Ventilation-Perfusion Scintigraphy in the PIOPED Study. Part I. Data Collection and Tabulation

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The Prospective Investigation of Pulmonary Embolism Diagnosis (PIOPED) study of more than 700 patients is the largest existing study of the accuracy of lung scintigraphy in the diagnosis of acute pulmonary embolism. Perfusion scans were obtained in all patients and ventilation scans in almost all, using standardized techniques. Chest radiographs were obtained in all patients within 12 hr of the lung scan. Most patients underwent pulmonary arteriography. The images were interpreted according to a set of interpretive criteria which remained constant throughout the trial. A standardized, detailed description of each image set was derived by consensus of teams of two readers blinded to clinical and arteriographic findings. This communication reports the methods used to describe and categorize the ventilation-perfusion scintigrams obtained in patients who were enrolled in the PIOPED study. Scintigraphic technique is reviewed briefly, probability assessment is described and the scan description is reviewed in detail. The form used to describe the findings on ventilation-perfusion scans is reproduced. Use of this standardized description permits retrospective evaluation of the PIOPED interpretive criteria. In addition, it represents a rigorous approach to scan analysis which could facilitate application of formal interpretive schemes and enhance the reproducibility of lung scan interpretations in the clinical setting.

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A description of the PIOPED study, including the organization, patient enrollment and initial results has been reported (1).

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The criteria used for categorical interpretation of the ventilation-perfusion (V/Q) scans in the PIOPED study were developed initially by the Nuclear Medicine Working Group* in late 1983. These criteria then were tested by the participating nuclear medicine physicians in 1984 in a series of practice sessions which were intended both as field tests of the criteria and as an effort to maximize interobserver agreement in scan interpretation once the trial began. After these sessions, the criteria were finalized and were not changed once patient recruitment began (January 1, 1985).

The PIOPED criteria were formulated using both the published data available at the time (which were based primarily upon retrospective studies) and the collective experience of the members of the Nuclear Medicine Working Group. The investigators involved in this process thus recognized the likelihood that the results of the trial and other subsequent data would demonstrate that some of the PIOPED criteria were invalid. Accordingly, we considered it very important to collect data which would allow a post-hoc analysis of the PIOPED diagnostic criteria. To achieve this goal, we used a computer-compatible data collection form to produce a detailed description of the V/Q images and chest radiograph. The purpose of this report is to present that description form and to explain how it was used.

METHODS

The nuclear medicine methods used in PIOPED have been described in detail (1), but we briefly summarize them again to clarify the entire data collection process.

Scintigraphic Technique

Ventilation studies were performed with 15-30 mCi of ¹³³Xe with patients in the erect position if possible (the supine position, however, was acceptable), using a posterior, 100,000-count single-breath image followed by two 2-min posterior equilibrium images. The washout phase consisted of three 45-sec posterior

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High probability

- ≥2 Large (>75% of a segment) segmental perfusion defects without corresponding ventilation or roentgenographic abnormalities or substantially larger than either matching ventilation or chest roentgenogram abnormalities.
- ≥2 Moderate segmental (≥25% and ≥75% of a segment) perfusion defects without matching ventilation or chest roentgenogram abnormalities and one large mismatched segmental defect.
- ≥4 Moderate segmental perfusion defects without ventilation or chest roentgenogram abnormalities.

Intermediate probability (indeterminate)

Not falling into normal, very-low-, low- or high-probability categories. Borderline high or borderline low.

Difficult to categorize as low or high.

Low probability

Nonsegmental perfusion defects (e.g., very small effusion causing blunting of the costophrenic angle, cardiomegaly, enlarged aorta, hila, mediastinum and elevated diaphragm).

Single moderate mismatched segmental perfusion defect with normal chest roentgenogram.

Any perfusion defect with a substantially larger chest roentgenogram abnormality.

Large or moderate segmental perfusion defects involving no more than 4 segments in 1 lung and no more than 3 segments in 1 lung region with *matching* ventilation defects either equal to or larger in size and chest roentgenogram either normal or with abnormalities substantially smaller than perfusion defects.

>3 Small segmental perfusion defects (<25% of a segment) with a normal chest roentgenogram.

Very low probability

≤3 Small segmental perfusion defects with a normal chest roentgenogram.

Normal

No perfusion defects present.

Perfusion outlines exactly the shape of the lungs as seen on the chest roentgenogram (hilar and aortic impressions may be seen, chest roentgenogram and/or ventilation study may be abnormal).

washout views, two 45-sec posterior oblique washout views and one final 45-sec posterior washout image. The posterior oblique views were included to provide information about the anteroposterior location of a region of abnormal ventilation.

Perfusion studies were performed with 4 mCi of ^{99m}Tc-MAA. A standard eight-view study was obtained with 750,000 counts collected per view for all views except the lateral views. The lateral view with best perfusion was imaged with 500,000 counts while the other lateral view was obtained using the same acquisition time.

Both ventilation and perfusion images were obtained using parallel-hole, low-energy all purpose collimation on gamma cameras with a 38-cm field of view. All PIOPED centers used comparable readout format, employing an 8×10 transparency which normally contained nine images.

Finally, all patients in the trial were required to have a chest radiograph done within 12 hr of the scan. All V/Q scans were interpreted together with the chest radiograph. Standard PA and lateral chest radiographs were preferred, but portable AP studies were acceptable.

Probability Assessment

The studies from all patients were interpreted at the local institutions, and copies then were made of the V/Q scan, chest radiograph and all relevant images from the angiogram. The copies were placed in the patient's hospital radiology file and the originals were sent to the Maryland Medical Research Institute data analysis center.

All V/Q scans were interpreted by at least two readers ("central readers") from the Nuclear Medicine Working Group, using the PIOPED criteria (Table 1) for scan categorization. The cases were submitted to the central readers for official study interpretation by the Maryland Medical Research Institute and no reader ever interpreted a case from his own institution.

The quality of ventilation and perfusion images was rated as satisfactory or unsatisfactory; if unsatisfactory, then as interpretable or uninterpretable.

The scans were categorized as high, intermediate, low or very low probability for pulmonary embolism (PE), or as normal. If a scan met the criteria for high probability, it was placed in that category regardless of whatever other findings may have been present. Therefore, findings compatible with the high probability category (mismatched perfusion defects) took precedence over other findings in assigning the scintigraphic diagnosis. On the other hand, a scan had to be completely free of criteria which violated the standards for low probability or very low probability in order to be placed in those categories. Readers were encouraged to categorize scans as intermediate if they had any uncertainty regarding high probability or low probability categorizations.

A definitive reading depended upon agreement of two readers that the categorical probability was high, intermediate or some combination of low, very low or normal. If the initial readers disagreed (1), a third reader was used with majority opinion prevailing. In those instances when all three readers disagreed, the

case was brought to the entire Nuclear Medicine Working Group for panel discussion and final probability assignment.

In addition to providing a categorical assessment of the probability of PE, each reader designated a point estimate of the probability of PE on a continuous (percentage) scale. This percent probability estimate was based not upon formal criteria but rather upon the reader's own individual experience and "gestalt" impression of the likelihood of PE.

Description of Findings

The final task for each case was to produce a detailed description of the lung scan (including correlations with the chest radiograph) for use in subsequent analyses of the PIOPED criteria or alternative criteria. At intervals throughout the course of the study, "consensus teams" (consisting of the two readers who independently had assessed each scan) met to develop a final consensus description of the V/Q scan which could then be computerized. Because of the different clinical backgrounds of the members of the working group (four were radiologists, four were internists), each team included both a radiologist and an internist. When the two individuals met for the consensus session, each brought his own preliminary V/Q scan description. The chest radiographs and V/Q scans for the patients were present and were reviewed again by both observers at the consensus meeting.

The following basic concepts were used to formulate the consensus descriptions:

- 1. Three types of segmental perfusion defects were recognized. These were the *small defect* (less than 25% of a segment, colloquially called "rat bites"); the *moderate defect* (25%-75% of segment, often called "subsegmental"); and the *large defect* (greater than 75% of a segment, often called "segmental" but not so designated here in order to avoid confusion with nonsegmental defects). No lobar defects were noted as such, rather, they were described by the segments involved.
- 2. The size of a perfusion defect was judged by the area of the region of decreased perfusion seen on the Q scan. It was not mandatory that perfusion be completely absent from a region of perfusion defect. We presumed that a partially occluding embolus could create a perfusion defect with perfusion that was diminished but not absent.
- 3. A mismatched lesion required that both chest radiograph and ventilation scan be normal in the *region* of the perfusion defect (note that "region" as used here and "zone" as used below, are considered to be equivalent terms).

A consensus description form was developed and is shown in Appendix 1. It was designed to be used as follows:

- 1. The consensus form began with a description of the mismatched perfusion defects in the lungs (Appendix 1, Part II, Items 5 and 6). Because of the multiple views available, all mismatched lesions could be localized anatomically to bronchopulmonary segments. However, when lesion localization depended on correlation with the chest x-ray or the ventilation scan, we used lung zones instead since it was felt that the correlative modalities could not render accurately the segmental anatomy. These zones were upper, middle and lower (obtained by dividing the lung into thirds craniocaudally without taking into account lung volume).
- 2. The readers then evaluated the number of small perfusion defects (Appendix 1, Part III).

- 3. This was followed by a description of lesions adjacent to the lung but not within it, such as mediastinal or diaphragmatic abnormalities. Then, any pleural effusions which were present were described (Appendix 1, Part IV, Items 8 and 9).
- 4. The detailed description for the purposes of the main study concluded by enumerating lung parenchymal abnormalities (Appendix 1, Part IV, Items 10 and 11). Lung parenchymal abnormalities were organized primarily according to lesions on the chest radiograph; however, the last entry in each lung zone was reserved for perfusion defects which were associated with a "matching" ventilation abnormality but no radiographic abnormality. For V and Q defects larger than the CXR lesion, the incongruent portions were coded as V/Q matches unassociated with CXR lesions. For example, Item 10A9 would be used for a left upper zone lesion. Perfusion defects larger than accompanying V defects were coded as V-Q mismatches in Part II. Thus, in Item 10 the perfusion defect could not be coded as larger than the corresponding ventilation or radiographic lesion.
- 5. Finally, we included assessment of possible adjunctive signs that were of specific interest to one or more members of the group (Appendix 1, Part V).

A small number of patients (1) were unable to complete ventilation scans. The perfusion images in these patients were compared only to the chest radiograph, using a form which was similar to the one reproduced in Appendix 1 but which omitted the ventilation information. These patients are not included in the analysis in Part II of this communication.

RESULTS

Perfusion scans were rated satisfactory or better in 96% of cases and ventilation scans were so rated in 95% (1).

As has been described elsewhere (1), the central readers were able, using this approach, to achieve relatively high levels of interobserver agreement in prospective assignments of diagnostic category. Agreement between readers was greater than 90% in the high probability (95%), very low probability (92%) and normal (94%) categories. However, agreement in the intermediate (75%) and low probability (70%) categories was less satisfactory, suggesting that further refinement and definition of criteria for these categories would be desirable. Less than 3% of cases required panel adjudication.

In addition, although no numerical measure is available, the consensus teams reported high levels of prospective agreement, as well as ease in achieving consensus, regarding the detailed description of scintigraphic findings.

DISCUSSION

The PIOPED study represents the largest prospective correlation of V/Q scans with pulmonary angiograms and clinical outcome ever performed. Since the enormous effort involved in labeling, collating, distributing and interpreting these scans is unlikely to be repeated, it was especially important that the original scan findings and interpretations be enumerated in a manner amenable to future retrospective statistical analysis. For this reason, it was considered especially important that all data regarding V/Q

scan findings be recorded in such a way as to be accessible by computer for statistical evaluation, not only based on criteria and investigative questions established prior to initiation of data collection, but also on future questions and diagnostic or interpretive algorithms conceived after performance of the study. The scan description form provided as Appendix 1 is the result of these efforts. Understanding of this form is necessary in order fully to appreciate the findings and analyses resulting from PIOPED.

The scan description form is likely to have additional uses for the medical community. Completing the form breaks scan interpretation into many small achievable tasks, a process which may otherwise be daunting to the uninitiated. It may thus provide a useful framework for organizing one's thoughts and thereby provide a useful teaching tool. The use of this form during clinical scan interpretation could be expected to improve internal consistency between members of a group and could be useful in reaching a consensus. Nothing is more distressing to the physician responsible for patient management than

a variety of inconsistent interpretations rendered by various nuclear medicine physicians. The PIOPED investigators were struck by the group's ability to reach consensus in virtually all cases using the standardized descriptor form.

It is hoped that the approach to scan interpretation and the scan description form described here will provide insight into the process by which the Nuclear Medicine Working Group generated data. The PIOPED data represent a vast resource for future analysis and evaluation of interpretive criteria and correlations between clinical, scintigraphic and angiographic manifestations of pulmonary embolism.

APPENDIX

This Appendix demonstrates the data form used for the detailed description of the V/Q images obtained on study patients, and thus the exact form of the data which was used in the analyses in Part II of this report.

PROSPECTIVE INVESTIGATION OF P CENTRAL SCAN IN		iosis			
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	A2. Signature	1	~		
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3. Do the films available for this interpretation	B2. Signature	1	-		
include satisfactory quality wentilation scans, perfusion scans and chest	******				
X rays? (1)(STOP) Yes No					
If satisfactory quality wentilation scame, perfusion scame and chest K rays are not available, complete either form 2Y or 2Z, whichever is					

PART II: Location of Perfusion Hismatch(es) 6. Right lung: Mismatched lesions present -----(1)(2) In this section report only those perfusion scan defects for which accompanying venti-Yes No lation scan is normal and chest X ray is clear (i.e., no airspace disease in the area of perfusion abnormality). If NO, proceed to Item 7. 5. Left lung: A. Whole lung: Mismatched lesions present ---- (1)(2) Absent perfusion ---- (1) Yes No Decreased perfusion ---- (2) If MO, proceed to Item 6. Absent or decreased perfusion in combination ---- (3) A. Whole lung: None of the above ---Absent perfusion --Decreased perfusion ---- (2) If ABSENT PERFUSION, DECREASED PERFUSION OF ABSENT OR DECREASED PERFUSION IN COMBINATION, Proceed Absent or decreased perfusion in combination --(3) to Item 7. Mone of the above ----- (4) B. Right upper lobe: If ABSENT PERFUSION, DECREASED PERFUSION OF ABSENT OR DECREASED PERFUSION IN COMBINATION, proceed 2 0 1 3 1. Number of segments mismatched ----- (0)(1)(2)(3) to Item 6. 2. Number of B. Left upper lobe: moderate subsegments 3 ` 1 mismatched ---- (0)(1)(2)(3) 1. Number of C. Right middle lobe: seemnts mismatched ---- (0) (1) (2) (3) 0 1 2 2. Number of 1. Number of moderate segments subs egments mismatched ----- (0)(1)(2) mismatched ----- (0) (1) (2) (3) 2. Number of C. Lingula: moderate subsegments 0 1 2 mismetched -- (0)(1)(2) 1. Number of D. Right lower lobe: seements mismatched ----- (0) (1) (2) 1 2 0 3 1. Number of 2. Number of moderate segments subsegments mismatched - (0)(1)(2)(3)(4) mismatched ---(0)(1)(2) 2. Number of D. Left lower lobe: moderate subsesments 1 2 3 mismatched - (0)(1)(2)(3)(4) 1. Number of segments mismatched = (0)(1)(2)(3)(4)2. Number of moderate subsecments mismatched = (0)(1)(2)(3)(4)ID No.

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ART IV: Description of Chest X R	ay and Ventilation	Images							
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9. Pleural effusions (check all	•••								
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If NONE, proceed to Item 10.	.]								
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c) Obscures disphragm — d) Up to 1/3 pleural car	vity (1)	(i)	(2) (2)	(3)	(4)	(i)	(2) (2)	(3)	(4
e) About 1/2 pleural car f) 2/3 or more pleural c	cavity (1)	(1)	(2)		(4)		(2) (2)	(3)	(4
g) Fills pleural cavity	(1)	(1)	(2)	(3)	(4)	(1)	(2)	(3)	(4
2. Left pleural effusion									
a) None									
b) Costophrenic angle ofc) Obscures diaphragm	(1)		(2) (2)		(4) (4)		(2) (2)		
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	E.	Other, specify		 (1)	(1)	(1)	(1)	(1)	(1)	(1)
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PART VI: Coordination	i3. Cor	sensus reading p	probability	for pulmonary e	mboli s m:		s.			
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