Adjustments in the diagnostic work-up, treatment and prognosis of pulmonary embolism
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Clinical impact of findings supporting an alternative diagnosis on computed tomography pulmonary angiography in patients with suspected pulmonary embolism

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ABSTRACT

Background: Computed tomography pulmonary angiography (CTPA) is commonly used as the first-line imaging test in the diagnostic work-up of patients with suspected pulmonary embolism (PE). Other CTPA findings may provide an alternative explanation for the signs and symptoms in this group of patients; however, the clinical impact of these findings is not clear.

Methods: In 203 consecutive patients with suspected PE, we prospectively evaluated the clinical implication of abnormalities on CTPA. Alternative diagnoses were defined on clinical grounds prior to performing CTPA; afterwards, all findings were systematically registered. Diagnostic and therapeutic consequences were assessed using a priori defined criteria.

Results: Of the total of 203 patients, 61 (30%) had no abnormality on CTPA. Thirty-nine (19%) patients were diagnosed with PE. Before CTPA, alternative diagnoses were suspected in 97 (48%) patients. Findings supporting an alternative diagnosis were detected in 88 (43%) patients. In 28 patients this was a new finding; in 18 patients, a conclusive and previously unknown alternative diagnosis for the complaints was made based on the outcome of the CTPA. Overall, findings supporting alternative diagnoses had therapeutic consequences in 10 (4.9%) patients. Incidental findings (nodules/lymph nodes) requiring diagnostic procedures were present in 17 (8.4%) patients, of which one (0.5%) had a therapeutic consequence.

Conclusion: In patients undergoing CTPA for suspected PE, findings supporting alternative diagnoses were found in almost half of the patients. However, in only few patients this had therapeutic consequences. Hence, CTPA should principally be used to find or exclude PE in high probability patients but not to establish an alternative diagnosis.
INTRODUCTION

Since the last decade, computed tomography pulmonary angiography (CTPA) has been increasingly used as first choice imaging test to confirm or exclude pulmonary embolism (PE) (1). Compared to the previous reference standard (ventilation perfusion scintigraphy and pulmonary angiography) advantages of CTPA are that it is easily accessible, quick and non-invasive. Besides, CTPA has high sensitivity, ranging from 80% to 100% with a specificity of 96% to 100% (2;3). Another potential advantage of CTPA is its possibility of detecting additional findings that explain the patient’s complaints or symptoms if PE is excluded (4;5). However, CTPA also harbors a risk of finding incidental findings, such as intrapulmonary nodules or enlarged lymph nodes. Although these findings may be suggestive of a malignant disease, in the majority of patients, follow-up of these incidental findings likely involves visitsations, invasive procedures, repeated CTPAs and therefore repeated exposure to radiation and contrast medium, and can be therefore burden for the patient (4). Especially, the exposure to radiation following repeat imaging is an important risk factor for developing a malignancy (6;7). The reported proportion of nodules that are actually malignant is approximately 1% (8). Screening with low-dose chest CT has not been proven to decrease the rate of detection of advanced cancer or to affect mortality resulting from lung cancer (8;9).

Still, some clinicians use CTPA to detect a potential alternative diagnosis, even if the clinical suspicion of PE is low (10). Several studies showed that CTPA will yield a reliable finding supporting an alternative diagnosis in 25-52% of patients with suspected PE (4;5;11). However, it is unclear whether these findings supporting alternative diagnoses, mostly pneumonia, could also at forehand be established by clinical presentation, laboratory results and the chest radiograph (12). In this cohort study we assessed the clinical impact of findings supporting alternative findings on CTPA ordered in the diagnostic work-up for PE, in terms of diagnostic or therapeutic consequences. Furthermore, we investigated whether findings supporting alternative diagnoses were already established or highly suspected before CT-scanning.

METHODS

Patients
Consecutive in- and outpatients with a clinical suspicion of acute PE in whom CTPA was performed at the Academic Medical Center, Amsterdam, the Netherlands between
August 2008 and April 2009 were eligible for this analysis. Patients with severely impaired renal function (creatinine clearance <30 ml/min using the Cockroft-Gault formula), who were younger than 18 years of age, or were pregnant were excluded. The study protocol was approved by the institutional ethical review boards.

**Study design**

The pretest clinical probability of PE was considered ‘unlikely’ in case of a Wells score ≤ 4 and ‘likely’ in case of a Wells score > 4 points (13). Patients categorized as ‘PE unlikely’ underwent D-dimer testing. A CTPA was performed in all patients with an abnormal D-dimer test result (> 500 µcg/L) and all patients classified as ‘PE likely’ (14).

Evaluation of the possibility or presence of alternative diagnoses was performed on three occasions:

1. Before CT-scanning, the ordering physician was requested to inform the emergency radiologist to explicitly mention an alternative diagnosis other than PE, based on signs, symptoms, physical examination, laboratory results and chest radiograph.
2. After scanning, the CTPA was assessed by the radiologist. Patients were treated by the attending physician based on the CTPA results in combination with other clinical information. The treating physician was asked immediately after hearing the results of the CTPA to judge whether a finding supporting an alternative diagnosis on CTPA could indeed explain the signs and symptoms of the patient and whether the findings had diagnostic or therapeutic consequences. All additional diagnostic tests and therapeutic consequences were separately recorded.
3. Finally, for this analysis, we evaluated whether findings or diagnoses documented at the time of inclusion had been revised three months later.

**CTPA analysis**

CTPA for diagnosing or excluding PE was performed using a 64-slice MDCT scanner (Siemens Sensation 64, Forchheim, Germany). Scan parameters were: collimation 64 * 0.6 mm with 100 kV and 200 mAs, rotation time 0.5, with pitch of 1.4 and a 4D automatic tube current modulation (CARE dose 4D Automatic Exposure Control, Siemens, Erlangen, Germany). Intravenous contrast medium (Ultravist® 300, Bayer Pharma AG, Berlin, Germany; 100 ml at 4 ml/s) was administered via an 18G peripheral canula, followed by a saline chase of 40 ml at 4 ml/s. Images were reconstructed at 1 mm axial, sagittal and coronal slices in soft kernel with additional coronal maximum intensity projection (MIP) reformats. All studies were read by the attending radiologist.
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or resident with second read by an experienced emergency radiologists using a picture archiving and communication system PACS (Impax 4.5, AGFA Gevaert, Mortsel, Belgium) using standard window settings with possibility to change these settings without restrictions. A CTPA was considered to be of non-diagnostic quality to detect PE if there was insufficient opacification (subjective interpretation of available contrast in the pulmonary arteries, Hounsfield units < 200) of the vessels or in case of major artifacts. For CTPA evaluation a structured reporting format was used by the radiologists.

CTPA findings

1. Findings supporting an alternative diagnosis

‘Findings supporting an alternative diagnosis’ were defined as all findings that potentially provided an alternative diagnosis for the patient’s signs and symptoms (e.g. chest pain, shortness of breath, hypoxemia, or tachycardia). This included pneumonia, pleural effusion, tumor (noted on the report as new mass suspicious for malignancy or progression of known malignancy, possibly combined with adenopathy), significant atelectasis, bronchiolitis, pericardial effusion, (progressive) chronic obstructive pulmonary disease (COPD), heart failure or other diagnoses. Significant atelectasis was only determined if it was not secondary to pleural effusion. In case multiple findings were found on one CTPA, all findings were reported and the most likely finding to explain the patient’s symptoms was registered as a finding supporting an alternative diagnosis.

This classification was irrespective of the assessment whether or not the finding truly explained the signs and symptoms of the patient, only that it potentially could explain the symptoms (group A, Table 2 and Figure 1). For instance: a pneumonic infiltrate was present, and classified as an alternative finding. However, judging more strictly, the infiltrate could be deemed too small to explain the clinical status. Therefore, an additional differentiation was made, selecting only those CT scans with findings that sufficiently explained the signs and symptoms of the patient as was concluded by the treating physician (group B, Table 2 and Figure 1). Furthermore, we classified the findings as “new” if the CTPA findings were not visible on the chest radiograph before CT-scanning.

2. Incidental findings

Incidental findings on CTPA included pulmonary nodules and enlarged lymph nodes either mediastinal or hilar. Adenopathy that required follow-up included (1) any lymph node larger than 1 cm in short axis diameter and not associated with pneumonia; (2)
any lymph node larger than 3 cm in diameter; or (3) presence of multiple mediastinal or hilar lymph nodes. An incidental finding was only defined as a new finding if no mass or nodule was evident on previous imaging reports or if no history of malignancy, mass, or nodule was noted in the patient’s local medical record. A pulmonary mass > 1 cm, which was not described as a nodule or lymph node was not considered an incidental finding, but categorized as the finding supporting the alternative diagnosis ‘tumor’.

3. Other findings
Findings that were not considered as findings supporting an alternative diagnosis and required less urgent or no follow-up included: previously known or non-progressive emphysema (changes described as emphysematous or consistent with emphysema or chronic obstructive pulmonary disease); mild atelectasis (read as atelectasis, collapse, or volume loss described as dependent or involving fewer than 3 pulmonary segments); previously known, unchanged systemic disease such as sarcoidosis, systemic sclerosis or tuberculosis, cardiomegaly; skeletal findings (degenerative changes and other nonmalignant anomalies in skeletal structures); other pulmonary process (any other pulmonary process not already recorded, such as scarring or calcifications).

Consequences of findings detected on the CTPA
A finding was considered to have diagnostic consequences in case one or more of the following procedures was performed: a thoracentesis, bronchoscopy, sputum culture, consultation of a pulmonologist or cardiologist or performance of other diagnostic tests. A therapeutic consequence was classified when antibiotics, diuretics, corticosteroids or chemotherapy was administered or if thoracentesis was performed – as a direct consequence of the CTPA or following a diagnostic thoracentesis. Both diagnostic and therapeutic consequences were only considered if a diagnosis was newly found at the current clinical episode and was not already known before CT-scanning (Figure 1).

Statistical analysis
Normally distributed variables are presented as mean and standard deviations (SD) and non-normally distributed variables are expressed as medians with ranges. Exact 95% confidence intervals (CI) of proportions were calculated using SPSS software, version 19.0 (SPSS Inc, Chicago, Ill).
RESULTS

Patient characteristics
A total of 203 consecutive patients with suspected PE were included. Mean age was 57 years (SD 17 years), 77 (38%) were male, 26 (13%) patients had a history of COPD, 10 (4.9%) patients had a history of heart failure and in 59 (29%) an active malignancy was present (Table 1).

Table 1. Clinical characteristics.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients</td>
<td>203</td>
</tr>
<tr>
<td>Age, mean in years (SD)</td>
<td>57 (17)</td>
</tr>
<tr>
<td>Male, n (%)</td>
<td>78 (38)</td>
</tr>
<tr>
<td>COPD, n (%)</td>
<td>26 (13)</td>
</tr>
<tr>
<td>Heart failure, n (%)</td>
<td>10 (4.9)</td>
</tr>
<tr>
<td>Malignancy, n (%)</td>
<td>46 (22)</td>
</tr>
<tr>
<td>Smoking, n (%)</td>
<td>79 (39)</td>
</tr>
<tr>
<td>Inpatient, n (%)</td>
<td>116 (57)</td>
</tr>
</tbody>
</table>

Suspected alternative diagnoses prior to CTPA
Before CT-scanning, alternative diagnoses were considered by the treating physician in 97 (48%) patients. Most prevalent of the differential diagnoses were: pneumonia in 37 (18%), isolated pleural fluid in 12 (5.9%), (progression of) tumor in 7 (3.4%), and COPD in 7 (3.4%) patients.

CTPA findings
PE was diagnosed in 39 patients (19%); 61 patients (30%) had no abnormalities on CTPA.

1. Findings supporting alternative diagnoses
CTPA findings supporting an alternative diagnosis that potentially explained the patient’s symptoms (Group A), were found in 88 patients (43%, 95% CI 37-50%) (Table 2 and Figure 1); 3 patients also had PE. Among these alternative diagnoses were one or more pneumonic infiltrates (n=28, 14%), significant pleural effusion (n=27, 13%), and
Table 2. Prevalence of radiographic findings, findings supporting alternative diagnoses, and incidental findings in the diagnostic work-up of pulmonary embolism (PE) in 203 CTPA scans, stated as numbers (% of the total cohort of 203 patients, 95% confidence interval).

| PE* | No abnormality 61 (30, 24-36) | Findings supporting alternative diagnoses* Group A** Findings supporting alternative diagnoses* Group B*** Unknown prior to CTPA Group A Unknown prior to CTPA Group B Diagnostic consequences Therapeutic consequences |
|-----|-----------------------------|-------------------------------------------------|---------------------------------|---------------------------------------------|---------------------------------|---------------------------------|---------------------------------|---------------------------------|---------------------------------|
|     | Total 88 (43, 37-50)        | Pneumonic infiltrates 28 (14, 0.7-19)            | Pleural effusion 27 (13, 9.3-18) | (progression of) Tumor/metastases 10 (49, 2.7-8.8) | Large atelectasis 5 (25, 1.1-5.6) | Bronchiolitis 4 (20, 0.8-4.9) | Pericardial effusion 2 (1.0, 0.3-3.1) |  |
|     |                             | 21 (10, 6.8-15)                                  | 17 (13, 9.3-18)                  | 3 (1.5, 0.5-4.2)                           | 2 (1.0, 0.3-3.1)                  | 3 (1.5, 0.5-4.2)                  | 2 (1.0, 0.3-3.1)                  | 1 (0.5, 0.1-2.7)                  | 1 (0.5, 0.1-2.7)                  |
|     |                             | 9 (4.4, 2.3-8.2)                                 | 4 (2.0, 0.8-4.9)                 | 2 (1.0, 0.3-3.1)                           | 2 (1.0, 0.3-3.1)                  | 6 (3.0, 1.4-6.3)                  | 3 (1.5, 0.5-4.2)                  | 0 (0)                           |  |
|     |                             | 6 (14, 9.7-19)                                  | 2 (1.0, 0.3-3.1)                 | 1 (1.5, 0.5-4.2)                           | 1 (1.0, 0.3-3.1)                  | 1 (1.5, 0.5-4.2)                  | 1 (1.0, 0.3-3.1)                  | 1 (0.5, 0.1-2.7)                  | 1 (0.5, 0.1-2.7)                  |
|     |                             | 18 (8.8, 5.7-14)                                | 11 (5.4, 3.1-9.4)                | 10 (4.9, 2.7-8.8)                          |  |
|     |                             | 10 (4.9, 2.7-8.8)                               |  |

* PE = Pulmonary Embolism
<table>
<thead>
<tr>
<th>Incidental finding*</th>
<th>Diagnostic consequences</th>
<th>Therapeutic consequences</th>
</tr>
</thead>
<tbody>
<tr>
<td>PE, pulmonary embolism</td>
<td>CI: confidence interval; n: number; CTPA, computed tomography pulmonary angiography;</td>
<td><strong>Group A</strong>: findings suggesting an alternative diagnosis that potentially provided a more complete explanation of the signs and symptoms of the patient. <strong>Group B</strong>: findings suggesting an alternative diagnosis that sufficiently provided a more complete explanation of the signs and symptoms of the patient, as was concluded by the treating physician.</td>
</tr>
<tr>
<td>Enlarged lymph nodes</td>
<td>13 (6.4-3.8-11)</td>
<td>10 (4.9-2.7-8.6)</td>
</tr>
<tr>
<td>Nodule</td>
<td>10 (4.9-2.7-8.6)</td>
<td>7 (3.4-1.7-6.9)</td>
</tr>
<tr>
<td>Total</td>
<td>23 (11.7-7.7-16)</td>
<td>17 (8.4-5.3-13)</td>
</tr>
</tbody>
</table>

*Patients may be classified as having more than one outcome: PE and/or alternative diagnosis and/or incidental finding, etc.
(progression of) tumor/metastases (n=10, 4.9%). These were new findings in 28 out of the 88 patients (Figure 1 Table 2).

Of these 88 patients with findings supporting an alternative diagnosis, the findings were scored as sufficiently explaining the symptoms in 56 of the CTPAs (56/203 (28%, 95%CI 22-34%)). Of these, 18 were new findings (Table 2, Figure 1).

2. Incidental findings

An incidental finding was found in 23 patients (11%, 95% CI 7.6-16%), of which 17 (8.3%, 95% CI 5.3-13%) required further diagnostic evaluation (5 diagnostic punctures, 5 consultations of a pulmonologist, 7 follow-up by radiologic imaging). In one patient the diagnostic evaluation of the lymph node had therapeutic consequences because of a diagnosis of cancer (chemotherapy).

3. Other findings

In 74 patients (36%, 95% CI 30-43%) minor findings were seen on CTPA, which were considered unrelated to the clinical signs and symptoms and did not require follow-up. These findings included residual abnormalities due to previous infections, mild emphysema, mild atelectasis, pre-existing systemic disease (tuberculosis, sarcoidosis, mixed connective tissue disease and CREST syndrome), post-operative and post-radiation therapy changes, skeletal changes and minimal and insignificant parenchymal findings (scarring, fibrosis, a specific small isolated nodules and small bullae). In 30 patients, these findings were diagnosed in addition to PE, an alternative diagnosis or an incidental finding.

Diagnostic and therapeutic consequences

In 11 patients (5.4%, 95% CI 3.1-9.1%), CTPA abnormalities had diagnostic consequences (Figure 1), mostly bronchoscopy, thoracentesis, sputum culture, cardiac evaluation or an MRI-scan. These diagnostic tests resulted in (change of) treatment in 5 patients.

Start or change of therapy was a (in-)direct result of the CTPA findings in 10 patients (4.9%, 95% CI 2.7-8.8%; Table 2, Figure 1). The therapeutic consequences were initiation of antibiotics in 7 patients, diuretics in 2 patients and corticosteroids in one patient. Of these 10 patients, the findings were an indirect consequence after a diagnostic step in 5 and were a direct consequence of the CTPA in another 5 patients.
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Comparison between diagnoses at baseline and three month follow-up

After three months, 13 patients (6.4%, 95% CI 3.8-11%) had died; none of the deaths were suspected to be due to PE. In the remaining 190 patients, the initial diagnosis (PE, finding supporting an alternative diagnosis or no abnormality) was unchanged in 187 patients (98%, 95% CI 96-99%) and had been adjusted by the treating physician in 3 patients (1.6%, 95% CI 0.6-4.2%). In one patient, the diagnosis of PE was changed into 'artifact' after re-evaluation by two different radiologists. Two diagnoses of tumor (newly found masses) were changed after puncture into 'inflammation secondary to a foreign body' and 'scar tissue', respectively. None of the patients was evaluated for deep venous thrombosis or PE during follow-up.

Figure 1. Flowchart of findings supporting an alternative diagnosis and the subsequent results in diagnostic and therapeutic consequences. Percentages in brackets reflect percentage of the total number of patients (203).

- Total of 203 CTPAs: PE n=39 (19%)
- Group A: CTPAs with findings supporting an alternative diagnosis n=88 (43%)
- Group B: CTPAs with an alternative diagnosis sufficiently explaining signs and symptoms n=56 (28%)
- Normal CTPA n= 61 (30%)
- Findings unsuspected prior to CTPA: n=28 (14%)
- Findings unsuspected prior to CTPA: n=18 (8.8%)
- Diagnostic consequences: n=11 (5.4%)
- Therapeutic consequences: n=10 (4.9%)**

* 3 of these patients also had PE
** the findings were an indirect consequence after a diagnostic step in 5 and were a direct consequence of the CTPA in another 5 patients.
DISCUSSION

This study demonstrates that in patients with suspected PE, CTPA is able to detect findings supporting an alternative diagnosis in 28% of the patients. However, two-thirds of these findings were already known or suspected before CTPA was performed. The findings supporting alternative diagnoses had therapeutic consequences in only 5% of all patients. Incidental findings on CTPA, such as lymph nodes or nodules resulted in further diagnostic steps in 8% of the patients with suspected PE, with limited therapeutic consequences.

Several studies addressed the issue of possible alternative diagnoses in patients who underwent CT-scanning for suspected PE. The proportion of alternative diagnoses ranged between 25-52% (4;5;11;15-17) and was comparable with our findings. Hall and colleagues found an alternative diagnosis in 33% of 589 patients, and an incidental finding requiring follow-up in 24%, far outnumbering the rate of PE in their study, which was 9% (4). A retrospective analysis of a large multicenter clinical management study on PE investigated the frequency of alternative diagnoses on CTPA in 512 consecutive patients (5). In 130/512 patients (25%, 95% CI 9.5-18%) without PE an alternative diagnosis was considered likely. However, whether these alternative diagnoses observed on the CTPA were already identified before CT-scanning and whether these findings were clinically significant in terms of actual therapeutic consequences was not assessed. To our knowledge, our prospective study is the first that assessed the proportion of findings supporting alternative diagnoses as well as the clinical impact in terms of diagnostic and therapeutic consequences. Furthermore, we systematically collected information on alternative diagnoses prior to CTPA, thus reducing the risk of bias by knowledge of the CTPA result. Not only were the majority of findings supporting alternative diagnoses already known prior to CTPA, these findings led to therapeutic actions in only 5% of all presenting patients. This indicates that the findings supporting alternative diagnoses can be established in the majority of cases using history, clinical presentation, laboratory results, and chest radiograph, and places the perceived additional value of CTPA for the diagnosis of PE over other imaging modalities (such as perfusion scintigraphy) in perspective.

Although guidelines do not recommend to perform CTPA in case of an ‘unlikely’ clinical decision rule and a normal D-dimer test-result, this advice is often not followed for several reasons (14;18-19). One of these reasons may be that some clinicians hope that CTPA will help them find an alternative diagnosis in a patient with a low
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likelihood of PE. In our study, 8% of the CTPAs showed an incidental finding requiring repeated exposure to radiation and contrast or an invasive procedure, with no life saving consequence in terms of early detection of a malignancy. This, together with the relatively low yield of previously unsuspected alternative diagnoses with therapeutic consequences, makes it at least arguable to liberally use CTPA with the additional aim to detect an alternative diagnosis in patients with a low clinical suspicion of PE in terms of ‘net clinical benefit’.

Some aspects of this study merit consideration. First, this study was conducted at a single tertiary care referral center, and results may not be generalizable to other settings. However, the prevalence of PE was similar to that of other PE studies in which clinical probability combined with the D-dimer (14) were used and it is likely that the rate of incidental findings would be comparable if similar evaluation and CTPA protocols and equipment were used. Furthermore, there may be significant variability between radiologists reporting. In our study, we used the observation of the radiologist on call, without an independent second radiologist confirming the diagnosis on the CTPA in the majority of cases. Although all CTPAs were assessed according to a pre-specified protocol, it cannot be ruled out that some of our patients were misclassified as having PE, an alternative finding or an incidental finding. However, this obviously reflects routine clinical practice of the diagnostic process of suspected PE. Another limitation is the moderate sample size of this study. As a result, the different findings supporting alternative diagnoses were rather small. However, the 95% CIs of the main results were rather narrow; we therefore think it unlikely that a larger sample size would lead to a materially different conclusion. We did not study the impact of CTPA on the confidence of physicians in the finding supporting an alternative diagnosis and consequential demands of the patients. It is intrinsically difficult to check validity of pretest therapeutic intentions, as verification could be influenced by the test findings. We can only speculate whether the CTPA in certain patients helped in converting a suspicion into confirmation of an alternative diagnosis, and its implications. Furthermore, the distinction we make between a liberal definition of findings supporting an alternative diagnosis including potentially explaining findings (group A), and a strict definition including only patients with sufficiently explaining findings (group B) is arbitrary. We, however, think this distinction makes our interpretations a more accurate reflection of clinical practice. It shows that there is a considerable group of patients in which it is difficult to prove that the observed finding supporting an alternative diagnosis is indeed an explanation for the complaints. When we used either the liberal or the strict definition, our main
findings did not change. Lastly, it was not possible to obtain a standard reference test for every suggested finding supporting an alternative diagnosis. As approximately 98% of the diagnoses of the surviving patients at baseline did not change at 3-month follow-up, we think that this study is a valid reflection of clinical practice.

In conclusion, although CTPA yields findings supporting alternative diagnoses in a considerable proportion of patients with suspected PE, these resulted in change or initiation of therapy in only 5% of the total population. Besides, incidental findings requiring diagnostic follow-up were found in 23 patients (11%). Hence, CTPA should primarily be used to find or exclude PE in patients in whom the clinical probability is high, based on clinical decision rule and the D-dimer test result, and not to establish a finding supporting an alternative diagnosis.

Reference List

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