Clinical audit

Diagnostic approach to patients with suspected pulmonary embolism: a report from the real world

G Saro, J F Campo, M J Hernández, M Anta, J M Olmos, J González-Macías, J A Riancho

Summary

This study was carried out to examine the diagnostic approach to patients with suspected pulmonary embolism (PE) in a university hospital. A retrospective case record review of 251 patients with suspected pulmonary embolism was carried out according to a standard protocol, which looked at the utilisation of imaging techniques and compared clinical diagnoses with a standardised diagnosis established according to current recommendations. Isotopic lung scan was the most commonly used technique (73%), followed by leg vein sonography (36%) and contrast venography (31%). Lung arteriography was done in only 7% of patients. Among the 205 patients with a clinical diagnosis of PE, 115 (56%) would be diagnosed as having PE according to the standard criteria, 84 (41%) would be unclassified, and six (3%) would not be regarded as having PE. Among patients who were diagnosed as having PE and received anticoagulant therapy, 32% did not have the diagnosis confirmed by an imaging technique. Most of these had a non-diagnostic lung scan which, despite evidence to the contrary, seemed to be interpreted as confirmation of PE. We conclude that clinicians do not seem to follow current recommendations when approaching patients with suspected PE. In particular, there is an over-reliance on lung scans, and the significance of non-diagnostic scans was often misinterpreted. Arteriography was underused. These results emphasise the need to take measures to implement practice guidelines and to explore the usefulness of newer non-invasive techniques.

Keywords: pulmonary embolism; diagnosis; lung scan; imaging techniques; audit

The approach to patients with suspected pulmonary embolism (PE) is a challenging clinical task. The mortality of untreated PE is high, but anticoagulation may also have serious adverse effects. Several non-invasive imaging techniques are available, but their diagnostic performance is less than ideal. Pulmonary arteriography, the gold-standard test at the present time, is not free of potentially serious complications. Thus, the clinician needs to consider carefully the results of ancillary studies, as well as the risks and benefits of

anticoagulation, in order to make a therapeutic decision.

In the last decade, many studies have analysed the performance of imaging techniques, and a number of algorithms have been proposed to help clinicians in their decision analysis. However, it is unclear to what extent these new developments have been incorporated into clinical practice. This study was set up to determine how patients with suspected PE are managed in a routine clinical setting.

Materials and methods

We retrospectively reviewed the charts of 251 patients suspected of having PE who were admitted to our hospital between 1 January 1994 and 31 December 1995. They included two overlapping groups: those admitted from the Emergency service because of suspicion of PE, and those who had a diagnosis of PE in the discharge clinical report. The study was performed in the Hospital Universitario Marqués de Valdecilla, a third-level 1000-bed facility serving a population of 500 000. The hospital had facilities to perform ultrasound leg scan and venography at any time, and lung arteriography and isotopic lung scans during regular working hours. Spiral computed tomography (CT) was not available. Most patients were admitted to the services of general internal medicine (39%), respiratory medicine (29%), or cardiology (8%). The remaining 24% were patients in the wards of other medical or surgical services.

The charts were reviewed, according to a standardised protocol, to establish the ancillary tests performed, diagnosis, and therapeutic measures taken. We compared the 'clinical diagnosis' (ie, the diagnosis established by clinicians caring for the patients), with a 'standardised diagnosis' based on explicit criteria as explained below. Following commonly accepted criteria, a normal lung scan was considered as evidence against PE, and a high-probability V/Q scan was regarded as diagnostic of PE.^{1,2} Imaging studies of the veins of lower extremities have high specificity; the frequency of PE in patients with deep vein thrombosis (DVT) and clinical suspicion of PE is considered to be virtually 100%. Hence, for the purposes of this study, we considered that all patients with a clinical suspicion of PE who had a positive vein sonogram or contrast study actually had PE. Therefore, we retrospectively classified patients into the following three groups according to a 'standardised diagnosis':

Department of Internal Medicine, Hospital M Valdecilla, University of Cantabria, Santander, Spain

G Saro
J F Campo
M J Hernández
M Anta
J M Olmos
J González-Macías
J A Riancho

Correspondence to
Jose A Riancho, Department
of Internal Medicine,
Hospital M Valdecilla,
Santander 39008, Spain

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Figure 1 Number of imaging studies performed in the group as a whole, expressed as a percentage of the total number of patients ($n=251$)

- patients were considered to have PE if they had (a) an autopsy diagnosis; or (b) positive pulmonary arteriography; or (c) a high-probability ventilation/perfusion (V/Q) lung scintigraphy; or (d) a duplex ultrasound scan or contrast venography showing DVT
- patients were considered not to be suffering from PE if they had (a) an autopsy excluding PE; or (b) a negative pulmonary arteriography; or (c) a normal or low-probability lung scan (V/Q or perfusion-only) and no new manifestations of venous thromboembolism during the following 6 months in the absence of anticoagulation
- patients were considered unclassifiable if they were not included in either of the above groups.

Results

IMAGING TECHNIQUES IN THE WHOLE GROUP

In the study group as a whole, lung scintigraphy, the most commonly used imaging technique, was performed in 185 patients (73%). In 103, V/Q scans were obtained, whereas in 82 only a perfusion scan was obtained. The frequencies of utilisation of other techniques are shown in figure 1. It is notable that lung arteriography was done in only 18 patients (7%). Figure 2 shows the frequencies of positive results. Forty-six (45%) of the 103 V/Q scans were considered as 'high probability', four were reported as normal, and 53 (51%) were non-diagnostic (reported as intermediate or low-probability, or in less accepted terms such as 'non-suggestive'). Among the 82 perfusion-only scans, 14 (17%) were considered as high probability (they had a normal X-ray); two (3%) were normal, and the remainder (80%) were non-diagnostic. Overall, 119 (64%) lung scans were non-diagnostic; 84 (71%) of these patients were subjected to other imaging techniques, while 35 cases (29%) did not undergo any other procedures. Among the latter group, 23 patients were given anticoagulants.

The clinical diagnosis and the imaging tests performed in these patients are shown in table 1. The patients are divided into the three diagnostic subgroups according to the standardised criteria described above. Among patients with DVT diagnosed by ultrasound or venography,

Figure 2 Distribution of the results of imaging studies in the group as a whole. The lighter areas represent the percentage of positive studies. For lung scans, the percentages of high probability (lightest area), normal (darkest area), and non-diagnostic (intermediate) studies are given

only 52% had clinical signs suspicious of DVT. Among patients with clinical signs of DVT, leg ultrasound scans were positive in 64%, whereas the scan was positive only in 18% of those without signs. Contrast venography was positive in 64% of patients with signs of DVT and in 52% of those without signs.

CONCORDANCE BETWEEN DIFFERENT IMAGING TECHNIQUES

A leg ultrasound scan and a contrast venography were obtained in 19 patients. Both techniques were negative in nine patients and positive in two. One patient had a positive ultrasound scan, but a negative venography, whereas seven patients had negative ultrasound but positive contrast venography (in six cases with thrombi in the region above the knee). In these 19 patients the concordance coefficient kappa was 0.13 (not significant).

Seventeen patients with a lung scan (12 non-diagnostic and five reported as high probability (two V/Q and three Q scans)) also had an arteriography. In two of these five patients (one V/Q and one Q scan) the arteriography was positive.

PATIENTS WITH A CLINICAL DIAGNOSIS OF PE

We then focused on the subgroup of patients with a clinical diagnosis of PE to find out how it was established and the concordance with the standardised diagnostic criteria. In 94 (46%) of the 205 patients with a diagnosis of PE in their final clinical report, the diagnosis was based on clinical data and basic ancillary tests (chest X-ray, blood gases, electrocardiogram). In the remaining cases the diagnosis was supported by at least one imaging study with a positive result (table 2).

Table 1 Clinical diagnosis, therapy and imaging tests performed in the three subgroups of patients classified according to the standardised criteria (see Methods)

		PE (n=124)	No-PE (n=29)	Unclassified (n=98)
Clinical diagnosis	PE	115	6	84
	DVT	5	1	0
	Other	4	22	14
Patients treated with anticoagulants		109	9	51
Test	Result			
	Positive	9	0	
	Negative	1	8	
Arteriography	Total	10	8	0
	Positive	44	0	0
	Negative	15	7	13
Venography	Total	59	7	13
	Positive	35	0	0
	Negative	22	14	20
Leg US scan	Total	57	14	20
	High-probability	6	2	6
	Normal	0	2	0
Lung scan Q	Non-diagnostic	26	6	34
	Total	32	10	40
Lung scan V/Q	High-probability	46	0	0
	Normal	0	4	0
	Non-diagnostic	23	15	15
Total		69	19	15

Table 2 Positive imaging studies in patients with a clinical diagnosis of PE. The lung scans include all ventilation-perfusion and perfusion scans reported as 'high probability'

	n (%)
None	94 (45.8)
One	84 (41.0)
Lung scan	33
Arteriography	5
Leg venography	28
Leg US scan	19
Two	26 (12.7)
Lung scan + leg venography	12
Lung scan + leg US scan	10
Lung scan + arteriography	1
Leg venography + US scan	2
Leg venography + arteriography	1
Three	1 (0.5)
Lung scan + arteriography + leg US	

Among the 205 patients with a clinical diagnosis of PE, 84 (41%) were considered unclassifiable according to the standard criteria (figure 3). Thirty-three of them did not receive anticoagulant therapy. The vast majority represented cases of sudden deterioration or very ill

patients in whom PE was suspected as a possible cause of death. Among the remaining 51 patients who were given anticoagulants, six had a perfusion-only high-probability lung scan, and 35 had a non-diagnostic scan. Ten patients were diagnosed and treated on the basis of clinical suspicion and basic ancillary tests or echocardiography only (figure 3).

Five patients with a clinical diagnosis of PE who were treated with anticoagulants were classified as non-PE according to the standard criteria (figure 3). Three had a normal arteriography, but a high clinical suspicion of PE; two were suspected of having PE, but it was excluded at autopsy.

Discussion

The diagnosis of PE remains a challenging clinical task. It is a serious disease that may be fatal if untreated. Pulmonary angiography, the gold standard for diagnosis, is not always available, nor is it free of complications. Other less invasive techniques, including lung scintigraphy and imaging studies of leg veins, have a less than optimal diagnostic performance. In the past 10 years there have been notable advances in this field, and a number of studies have determined the diagnostic accuracy of the different imaging techniques. In particular, the PIOPED study was a seminal work in establishing the actual value of V/Q scans.² Other studies have analysed the performance of contrast venography,³ leg vein sonography,⁴⁻⁷ and plethysmography.⁸ Nevertheless, given the sub-optimal performance of these techniques, when approaching patients with suspected PE, clinicians need to consider carefully both clinical data and data from basic ancillary studies (such as blood gases and electrocardiogram), along with results from imaging studies. A number of algorithms have been proposed to help clinicians to use this information in a systematic way.⁹⁻¹³ However, it is unclear to what extent this information has been incorporated into current clinical practice.

The results of our study confirm that lung scanning is the most commonly used technique

Figure 3 Distribution of patients with a clinical diagnosis of PE according to the standardised criteria used. The numbers of patients receiving anticoagulants and the imaging studies supporting the clinical diagnosis in those unclassified according to these criteria are also shown

in patients with suspected PE. Certainly, it directly explores the organ in which the suspected abnormality resides and is free of serious complications. Hence it is not surprising that it has become such a widely used technique. However, the diagnostic performance of lung scintigraphy is far from ideal. It is commonly accepted that a normal scan makes PE very unlikely, and allows anticoagulant therapy to be withheld in cases without a very high clinical suspicion of PE. On the other hand, a high-probability V/Q scan is highly suggestive of PE. Unfortunately, a minority of our patients had any of these 'diagnostic scans'. In most cases (64% in the present study, and similar figures in other reports²) scans are non-diagnostic or indeterminate. Thus, most authorities recommend pursuing the diagnosis with other techniques, including leg vein ultrasound or contrast radiography, lung arteriography, and spiral CT scan.¹²⁻¹⁴ However, in everyday clinical practice, clinicians often appear to establish the diagnosis of PE (or to rule it out) on the basis of an indeterminate scan.¹⁵⁻¹⁸ In fact, in almost one third of the patients with such a non-diagnostic scan in our study, no other imaging techniques were performed. In most of these patients a diagnosis of PE was established and they were prescribed anticoagulants.

Eighty-four (41%) of 205 patients with a clinical diagnosis of PE should be considered as unclassified according to the standard criteria defined in this study. This merits some comments. Thirty-three of these patients were not treated with anticoagulants, suggesting that clinicians suspected the diagnosis but they may not have critically appraised or seriously considered it. However, 51 out of 160 patients who were diagnosed and treated for PE (32%) did not have confirmation of the diagnosis by an imaging technique (figure 3). Most of them

(61%) had indeterminate lung scans. The prevalence of PE in patients with indeterminate scans may fluctuate between 16 and 66% depending on their clinical features.² On the other hand, the accuracy of clinicians in estimating pre-test probability of PE is not higher than 70%, with only moderate inter-clinician agreement, as represented by a kappa coefficient of 0.44.¹⁹ A typical 6-month course of anticoagulant therapy for PE carries a 7% risk of serious bleeding.¹³ Thus it clearly seems worthwhile to define further the probability of PE by objective means in patients with indeterminate scans and not to rely only on basic ancillary data and clinical suspicion.

This is a retrospective study of routine clinical practice and the diagnostic procedures were selected by clinicians in a non-systematic way. Thus, it is not feasible to make a meaningful comparison of the diagnostic performance of different techniques. However, some data about the concordance between leg sonography and contrast venography, and between lung scans and arteriography, are disturbing because they suggest that the diagnostic accuracy of those techniques in the routine clinical setting may be considerably lower than in controlled published studies.

In summary, clinicians do not appear to follow the published guidelines when approaching patients with PE. It is unclear whether this reflects difficulties in applying the guidelines in the usual clinical setting, an informed disagreement with them, or insufficient knowledge about the diagnostic performance of the techniques available. Whatever the reason, there seems to be an urgent need to establish and implement consensus hospital protocols, so as to encourage optimal, standardised, treatment of these patients. This would allow the actual diagnostic accuracy of each technique to be established at a local level.

- 1 Miniati M, Pistolesi M, Marini C, et al. Value of perfusion lung scan in the diagnosis of pulmonary embolism: results of the prospective investigative study of acute pulmonary embolism (PISA-PED). *Am J Resp Crit Care Med* 1996;154:1387-93.
- 2 PIOPE investigators. Value of the ventilation/perfusion scan in acute pulmonary embolism. Results of the Prospective Investigation of Pulmonary Embolism Diagnosis (PIOPE). *JAMA* 1990;263:2753-9.
- 3 Hull RD, Hirsh J, Carter CJ, et al. Pulmonary angiography, ventilation lung scanning, and venography for clinically suspected pulmonary embolism with abnormal perfusion lung scan. *Ann Intern Med* 1983;98:891-9.
- 4 Wells PS, Lensing AWA, Davidson BL, Prins MH, Hirsh J. Accuracy of ultrasound for the diagnosis of deep venous thrombosis in asymptomatic patients after orthopedic surgery - a meta-analysis. *Ann Intern Med* 1995;122:47-53.
- 5 Turkstra F, Kuijer PMM, van Beek EJR, Brandjes DPM, ten Cate JW, Buller HR. Diagnostic utility of ultrasonography of leg veins in patients suspected of having pulmonary embolism. *Ann Intern Med* 1997;126:775-81.
- 6 Christiansen F, Kellerth T, Andersson T, Ragnarsson A, Hjortevang F. Ultrasound at scintigraphic "intermediate probability of lung embolism". *Acta Radiol* 1996;37:14-7.
- 7 Bendick PJ, Glover JL, Brown W, Ranval TJ. Serial duplex ultrasound examinations for deep vein thrombosis in patients with suspected pulmonary embolism. *J Vasc Surg* 1996;24:732-7.
- 8 Ginsberg JS, Wells PS, Hirsh J, et al. Reevaluation of the sensitivity of impedance plethysmography for the detection of proximal deep vein thrombosis. *Arch Intern Med* 1994;154:1930-3.
- 9 Quinn RJ, Butler SP. A decision analysis approach to the treatment of patients with suspected pulmonary emboli and an intermediate probability lung scan. *J Nucl Med* 1991;32:2050-6.
- 10 Waltman A. A decision analysis approach to the treatment of the patient with suspected pulmonary emboli and an intermediate lung probability lung scan. *J Nucl Med* 1991;32:2056.
- 11 Hull RD, Raskob GE, Ginsberg JS, et al. A noninvasive strategy for the treatment of patients with suspected pulmonary embolism. *Arch Intern Med* 1994;154:289-97.
- 12 Hirsch J, Hoak J. Management of deep vein thrombosis and pulmonary embolism. *Circulation* 1996;93:2212-45.
- 13 Riancho JA. Actitud diagnóstica y terapéutica ante los pacientes con sospecha de embolismo pulmonar: aplicación del análisis de decisiones. *Med Clin (Barc)* 1996;106:737-46.
- 14 Ginsberg JS. Management of venous thromboembolism. *N Engl J Med* 1996;335:1816-28.
- 15 Khorasani R, Gudas TF, Nikpoor N, Polak JF. Treatment of patients with suspected pulmonary embolism and intermediate-probability lung scans: is diagnostic imaging underused? *AJR* 1997;169:1355-7.
- 16 van Beek EJ, Buller HR, Brandjes DP, Rutten GC, Tencate JW. Diagnosis of clinically suspected pulmonary embolism: a survey of current practice in a teaching hospital. *Neth J Med* 1994;44:50-5.
- 17 Schlager N, Henschke C, King T, et al. Diagnosis of pulmonary embolism at a large teaching hospital. *J Thorac Imaging* 1994;9:180-4.
- 18 Kember PG, Euinton HA, Morcos SK. Clinicians interpretation of the indeterminate ventilation-perfusion of the scan report. *Br J Radiol* 1997;70:1109-11.
- 19 Campo JF, Hernández MJ, Anta M, Saro G, Olmos JM, Riancho JA. Concordancia en el diagnóstico clínico de la tromboembolia pulmonar. *Med Clin (Barc)* 1998;111:121-4.