). Interobserver agreement was high (κ = 0.823 to 0.902). The false-negative rate was lower for helical CT used after initial negative results on ultrasonography than for helical CT alone (21% vs. 30%). Use of helical CT after normal results on initial ultrasonography and nondiagnostic results on lung scanning had a false-negative rate of only 5% and a false-positive rate of only 7%.**

Conclusion: **Helical CT should not be used alone for suspected pulmonary embolism but could replace angiography in combined strategies that include ultrasonography and lung scanning.**

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Pulmonary embolism is a common and potentially fatal disorder (1). However, the prevalence of pulmonary embolism in suspected cases is only approximately 25% to 35% (2, 3). This figure seems to be decreasing (4), underscoring the interest in noninvasive diagnostic approaches developed in recent years. Assessment of the clinical likelihood of pulmonary embolism, whether empirically or by a prediction rule, has proven accurate enough to guide subsequent investigations (2, 4, 5). Indeed, most patients with a low clinical probability of pulmonary embolism may be managed entirely by noninvasive means (2–4, 6).

Plasma D-dimer measurement by use of an enzyme-linked immunosorbent assay (ELISA) (7, 8) has been shown to be safe and effective in outpatients, ruling out pulmonary embolism in approximately 30% of patients when used as a first-line test (3). Lower-limb venous compression ultrasonography (9, 10) shows deep venous thrombosis in 30% to 50% of patients with proven pulmonary embolism (3, 11). Lung scanning is diagnostic in 25% to 40% of patients; normal or near-normal results rule out pulmonary embolism, while a high-probability pattern establishes the diagnosis with a greater than 90% probability (2, 4, 6, 12). If combinations of all of these instruments are used, pulmonary angiography is necessary in only 4% to 11% of cases, as recently demonstrated in two large-scale outcome studies (3, 4). In these studies, the risk for a thromboembolic event over a 3-month period was less than 1% in patients who were classified as not having pulmonary embolism and were therefore not treated. However, in many smaller centers, the practical usefulness of these approaches is limited by the availability of the tests, particularly lung scanning and pulmonary angiography (3, 4). Furthermore, the strategy that relies on serial lower-limb ultrasonography (4) is resource intensive and potentially inconvenient for the patient.

The possibility of visualizing the pulmonary vessels at the peak concentration of the contrast agent by using helical computed tomography (CT), a now widely available test, has elicited tremendous interest. However, as recent reviews have shown (13, 14), the first reports on the characteristics of helical CT in suspected pulmonary embolism may have been unduly optimistic, and wide

variations in sensitivity (53% to 100%) and specificity (73% to 100%) have been reported (15–24). Patient selection, different imaging protocols and algorithms, and the level of pulmonary vasculature studied may in part explain these differences. Furthermore, none of the studies published to date fulfilled the methodologic criteria for adequately evaluating the performance of a diagnostic test (25, 26). Therefore, we evaluated the sensitivity and specificity of helical CT in a cohort of consecutive nonselected patients presenting to the emergency department with suspected acute pulmonary embolism. Helical CT scans were interpreted in a blinded fashion, and the diagnostic standard for pulmonary embolism was the diagnosis established by using a validated strategy (3), including 3-month clinical follow-up.

METHODS

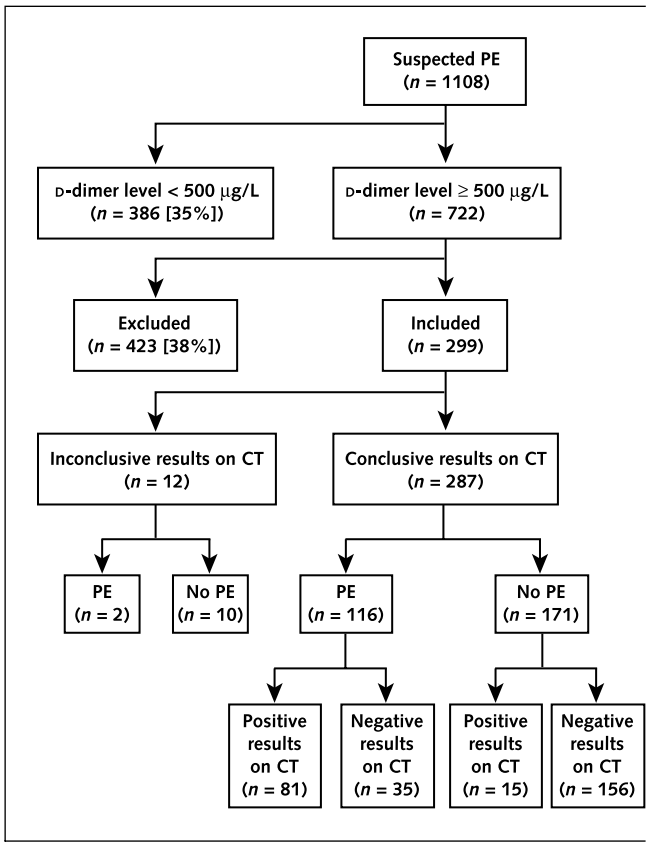
Patients

We prospectively studied 1108 consecutive patients presenting with clinically suspected pulmonary embolism at the emergency center of the University Hospital of Geneva (Geneva, Switzerland) between 1 March 1998 and 31 March 2000. Inclusion criteria were clinical suspicion of pulmonary embolism, age older than 16 years, and a plasma D-dimer level greater than 500 μg/L. A normal D-dimer level on ELISA has a high negative predictive value for pulmonary embolism (3) and is routinely used at our institution to rule out the disease. We excluded 386 of 1108 consecutive patients (35%) from further study because they had normal D-dimer levels.

Two hundred sixty-seven patients with abnormal D-dimer levels (24%) were excluded because they had contraindications to CT (serum creatinine concentration > 150 μmol/L [1.69 mg/dL] [n = 47], allergy to contrast agent [n = 14], asthma [n = 12], or pregnancy [n = 9]), declined to participate in the study or were unable to consent (n = 139), had been treated with oral anticoagulants at study entry (n = 13), had contraindications to anticoagulants (n = 5), were likely to be impossible to follow (n = 6), or were expected to survive for less than 3 months (n = 22). In addition, helical CT was unavailable or could not be used for study purposes in 108 patients (10%). For 13 of these 108 patients, helical CT could not be performed for technical reasons; for 10 patients, helical CT was performed elsewhere. In 7 of these 108 patients, the physician in charge requested immediate interpretation of the helical CT scan; also, 2 patients died, 21 had alternative diagnoses established, and 55 left the hospital or were transferred before helical CT was performed. The diagnostic work-up was incomplete in 48 patients (4%) because of missing tests (lower-limb ultrasonography [n = 1], lung scanning [n = 14], and pulmonary angiography [n = 30]) or was interrupted because of another indication for anticoagulant treatment (n = 3). Overall, 423 patients with abnormal D-dimer levels (38%) were excluded from the study (**Figure**). Two hundred ninety-nine patients were available for analysis. No clinically significant differences were seen between included and excluded patients in terms of age, sex, risk factors, clinical presentation, and clinical probability of pulmonary embolism.

The Ethics Committee of the Department of Medicine, University of Geneva, approved the protocol, and written informed consent was obtained from all patients.

Figure. **Flow chart of the study.**



Percentages given are percentages of the entire sample of patients with suspected pulmonary embolism (*PE*) (n = 1108). CT = helical computed tomography.

Study Design

We designed an observational study in which the sensitivity and specificity of helical CT for pulmonary embolism would be established by comparison with the final diagnosis established by a recently validated diagnostic algorithm (3), including 3-month clinical follow-up. Diagnostic criteria for pulmonary embolism were pulmonary angiography showing pulmonary embolism, high-probability lung scan (interpreted according to the revised Prospective Investigation of Pulmonary Embolism Diagnosis criteria [27]), or deep venous thrombosis shown by lower-limb venous compression ultrasonography and a clinical suspicion of pulmonary embolism. Pulmonary embolism was considered absent in the presence of normal results on angiography; a normal or near-normal lung scan; or low clinical probability of pulmonary embolism, nondiagnostic results on lung scintigraphy, and absence of deep venous thrombosis on lower-limb ultrasonography. In patients with the last combination, pulmonary embolism is very unlikely (6). Patients who were not considered to have pulmonary embolism did not receive treatment. All patients were followed for 3 months. To establish the performance of helical CT, the diagnostic algorithm was considered to have yielded false-negative results for patients who were classified as having no pulmonary embolism at discharge but presented with a thromboembolic event during follow-up.

Diagnostic Studies

The techniques used to perform lung scanning and pulmonary angiography and interpret the results have been described elsewhere (5, 28). Lung scintigraphy consisted of ventilation–perfusion scans, which were systematically compared with results of contemporaneously acquired chest radiography. A technician who was unaware of the clinical data measured D-dimer levels using rapid ELISA (Vidas DD, bioMérieux, Marcy l'Etoile, France) (3, 29). Trained staff performed lower-limb B-mode venous compression ultrasonography for all patients within 24 hours of presentation. The examination consisted of real-time B-mode examination of the common femoral and popliteal veins. The criterion for diagnosing deep venous thrombosis was noncompressibility of the vein (30).

Helical CT was performed by using a HiSpeed Advantage scanner (GE Medical Systems, Milwaukee, Wisconsin) or a PQ 5000 scanner (Picker, Cleveland, Ohio), and pulmonary arteries were evaluated up to and including the segmental vessels from the level of the aortic arch to the lowest hemidiaphragm. The patients were examined during suspended inspiration or shallow breathing, depending on the level of dyspnea. A total volume of 120 mL of nonionic contrast material was injected with a power injector at 3 mL/sec. Imaging commenced 12 to 15 seconds after initiation of the contrast material injection. Scans were performed at 3 mm per section with 120 kV, 200 mA, and a pitch of 2.0 mm. Each rotation required 1.0 second. The images were reconstructed at 2-mm intervals. Each vessel was scored for the presence or absence of clot, including subsegmental vessels, when visualized. A clot was present if contrast material outlined a central intraluminal defect or if a vessel was totally occluded by low-attenuation material. A subspecialty-trained chest radiologist prospectively recorded the findings.

To ensure that a completely independent reading was done and that results of helical CT did not influence patient management, results were withheld from the clinicians in charge of each patient. Exceptions were made for rare cases in which chest radiography showed an anomaly that necessitated thoracic CT for a reason distinct from suspected pulmonary embolism (for example, a pulmonary nodule). We excluded from the study patients for whom such exceptions were made. Each helical CT scan was rendered anonymous, and all scans were retrieved from optical disk storage and read on a workstation at mediastinal and lung parenchymal window settings at least 3 months after acquisition by radiologists who were blinded to all clinical data and other test results. We compared interpretation of helical CT with clinically generated reports of ultrasonography, lung scanning, and pulmonary angiography. To calculate interobserver variability, helical CT scans were also read by a cardiovascular radiologist and a general radiologist.

Three-Month Follow-Up

Venous thromboembolic events (deep venous thrombosis or pulmonary embolism) and episodes of bleeding were recorded during the 3-month follow-up. Diagnoses of venous thromboembolic events were established by using usual criteria (abnormal findings on ultrasonography or phlebography for deep venous thrombosis; high-probability ventilation–perfusion scan or abnormal results

on angiography for pulmonary embolism). Bleeding was considered major if it was fatal, intracranial, intraocular, retroperitoneal, or gastrointestinal (melena or hematemesis); if any manifest bleeding was accompanied by a decrease in hemoglobin level of at least 20 g/L; if the patient needed a blood transfusion (≥2 units of packed red blood cells); or if anticoagulation was permanently interrupted.

After discharge from the hospital, patients were managed by their family physicians. One of the study coordinators interviewed all living patients by telephone at the end of the follow-up period. If a patient reported any event that suggested venous thromboembolism, the coordinator contacted the family physician. In addition, we systematically reviewed the charts of patients readmitted to the hospital for any reason. For patients who died, cause of death was ascertained by autopsy or by death certificate. Follow-up was completed for all patients.

Statistical Analysis

Sensitivity was defined as the proportion of patients with positive results on helical CT divided by the total number of patients with pulmonary embolism. Specificity was defined as the proportion of patients with negative results on helical CT divided by the total number of patients without the disease. Accuracy consisted of the sum of true-positives and true-negatives divided by the total number of patients evaluated. Likelihood ratios were computed as follows: Likelihood ratio for a positive test result = sensitivity/(1 − specificity); likelihood ratio for a negative test result = (1 − sensitivity)/specificity. The exact 95% CIs for sensitivity and specificity of helical CT were calculated from the binomial distribution by using CIA computer software (Confidence Interval Analysis, version 1.0 [Gardner MJ, *British Medical Journal*, 1989]). Performance of helical CT was established from the chest radiologist's interpretation. Interobserver agreement among the three participating radiologists was evaluated by using the κ statistic.

Role of the Funding Sources

The funding sources had no role in the collection, analysis, or interpretation of the data or in the decision to submit the paper for publication.

Table 1. **Characteristics of the Study Sample (*n* = 299)***

Characteristic	Data
Median age (range), *y*	69 (21–99)
Female sex, *n (%)*	161 (54)
Risk factors, *n (%)*	
Family history of venous thromboembolism	26 (9)
Previous DVT or pulmonary embolism	60 (20)
Chronic venous insufficiency	118 (39)
Heart failure	114 (38)
Chronic obstructive pulmonary disease	36 (12)
Cancer	38 (13)
Surgery or trauma	36 (12)
Immobilization	59 (20)
Oral contraceptives or hormone replacement therapy	34 (11)
Clinical presentation, *n (%)*	
New onset or worsening dyspnea	231 (77)
Pleuritic chest pain	210 (70)
Recent cough	91 (30)
Hemoptysis	23 (8)
Calf pain	59 (20)
Signs of DVT	22 (7)
Abnormal results on chest radiography†	100 (33)
Pulmonary embolism, *n (%)*	
Clinical probability	
Low	122 (41)
Intermediate	136 (45)
High	41 (14)
Overall	299 (100)
Prevalence	
Low clinical probability	18 (15)
Intermediate clinical probability	69 (51)
High clinical probability	31 (76)
Overall	118 (39)

* DVT = deep venous thrombosis.
† Platelike atelectasis, pleural effusion, or elevated hemidiaphragm.

RESULTS

Pulmonary embolism was present in 118 (39%) of the 299 evaluable patients. If the patients with a normal D-dimer level had been included, the prevalence would have been 17% (118 of 685 patients). The median age of all 299 patients was 69 years (range, 21 to 99 years), compared with 45 years (range, 17 to 95 years) for patients with a normal D-dimer level. Clinical presentation and risk factors for venous thromboembolism are shown in **Table 1**.

Diagnosis of Pulmonary Embolism

Pulmonary embolism was diagnosed by a high-probability lung scan in 61 patients (20% of the study sample), deep venous thrombosis shown by lower-limb venous ultrasonography and a clinical suspicion of pulmonary embolism in 44 patients (15%), and angiography showing pulmonary embolism in 12 patients (4%) (**Table 2**). One patient, who was initially classified as

Table 2. **Comparison between Helical Computed Tomography and Results of Other Diagnostic Tests***

Variable	Patients with CT Results Positive for Pulmonary Embolism	Patients with CT Results Negative for Pulmonary Embolism	Patients with CT Results Inconclusive for Pulmonary Embolism	All Patients
	← *n* →			*n (%)*
Pulmonary embolism present				
High-probability lung scanning	42	19	–	61 (20)
DVT shown by lower-limb venous compression ultrasonography	30	12	2	44 (15)
Abnormal results on pulmonary angiography	9	3	–	12 (4)
DVT during follow-up	–	1	–	1 (0.33)
Total with pulmonary embolism	81	35	2	118 (39)
Pulmonary embolism absent				
Normal or near-normal results on lung scanning	3	41	–	44 (15)
Low clinical probability, normal results on lower-limb venous compression ultrasonography, nondiagnostic scintigraphy, uneventful 3-month follow-up	5	68	6	79 (26)
Normal results on pulmonary angiography	7	47	4	58 (19)
Total with no pulmonary embolism	15	156	10	181 (61)
All patients	96	191	12	299 (100)

* CT = helical computed tomography; DVT = deep venous thrombosis.

not having the disease on the basis of near-normal results on lung scanning, had lower-limb ultrasonography 10 weeks after study inclusion because of pain in the calf. She was shown to have calf deep venous thrombosis, which was included as a pulmonary embolism for the purpose of establishing the performance of helical CT. Pulmonary embolism was ruled out in 181 patients. Of these 181 patients, 44 had normal or near-normal results on lung scanning (15%); 58 had normal results on pulmonary angiography (19%); and 79 had low clinical probability of pulmonary embolism, normal results on ultrasonography, and nondiagnostic results on scintigraphy (26%) (**Table 2**).

Characteristics of Helical CT

The performance of helical CT is summarized in **Table 3** and in the **Figure**. In 12 patients (4%), results of helical CT were inconclusive because of motion artifacts or insufficient contrast enhancement. Two of these

Table 3. **Performance of Helical Computed Tomography in Patients with Suspected Pulmonary Embolism according to Various Diagnostic Standards***

Diagnostic Standard	Total Patients Evaluated	Sensitivity		Specificity		Likelihood Ratio with Positive CT Results (95% CI)	Likelihood Ratio with Negative CT Results (95% CI)
		Positive CT Results/ Pulmonary Embolism	Value (95% CI)	Negative CT Results/ Pulmonary Embolism	Value (95% CI)		
	n	*n/n*	%	*n/n*	%		
Clinical probability, lower-limb venous compression ultrasonography, lung scanning, and angiography†	299	81/116	70 (62–78)	156/171	91 (86–95)	8.0 (4.8–13.1)	0.3 (0.2–0.4)
Lower-limb venous compression ultrasonography, lung scanning, and angiography‡	214	81/116	70 (62–78)	88/98	90 (82–95)	6.8 (3.8–12.5)	0.3 (0.3–0.5)
Lung scanning and angiography§	172	51/74	69 (57–79)	88/98	90 (82–95)	6.8 (3.7–12.4)	0.4 (0.2–0.5)

* CT = computed tomography.
† Corresponds to the gold standard strategy for diagnosing pulmonary embolism described in the Methods section.
‡ Excluding patients in whom pulmonary embolism was ruled out partly because of clinical probability (patients with a low clinical probability, a nondiagnostic lung scan, and normal results on venous ultrasonography).
§ Excluding patients in whom pulmonary embolism was ruled out partly because of clinical probability and those in whom pulmonary embolism was established by abnormal results on compression ultrasonography.

Table 4. **Performance of Helical Computed Tomography in Patients with Suspected Pulmonary Embolism according to the Anatomic Level Studied**

Variable	Pulmonary Embolism Present	Pulmonary Embolism Absent
	n	
Positive results on computed tomography		
Main pulmonary artery*	28	0
Lobar artery*	40	7
Segmental artery*	13	8
Subsegmental artery*	–	–
All	81	15
Negative results on computed tomography	35	156
Inconclusive results on computed tomography	2	10
Total	118	181

* Most proximal anatomic level of pulmonary embolism shown by computed tomography scan.

patients had a pulmonary embolism. Among patients with conclusive results, sensitivity of helical CT was 70% (95% CI, 62% to 78%) and specificity was 91% (CI, 86% to 95%). Therefore, the likelihood ratio was 8.0 (CI, 4.8 to 13.1) for positive results on helical CT and 0.3 (CI, 0.2 to 0.4) for negative results. In the 35 patients with false-negative results on helical CT, pulmonary embolism was diagnosed by high-probability lung scan in 19 patients and deep venous thrombosis was shown by ultrasonography in 12 patients, by pulmonary angiography in 3 patients, and during follow-up in 1 patient (**Table 2**). In the 15 patients with false-positive results on helical CT, pulmonary embolism was ruled out by normal or near-normal results on lung scanning in 3 patients; by pulmonary angiography in 7 patients; and by low clinical probability of pulmonary embolism, nondiagnostic results on lung scanning, normal results on ultrasonography, and an uneventful 3-month follow-up in 5 patients (**Table 2**). **Table 3** also shows that use of more stringent diagnostic criteria for pulmonary embolism would not change the sensitivity and specificity of helical CT observed in the entire sample. When the 79 patients whose diagnosis was established by low clinical probability, a non–high-probability lung scan, and normal results on ultrasonography were excluded from analysis, the sensitivity and specificity of helical CT did not change (sensitivity, 70%; specificity, 90%). In addition, the performance of helical CT was unchanged in the 172 patients whose diagnosis was based only on a diagnostic lung scan (normal or near-normal results or high probability) or pulmonary angiography (sensitivity, 69%; specificity, 90%).

As shown in **Table 4**, although the pulmonary vessels were examined up to the subsegmental level, helical CT did not show any isolated subsegmental emboli. Most thrombi shown by helical CT were at the main left and right pulmonary artery and lobar artery levels (84%). Moreover, the likelihood of false-positive results on helical CT increased according to the anatomic level studied (main pulmonary artery, 0%; lobar pulmonary artery, 15%; segmental pulmonary artery, 38%). Interobserver agreement was excellent, as shown by nonweighted κ coefficients between 0.823 and 0.902 (**Table 5**). The sensitivity (range, 66% to 70%) and specificity (range, 91% to 92%) of the three readers' interpretations were also very similar.

Combined Strategies That Included Helical Computed Tomography

Since helical CT is unlikely to be used as a single test because of its low sensitivity, we analyzed the potential diagnostic yield of two combination strategies. In our sample, an algorithm that would recommend performing helical CT if results on lower-limb venous ultrasonography are negative would have had an overall accuracy of 87% and a false-negative rate of 21% (vs. 30% for helical CT alone). If patients had undergone helical CT after normal results on ultrasonography and nondiagnostic results on lung scanning, the diagnostic accuracy would have been 94%, with a 5% false-negative rate and a 7% false-positive rate. We could not assess the performance of a strategy that combined lung scanning and helical CT but did not include ultrasonog-

Table 5. **Helical Computed Tomography in Suspected Pulmonary Embolism: Interobserver Agreement***

Variable	Observer 1	Observer 2	Observer 3
Sensitivity (95% CI), %	70 (62–78)	69 (60–77)	66 (58–75)
Specificity (95% CI), %	91 (86–95)	92 (87–96)	91 (86–95)
κ coefficient			
Compared with observer 1	–	0.902	0.823
Compared with observer 2	0.902	–	0.834
Compared with observer 3	0.823	0.834	–

* The sensitivity and the specificity of the observers' readings are compared with a common diagnostic standard (that is, the diagnosis of pulmonary embolism as established by the study criteria).

raphy, because lung scanning was performed only in patients who had normal results on ultrasonography.

Three-Month Follow-Up

Seven of the 118 patients with pulmonary embolism died (5.9%), 3 of a probable recurrence of pulmonary embolism and 4 of cancer. Two patients had a major bleeding episode (gastrointestinal bleeding with melena in 1 patient and retroperitoneal bleeding requiring interruption of anticoagulation and insertion of a caval filter in 1 patient). Nine of the 181 patients without pulmonary embolism died (4.9%), 5 of cancer, 2 of cardiovascular causes, and 2 of respiratory failure; none died of pulmonary embolism, and none had a nonfatal venous thromboembolic event. One of the 181 patients without pulmonary embolism had a major bleeding episode at the femoral arterial puncture site for coronary angiography.

DISCUSSION

The sensitivity of helical CT observed in our study (70% [CI, 62% to 78%]) is among the lowest values found to date. The specificity of CT (91% [CI, 86% to 95%]) is also in the lower range of specificities reported in previous studies (13, 14). Indeed, in a pooled analysis of the only studies that included more than 100 patients (18, 21, 23) (398 patients total), the sensitivity of CT was 91% (CI, 85% to 96%) and the specificity was 93% (CI, 89% to 96%). However, our study fulfilled most of the methodologic criteria for a valid assessment of the characteristics of a diagnostic test (25, 26). We studied consecutive patients admitted to the emergency department with suspected pulmonary embolism. The spectrum of patients was broad, as reflected by patient characteristics and the range of clinical probabilities of pulmonary embolism (**Table 1**). The proportion of patients in each category of clinical probability was identical to that in previous studies at our institution (3, 5). The proportion of inconclusive helical CT scans (4%) was similar to that in comparable studies. The CT scans were interpreted after 3 months by a radiologist blinded to all clinical data and other test results. Likewise, diagnostic tests, such as lower-limb ultrasonography, lung scanning, and pulmonary angiography, were interpreted by staff who had no knowledge of helical CT findings. The pulmonary vessels were examined up to the segmental level. Therefore, the difference in performance does not seem to be linked to any major bias. Poor performance of the radiologists who interpreted the CT scans is also an unlikely explanation. As shown in **Table 5**, the interobserver agreement was very high, with κ coefficients between 0.823 and 0.902; in addition, the sensitivity and specificity values calculated by the three radiologists were very similar. Therefore, we believe that the values in our study are likely to be more realistic than those of previous studies.

Our findings have important clinical implications. First, the sensitivity of helical CT (70% [CI, 62% to 78%]) was too low to rule out pulmonary embolism without additional tests. Indeed, the likelihood ratio of negative results on helical CT (0.3) was close to that of a low-probability lung scan (2), a finding that has repeatedly been shown to be unsatisfactory for excluding pulmonary embolism. Second, the proportion of false-positive thrombi images depended on the anatomic level studied. Thrombi in the main pulmonary arteries were almost always true positives, while 15% of thrombi at the lobar level and 38% of those at the segmental level were false positives. Therefore, patients who have thrombi in the main or lobar pulmonary arteries on helical CT should probably be treated, especially if the clinical probability of pulmonary embolism is intermediate or high. However, pulmonary embolism is less certain in patients with isolated thrombi at the segmental level and a low clinical probability of the disease. Third, approximately 4% of results on helical CT were not conclusive because of motion or technical artifacts or insufficient contrast enhancement. Therefore, they do not modify the prior probability of disease. Patients with an inconclusive scan should undergo further tests. Finally, helical CT is potentially useful for diagnosis of pulmonary embolism when used in combination with other tests. In our study, an approach combining helical CT and lower-limb ultrasonography would have reduced the false-negative rate to 21%. An algorithm in which helical CT replaces angiography in patients with normal results on ultrasonography and nondiagnostic results on lung scanning would have had an accuracy of 94%, with a 5% false-negative rate and a 7% false-positive rate.

Our study has several limitations. First, our results may not apply to hospitalized patients with suspected pulmonary embolism because we did not include such

patients in our study. However, helical CT is unlikely to perform better in hospitalized patients because they have many comorbid conditions that may further decrease the test's specificity. Second, although we systematically searched for isolated subsegmental emboli, our image acquisition technique was not optimal for detecting them (31). The recent advent of multidetector helical CT systems, which can reduce collimation to 1.00 mm to 1.25 mm while maintaining or improving the scanning speed, may improve the performance of helical CT (32). Moreover, simultaneous CT venography, a recently developed technique (33, 34), would increase the overall diagnostic yield of helical CT, although its benefit over compression ultrasonography remains to be demonstrated. Since the principal aim of this study was to define the sensitivity and specificity of helical CT, we did not evaluate the frequency or usefulness of other diagnostic findings that the test provided.

Third, although we used an accepted diagnostic criterion in most patients (**Table 2**), pulmonary embolism was declared absent in 79 of 181 patients by a combined standard, including a low clinical probability of the disease, a non–high-probability lung scan, and normal results on lower-limb ultrasonography. However, since these 79 patients were not treated and had no venous thromboembolic events during follow-up, initial misclassification is unlikely. In addition, sensitivity and specificity of helical CT were unchanged after these 79 patients were excluded (**Table 3**). Last, we did not perform helical CT in patients whose D-dimer levels were normal on ELISA. Since none of these patients had a pulmonary embolism, the sensitivity values in our study may be applied to the entire cohort. Provided the specificity was unchanged, the lower prevalence of pulmonary embolism (17%) would further decrease the positive predictive value to 62% but increase the negative predictive value to 94%. Although we do not know how inclusion of patients with a normal D-dimer level would have influenced the specificity of helical CT, a reduced specificity is unlikely. Indeed, patients with normal D-dimer levels are substantially younger and are less likely to have comorbid conditions. Therefore, our study may in fact somewhat underestimate specificity.

In summary, the sensitivity of helical CT is too low to rule out pulmonary embolism. Specificity is higher at the level of the main and lobar pulmonary arteries than at the segmental level. Nevertheless, it may be useful to replace angiography with helical CT in combined strategies that include lower-limb ultrasonography. Such strategies should be validated in well-designed outcome studies.

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