A Retrospective Study of the Diagnostic Accuracy of a Community Hospital-Based PET Center for the Detection of Coronary Artery Disease Using Rubidium-82

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A retrospective analysis has been carried out to determine the diagnostic accuracy of PET of the heart with ^{82}Rb at a community hospital based center. **Methods:** Utilization statistics were derived from a total of 1460 patients scanned for the first 36 mo of the center's operation. Diagnostic accuracy for detection of coronary artery disease (CAD) was assessed using three readers blinded to the clinical information. A total of 287 rest and dipyridamole-stress scans of patients who had coronary angiograms within 6 mo of the PET scan were selected by the computer for this study. Each rest/stress scan was read by at least two of the three readers. **Results:** The average sensitivity for all three readers was 87% for greater than 67% diameter stenosis and the average specificity was 88% for myocardial regions perfused by normal coronary arteries. The average accuracy was 88% for patients with greater than 67% diameter stenosis. Sensitivity and accuracy improved to 92% and 91% respectively for stenosis greater than 90% in diameter. **Conclusion:** These results compare well with published results from major hospital-based centers and the recently published results from a private PET center in Georgia.

Key Words: PET; rubidium-82; coronary artery disease; sensitivity; specificity; accuracy; PET utilization

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A retrospective study was conducted to obtain utilization statistics and diagnostic accuracy for detecting CAD by PET and ^{82}Rb, at a nonhospital-based center. Most previous reports of the diagnostic accuracy of PET for CAD detection, or reports on detecting CAD by PET, have been from centers at universities or large hospitals (*1–16*), where a staff of support personnel exists for helping with the development of the studies, and where the patient population generally includes a large number of inpatients from the affiliated hospital. Recently, Simone et al. (*17*) published a report on the diagnostic accuracy of coronary artery disease detection with PET and ^{82}Rb at a private PET center in Georgia. This report describes the utilization statistics and diagnostic accuracy of cardiac PET imaging with ^{82}Rb at the first community hospital-based Cardiac PET Center, during it's first 36 mo of operation. The center was operated by private practice physicians using a standard protocol for imaging patients suspected of having CAD.

The imaging protocol was similar to that developed at the University of Texas Medical School in Houston (*1,2*) and used by Simone et al. (*17*). Diagnostic accuracy of ^{82}Rb PET was visually interpreted by three readers blinded to the patient information and compared to standard, visually interpreted, coronary angiograms. As a result of this, there is some inherent inaccuracy built into this study due to the difficulty for the angiographing cardiologists to accurately determine the severity of a coronary artery stenosis (*18–19*). Fleming et al. (*20*) have shown that most cardiologists tend to overestimate the severity of the stenosis and have a trimodal distribution of readings with peaks at 0, 50 and 100% diameter stenosis. Simone et al. (*17*) have also shown a trimodal distribution of the percentage of diameter stenosis as read visually by the catheterization physician at Kennestone Hospital in Marietta, Georgia. We have adopted the trimodal strategy for classifying the severity of stenosis when comparing the detection of perfusion defect by ^{82}Rb PET to coronary artery stenosis severity. Details of the technique used for this classification are presented in the methods section.

METHODS

Utilization Statistics

A computerized database was used to record patient history including coronary angiograms, coronary artery bypass graft (CABG) surgery, percutaneous transluminal coronary angioplasty (PTCA) and rest-stress ^{82}Rb PET data for every patient scanned. Patient data for the first 36 mo of operation, from April, 1988 through March, 1991, were then analyzed for statistics such as

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percentage of patients who had coronary angiograms, percentage of patients who have had a myocardial infarction (MI), percentage of patients who have had more than two coronary angiograms, percentage of patients who have had a thallium scan, percentage of patients who have had CABG surgery, and the percentage of patients who have had a PTCA intervention. Average age and gender of the patient population were also computed and presented.

Diagnostic Accuracy Study Patients

Of 1460 patients scanned from April 1988 through March 1991, 287 patients who had a ^{82}Rb PET scan and a coronary angiogram within a six month period were selected by computer. The reason for this selection process was to present a reduced but representative subset of the population of patient studies to the blinded readers for the analysis of diagnostic accuracy. There were 215 males and 72 females in the group; some of these patients were scanned more than once to evaluate interventions. Of the 287 patients selected, 122 (42.5%) had both PTCA and coronary angiograms, 45 (15.7%) had CABG, and 148 (51.6%) had a history of MI confirmed either by EKG, enzymes, thallium scans or coronary angiography. Clinical indications for PET scans were diagnosis of CAD, evaluation of PTCA, or evaluation of CABG. Coronary angiograms were performed for diagnosis of CAD, and for pre PTCA or CABG evaluations.

Positron Emission Tomography

Patients were fasted for a minimum of eight hr prior to the scan. Caffeine and theophyline were withheld for 24 hr before imaging to reduce blunting of the hyperemic effects of dipyridamole. The location of the heart was marked by x-ray fluoroscopy prior to PET imaging. Scans were performed with the Posicam 6.5 BGO positron camera (*21*) which collects 21 slices simultaneously with a separation of 5.25 mm. Images were reconstructed to approximately 10 mm FWHM resolution. The axial resolution of the slices is 12.5 mm. The patient was positioned in the PET camera at the level of the heart. An attenuation correction scan was performed which collected approximately 200 million counts in 20 to 30 min by scanning the patient with a ring source of ^{68}Ga positron emitter.

Two emission images were obtained during rest and dipyridamole stress with ^{82}Rb chloride as the myocardial perfusion tracer (*22,23*). Rubidium-82 was produced by a portable generator (*24,25*) and infused intravenously into the patient by an automated infusion system (*3*). For each emission scan, 40–60 mCi of ^{82}Rb chloride was infused as a bolus delivered in 10–30 sec. Data collection was started 60 sec following the end of ^{82}Rb infusion to allow for ventricular cavity clearance of ^{82}Rb. Data was acquired over seven min for a total of 20–40 million counts.

Dipyridamole stress images were obtained ten min following the completion of the rest scan. Each patient received 0.142 mg/kg/min of dipyridamole infused for a period of 4 min. Two min following the infusion, hand grip stress at the level of 25% of maximum began as described by Brown et al. (*26*). At 8 min from onset of the infusion of dipyridamole, a second dose of the same amount of ^{82}Rb was injected and the stress emission scan was collected (*1*). Patients who developed angina or side effects from the dipyridamole were given a dose of 50 to 200 mg of aminophylline intravenously. Only those patients who completed both rest and stress scans were selected for this study.

Coronary Angiography

A majority of the patients referred to the PET center for scans were catheterized at Saint Joseph's Hospital of Atlanta, Georgia. The remaining patients were catheterized at either Kennestone Hospital, Emory University or another hospital in Georgia. Coronary angiograms were carried out using the standard protocol by staff cardiologists approved at each of the hospitals. Stenosis severity for each segment of the coronary artery tree structure was visually estimated as percentage of the proximal dimension of the artery by the angiographer, and the data was input to the patient database. A frequency histogram of the recorded percentage diameter stenosis for the coronary angiograms shows a trimodal distribution as predicted (Fig. 1). Since visual methods of estimating stenosis dimension are not very accurate, coronary angiogram data were grouped into three categories based on the estimated percentage diameter stenosis using the trimodal distribution of the data. The three groups were as follows: mild disease, 1%–33% diameter; moderate disease, 34%–66% diameter; and severe disease, 67%–100% diameter. Arteries with greater than 67% diameter stenosis were considered to have a moderately high probability of CAD and were used in the analysis of detecting CAD sensitivity by ^{82}Rb PET.

Image Presentation, Interpretation, and Data Analysis

Emission images of the heart were presented to the reader in three Polaroid images: image 1, the original transaxial images for rest and stress scans; image 2, rotated and transformed images for rest and stress in the short axis and long axis views; image 3, multiple Bullseye views of rest, stress, relative ratio, and absolute ratio images as described by Hicks et al. (*27*). Images were displayed in a special color scale with 3% gradation between colors. There was some variation in image presentation for all patients since some of the software used for image analysis was being refined during the first few months of installation of the PET camera.

Image analysis was carried out by dividing the heart into ten myocardial regions: anterior, anterior-lateral, lateral, posterior-lateral, posterior, inferior, posterior-septal, septal, anterior-septal

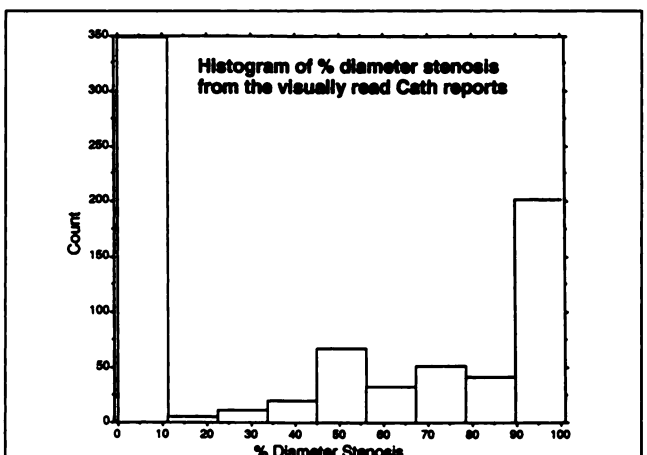

FIGURE 1. A frequency histogram of percentage diameter stenosis visually assessed by the cardiologists for the 287 patient study population. A trimodal distribution is consistent with the published results of Fleming et al. (*20*). The value for no stenosis (0%) has been truncated for display in the graph since many more segments of the arteries had no detected disease.

and apical (Fig. 2). A perfusion defect in each region was characterized as mild, moderate or severe with the extent of the defect subclassified as small, medium and large. Normal perfusion was classified as normal or probably normal. Equivocal classification was not used except to classify an unreadable image. Determination of the severity of perfusion deficit was done visually with the color scale used to obtain approximate range of values. Each PET scan was read by three readers (Reader 1, NM; Reader 2, BW; Reader 3, DJ) blinded to patient history and information. All the readers were blinded to the angiographic information.

Statistical analysis of the results were carried out using the Chi squared and the Fisher's Exact tests. Significance of differences in the results were computed.

Sensitivity

Sensitivity was computed by identifying severely diseased arteries in non CABG or PTCA patients. To minimize errors due to changes in the coronary artery stenosis, during the time between the ^{82}Rb PET scan and the coronary angiogram study only the studies carried out within six mo of each test were used in the analysis. Furthermore, patients were screened for cardiac interventions between the PET scan and the angiograms. Severely diseased was interpreted as greater than 67% diameter stenosis in the proximal third of the artery or one of its major branches. PET scans were analyzed as either positive or negative and compared to catheterization results.

Allocation of PET regions by arteries for sensitivity measurements were as follows; left anterior descending, (LAD): anterior, anterior-septal, apex, septal, anterior-lateral; circumflex, (Cx): anterior-lateral, lateral, posterior-lateral; right coronary artery, (RCA): posterior, inferior, postericr-septal, posterior-lateral, septal. Three PET regions, septal, anterior-lateral, and posterior-lateral, are defined as cross-over regions in which there is a high probability of perfusion from either of the two arteries supplying that region.

Specificity

Specificity was computed using the technique of Demer et al. (*1*) and Simone et al. (*17*) in which the patients with single-vessel disease are selected for normal myocardial regions. Patients with a history of myocardial infarction or CABG were excluded from this group and only patients with no documented changes in the normal arteries within the six mo period were used. Myocardial regions corresponding to normal arteries are then compared to PET regions to compute specificity. Allocation of myocardial regions to coronary arteries is similar to that defined for sensitivity analysis. Myocardial regions with a high probability of being perfused by more than one artery were not used for this analysis.

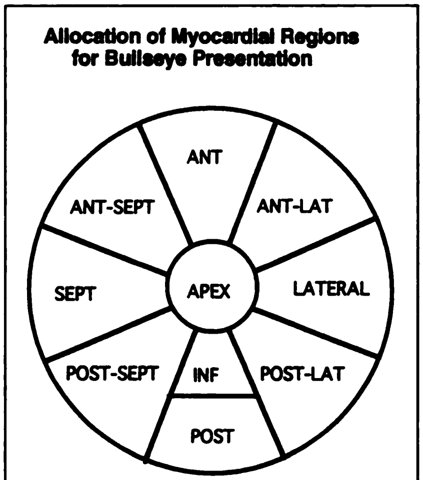

FIGURE 2. Allocation of myocardial regions for Bullseye presentation and image interpretation of PET data.

TABLE 1
Characteristics of Saint Joseph's PET Center Scan Population from April 1988 Through March 1991

Category	Number	Percentage
Number of patient scans	1460	100
Coronary angiograms	740	50.7
Myocardial infarction	473	32.4
PTCA	386	26.4
CABG	264	18.1
Thallium stress scan	302	20.7
High blood pressure	594	35.5

Interobserver Variations

Most previously published studies have used two readers blinded to the clinical data. In case of a disagreement between the two readers, either a third independent reader is brought in to arbitrate the readings, or the readers are asked to reread the images with the knowledge of the existence of a disagreement. The readings with known disagreement are then modified. We have used three readers so that all the images are read by at least two readers. No modification of the reading was done once the images were read. Sensitivity and specificity for each reader was computed independently and average values obtained. Values of sensitivity for two or more readers in agreement were computed and agreement between readers was analyzed.

RESULTS

Utilization Statistics

The PET center scanned 1460 patients with ^{82}Rb PET and dipyridamole-induced stress test during the first 36 mo of operation. Out of the 1460 total patients scanned, 740 (50.7%) had a coronary angiogram, 473 (32.4%) had a history of MI, 264 (18.1%) had CABG surgery, 386 (26.4%) had PTCA, and 302 (20.7%) had thallium stress test. A summary of the data is tabulated in Table 1.

A subset of these patients who had a Cath and PET within six mo of each test were selected by computer for blinded reads. An analysis of the 287 patient subset of this population showed that 51.6% had a history of MI, 42.5% had PTCA and 15.7% had CABG surgery. This data is presented in Table 2.

TABLE 2
Characteristics of the 287 Patients Selected for Diagnostic Accuracy Readings

Category	Number	Percentage
Number of patient scans	287	100
Males	215	74.9
Myocardial Infarction	148	51.6
PTCAs	122	42.5
CABG	45	15.7

TABLE 3
Sensitivity, Specificity and Accuracy as a Function of Percent Diameter Stenosis for All Three Readers

	% Dia. stenosis	Reader 1	Reader 2	Reader 3
Sensitivity				
	67.0	88/101 (87%)	51/57 (90%)	53/64 (83%)
	83.5	76/85 (89%)	43/47 (92%)	47/52 (90%)
	90.0	66/73 (90%)	35/37 (95%)	43/45 (96%)
Specificity				
	0.0	96/112 (86%)	38/44 (86%)	70/75 (93%)
Accuracy				
	67.0	194/223 (87%)	89/101 (88%)	123/139 (89%)
	83.5	172/195 (88%)	81/91 (89%)	117/127 (92%)
	90.0	162/183 (89%)	73/81 (90%)	113/120 (94%)

Sensitivity, Specificity and Accuracy

Table 3 lists the values of sensitivity, specificity and accuracy for all three readers. Sensitivity values ranged from 83%–90% for the three readers, while specificity values ranged from 86%–93%. The average sensitivity value for the three readers was 87% for stenosis dimensions of greater than 67%. For arteries with greater than 83.5% diameter stenosis, the sensitivity value was 90%, and for greater than 90% diameter stenosis the sensitivity value was 92%. The change in average sensitivity values from 67%–90% diameter stenosis was found to be statistically significant with a chi-squared p value of less than 0.05. The average specificity values for the three readers was 88%. Accuracy values for the three readers were very close at 87%, 88% and 89%, and the differences in these values is not statistically significant. Average accuracy values for the three readers were 88%, 90% and 91% for stenosis diameters equal to or greater than 67%, 83.5% and 100% respectively (Table 4).

The interobserver differences in sensitivity, specificity and accuracy were not found to be statistically significant for the three readers. There is a slight trend for a reader with high sensitivity to have slightly lower specificity and vice versa. However, this observation is not statistically supported by this study. The changes in accuracy of the average readings for 67% and 90% diameter stenosis were also not statistically significant.

DISCUSSION

Utilization Statistics

We have reported on some of the statistics related to the utilization of this PET center because it was the first community hospital-based center established in the United States for CAD detection using ^{82}Rb and PET. In analyzing the utilization statistics for the Saint Joseph's Hospital PET center, there are several important issues to be considered. First, the PET center was started at a time when ^{82}Rb had not yet been granted a New Drug Approval (NDA) status from the FDA. For several months it operated under an Investigational New Drug (IND) status and there were some restrictions on who should be scanned. Reimbursement for cardiac PET scans has not yet been approved for Medicare and Blue Cross patients in the state of Georgia. Since these two medical insurance agencies account for over 60% of patients insured, many of these patients could not be scanned.

Diagnostic Accuracy

This study was designed to document the diagnostic accuracy of clinical cardiac PET with ^{82}Rb at a clinical site where physicians use this technology in every day practice. The images read in this study were assessed using the traditional clinical evaluation techniques of that time. Since then, newer software and image presentation schemes have improved the quantitative aspect of image interpretation. Also, angiographers are using some form of quantitative method to measure stenosis severity. Perhaps the most important aspect of this study is that it includes data from the first day of operation. Several of the patients were imaged with software that was being tested in a clinical setting.

Comparison of Accuracy Results with Other PET Studies

A strict comparison of the results obtained with this study to another published study is difficult because of differences in patient populations and methods of data analysis used. However, a comparison can be made with the Kennestone study (*17*) because of the similarity of equipment, isotopes and the patient imaging protocol. In

TABLE 4
Average of Three Readers for Sensitivity, Specificity and Accuracy Values

	% Diameter stenosis	Combined total	Average
Sensitivity			
	67.0	(192/222)	87%
	83.5	(166/184)	90%
	90.0	(144/155)	92%
Specificity			
	0.0	(204/231)	88%
Accuracy			
	67.0	(406/463)	88%
	83.5	(320/413)	90%
	90.0	(348/384)	91%

TABLE 5
Comparison of Sensitivity, Specificity and Accuracy of ^{82}Rb PET with Other Published Results

Study	No. of patients	Sensitivity (%)	Specificity (%)	Accuracy (%)
Go et al. (*3*)*	202	93	78	90
[Go et al. (*3*)]†	(132)	(95)	(82)	(92)
This study	287	87	88	88
Simone et al. (*17*)	225	83	91	89
Stewart et al. (*4*)*	81	84	88	85

*−50% diameter stenosis.
†Subset of patients without cardiac interventions.

Table 5, a comparison of our results with the Kennestone study published by Simone et al. (*17*) and two other studies, one by Go et al. (*3*) from Cleveland Clinic and the other by Stewart et al. (*4*) from Michigan University are presented.

The results from this study are comparable to the Kennestone study. The diagnostic accuracy obtained in this study for the three readers is 88% compared to 89% for Simone et al. Go et al. (*3*) have found an accuracy of 90% (92% for nonintervention patients subset) and Stewart et al. (*4*) have found 85%. Sensitivity for greater than 67% diameter stenosis was better in this study at 87% compared to 83% published by Simone et al. (*17*). Specificity in this study (88%) was slightly lower than the Simone study at 91%. Neither the sensitivity nor the specificity differences are statistically significant. Comparing the results from Go et al. (*3*) and Stewart et al. (*4*) with this study, we find at 88% the accuracy of this study falls between that of Go et al. (*3*) at 90% and 85% for Stewart et al. The sensitivity is higher for Go et al. (*3*) at 93% compared to 87% for this study and 84% for Stewart et al. (*4*). Specificity is lower (78%) for Go et al. (*3*) than for this study (88%).

Combining the Results with the Kennestone Study

Since this study and the Kennestone study (*17*) use the same PET equipment (Posicam), software, imaging protocol, and image analysis procedures, it is possible to combine the results from these two studies (Table 6). The three readers for the Kennestone study were Reader 1-NM, Reader 2-GS and Reader 3-DP. The combined data set includes a total of 512 patient studies read by five different readers. Reader 1 in both the studies is NM. The individual sensitivity values for 67% diameter stenosis range from a low of 76% to a high of 90% for an average of 85%. Specificity values ranged from a low of 86% to a high of 93% for an average value of 90%. Accuracy ranged from 86% to 91% for an average of 88%. Differences in the accuracy values for the different readers were not found to be statistically significant. Similarly, differences in the averaged values of sensitivity, specificity, and accuracy for the two sites were not found to be statistically significant.

Sensitivity as a Function of Severity of Disease

The sensitivity values for the detection of CAD by ^{82}Rb PET were found to be a function of the severity of the disease for all three readers. Table 7 lists the average sensitivity values for three readers as a function of the diameter of stenosis and the presence of myocardial infarction. The average sensitivity for the three readers improved from 87% to 92% when the severity of the disease was changed from 67% to 90% diameter stenosis ($p = 0.049$). The average sensitivity value for 50% diameter stenosis of 81% is significantly different ($p = 0.001$) than for 90% diameter stenosis of 92%. Average sensitivity for patients with a history of myocardial infarction was 92%, signifi-

TABLE 6
Analysis of the Combined Data from the Kennestone and the Saint Joseph Studies

Institution	Reader	% Dia.	Sensitivity	Specificity	Accuracy
Ken	Reader 1	67%	24/29 (83%)	103/111 (93%)	127/140 (91%)
Ken	Reader 2	67%	22/29 (76%)	114/124 (92%)	136/153 (89%)
Ken	Reader 3	67%	26/29 (90%)	108/124 (87%)	134/153 (89%)
St. J	Reader 1	67%	88/101 (87%)	96/112 (86%)	194/223 (87%)
St. J	Reader 2	67%	51/57 (90%)	38/44 (86%)	89/101 (88%)
St. J	Reader 3	67%	53/64 (83%)	70/75 (93%)	123/139 (89%)
Total	(Average)	67%	264/309 (85%)	529/590 (90%)	803/909 (88%)

Differences in accuracy among readers is not statistically significant. Total number of patients: 512.

TABLE 7
Change in Sensitivity as a Function of Severity of Coronary Artery Disease

%Diameter stenosis	Avg. Sn	Statistical significance
50%	81%	Highly significant for 50%–90%
67%	87%	Significant for 67%–90% stenosis
83.5%	90%	ns
90%	92%	
Non-MI patients	73%	Highly significant
MI patients	92%	

Sensitivity values are averaged for the three readers and shown as a function of the diameter of stenosis and for the case of patients with or without myocardial infarction.

cantly different from 73% for patients with no history of myocardial infarction.

Improved sensitivity with increased severity of CAD is not surprising. In a theoretical study Mullani (*28*) has shown that perfusion severity detected by PET is directly related to the severity of the coronary artery stenosis. Therefore, the more severe the stenosis, the greater the perfusion deficit and the higher the probability of being detected noninvasively by PET. Simone et al. (*17*) have shown a similar improvement in sensitivity as a function of the size of the stenosis in their PET study.

CONCLUSION

We have presented the utilization statistics and diagnostic accuracy results from a community hospital-based PET center using ^{82}Rb PET to diagnose CAD. The accuracy of detecting coronary artery disease compares well with other PET centers. The diagnostic accuracy of 88% obtained is not significantly different from the diagnostic accuracy reported in three previously published studies using ^{82}Rb PET. A community hospital based PET center can be operated effectively and accurately for a prescribed diagnostic test if proper imaging protocols and quality control are implemented.

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(continued from page 7A)

FIRST IMPRESSIONS

Fluid Connection from Peritoneum to Massive Hydroceles

FIGURE 1.

PURPOSE

A 35-yr-old male, intravenous drug user developed endstage liver disease secondary to chronic, active hepatitis. A Denver shunt—a conduit with a one-way valve from the peritoneum to the superior vena cava—had been inserted. Subsequently, there was an episode of peritonitis, which was treated with antibiotics. To evaluate shunt patency, radiolabeled macroaggregated albumin (MAA) was placed into the peritoneal fluid via a left lower-quadrant injection. Tracer distribution is seen within the peritoneal fluid, separated by loops of the bowel. On the initial images, activity is seen extending toward the bottom of the field of view. After repositioning, two "fingers" of radioactivity were noted to extend below the usual peritoneal boundary. This represents radiotracer entering massive hydroceles via fluid connections. This pathway was confirmed a few days later at autopsy. Significant intra-abdominal fluid may have unusual sites of distribution, such as into hernial sacs as well as in to the thorax. This image demonstrates the importance of tracing limits of radiotracer activity seen at the periphery of a field of view.

TRACER

Technetium-99m-MAA

ROUTE OF ADMINISTRATION

Intraperitoneal tap

TIME AFTER ADMINISTRATION

2.50 hours

INSTRUMENTATION

Searle ROTA gamma camera.

CONTRIBUTORS

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INSTITUTION

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