# Reproducibility of Thallium-201 Exercise SPECT Studies

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A detailed analysis of intrapatient reproducibility of exercise SPECT thallium studies is presented. Methods: Twenty patients in stable condition were re-examined with exercise-redistribution SPECT <sup>201</sup>Tl within 3–9 days without intervening procedures. At peak stress, 3.5 mCi <sup>201</sup>Tl were given intravenously 1 min prior to exercise termination. SPECT imaging started at 5 and 180 min. Acquisition and processing protocols were the same for all studies. Coronary angiography was performed on 19 patients and showed coronary artery disease (CAD) in 18, and no CAD in one; one patient did not have coronary arteriography. Results: For 16 of 20 patients, exercise levels and ECG were comparable for both studies. Ten patients reproduced ST-segment depression; two reproduced angina; one had left bundle branch block (LBBB) on both studies after 1 min of exercise. The remaining seven patients had no ECG changes or symptoms during exercise. Four of 20 (20%) thallium scans differed: three in degree of redistribution and one (5%) in presence of a second stress defect. In three of four patients whose thallium studies showed some nonreproducibility, there were differences in exercise. Thallium results were identical in 15 of 16 patients whose ECG/exercise tests were reproducible (94%). Interobserver agreement was 95%. Conclusion: There was excellent reproducibility of <sup>201</sup>TI SPECT scintigraphy in patients who reproduced exercise test performance and symptoms.

Key Words: thallium-201; cardiac SPECT; reproducibility; coronary artery disease

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Diagnostic medicine depends on the accuracy of its tests. In the case of stress thallium SPECT myocardial perfusion imaging, accuracy is linked to reproducibility of images and of image interpretation. Considerable attention in the published literature has focused on interobserver and intraobserver variabilities in interpreting these studies (1), on technical and processing variabilities in reproducing the studies (2), and quantitative approaches to standardize these variables (3-6), particularly interpretive variables. There has been, however, no definition of inherent variabilities of the test itself as demonstrated in the same patient from one day to the next.

The purpose of this study is to define the reproducibility of SPECT exercise thallium myocardial perfusion images and quantitative bull's-eye, focusing on the inherent variabilities in the test as measured by repeat studies on the same patient and excluding as much as possible interobserver, intraobserver interpretive variabilities or technical and processing variabilities. Since thallium studies are primarily used in patients with coronary artery disease (CAD), the subject population for this study consisted primarily of patients with stable CAD and some patients who were evaluated for suspicion of CAD, but were found to be normal.

#### METHOD

Twenty stable patients referred for a treadmill exercise SPECT thallium study for evaluation of CAD agreed to a repeat treadmill exercise SPECT thallium study within 3–10 days. There was no change in medications and no procedures were performed between the two studies. The study was approved by the Emory University Institutional Review Board, and informed consent was obtained from all participants.

Both studies were performed using an identical methodology. All patients underwent symptom-limited treadmill exercise, using the Bruce protocol, between 8:30 a.m. and noon. Exercise time and heart rate achieved on the first exam were repeated as closely as possible on the second exam.

At peak exercise, 3.5 mCi of  $^{201}$ Tl were injected intravenously; exercise was maintained for an additional minute and tomographic imaging was performed 5 and 180 min later. Acquisition and processing protocols were the same for all 40 studies. A single-head SPECT scintillation camera was used to acquire 32 views over 180° with step-and-shoot methodology for 40 sec per stop, progressing from the 45° RAO to the 45° LPO projections. Low-energy, all-purpose collimation was used with the camera peaked at 72 keV using a 20% window. Processing was performed using ramp-Hanning filtered backprojection to transaxial tomographic

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images which were reformatted in the short, vertical and horizontal long axes.

## Patients

The study population consisted of 17 men and 3 women with ages ranging from 39 to 79 yr (mean  $58 \pm 10$  yr). Eighteen patients had CAD (13 of 18 patients had undergone postrevascularization procedures). One patient had normal coronary arteries and one with a normal thallium study did not have catheterization. Coronary angiography was performed within 1–7 days before or after <sup>201</sup>Tl imaging in 14 patients. Five patients had catheterization 9–12 mo before <sup>201</sup>Tl imaging.

# **Quantitative Analysis**

Quantitative bull's-eye analysis for stress and delayed data was performed using the Emory technique as previously described (4). Global myocardial perfusion was mapped to a polar display consisting of 600 pixels, with the intensity for each pixel related to the maximal thallium uptake for a corresponding area of myocardium.

Each patient's perfusion was compared to a gender-matched normal file for stress and delayed imaging. Pixels were defined as abnormal on quantitative analysis when <sup>201</sup>Tl uptake was >2.5 s.d.s below the gender-matched normal file.

Acquisition, tomographic reconstruction parameters, bull'seye processing, quantitative values of extent scores (pixels >2.5 s.d.s below gender-matched normal file data), severity scores (total number of s.d.s lower than normal file mean values for all pixels in the defect region) and reversibility scores have been previously described (4, 7, 8).

The extent score describes the size of the defect and is calculated by summing the number of abnormal pixels (those where counts are >2.5 s.d.s below the gender-matched normal file mean values).

The severity score reflects both size and severity of the abnormality and is calculated by summing the number of standard deviations of pixels exceeding 2.5 s.d.s below mean normal levels for all pixels in the defect. Thus, the minimum severity score is 2.5 multiplied by the extent score.

The s.d. of the normal file are generally larger for delayed images than stress images. For this reason, direct comparison of stress to delay extent scores as well as stress to delay severity scores is not appropriate for assessing degree of reversibility. Thus, with use of this approach, the stress defect of a true fixed defect might appear more extensive and severe when compared to the stress normal file than the delayed defect compared to its normal file and might therefore appear reversible.

The reversibility bull's-eye score reflects significant change from stress to delay regional counts in a defect (ischemic). It is derived by comparing pixels in the bull's-eye at stress to delayed data. After normalization, the stress pixels are subtracted from delayed data and displayed as a polar bull's-eye plot so that positive values show reversible areas. An initial stress defect is reversible if it improves by >1.5 s.d. as compared to gendermatched Emory normal controls in more than 25% of the initial abnormal area.

Visual analysis represents independent assessment of 40 thallium SPECT studies (from 20 patients) conducted by two experienced readers (NA, JZ). The left ventricle was divided into three vascular territories: LAD, RCA/PDA and LCX (4). Each study was evaluated for defect size, presence of and degree of redistribution and vascular territory of lesion (location of the defect).

A defect overlapping two vascular territories was assigned to the territory in which more than half the defect was located. Using a clock-face analogy, an inferolateral defect which crossed the 6 o'clock line was assigned to the RCA/PDA territory; if it crossed the 3 o'clock line, it was assigned to the LCX territory; if it crossed both lines, it was assigned to both territories; if it crossed neither line, it was assigned to the territory closest to more than half of the defect area.

*Criteria for Defect Size.* Based on the reader's synthesis of visual and quantitative data, the following criteria for defining defect size were used:

- 1. Large defects in the LAD territory were perfusion deficits exceeding one-third of the total territory. For RCA/PDA or LCX territories, a large defect occupies more than half of each territory (Fig. 1).
- 2. Moderate defects occupied one-sixth to one-third of the LAD territory, one-fourth to one-half of the LCX or RCA/ PDA territory.
- 3. Small defects occupied less than one-sixth of the LAD territory, less than one-fourth of the RCA/PDA and less than one-fourth of the LCX territory.

Criteria for Degree of Redistribution. None (no redistribution) indicated no change between initial and 3-hr delayed images. Partial indicated some redistribution but less than 50% normalization of the initial perfusion defect's extent and severity. Nearly complete and complete redistribution was recognized when perfusion deficits seen on initial images were not as apparent on the 3-hr delayed images with more than 50% normalization of extent and severity of the initial defect. For complete redistribution, more than 75% normalization was evident. Reverse redistribution occurred when relative thallium uptake in the initial stress defect region relative to other normal areas was decreased on 3-hr delay compared to initial images. Total agreement was present when readers identified a defect in the same anatomical location with the same degree of redistribution and size on both studies.

Statistical Analysis for Severity (Sds) and Extent (Pixels). All possible combinations of severity and extent scores were compared regarding stress/delay and Day 1/Day 2 results. Three sets of paired samples based on extent scores (see Table 4), including stress scores Day 1/stress scores Day 2, delay scores Day 1/delay scores Day 2, and reversibility Day 1/reversibility Day 2, yielded six sets of variables (mean  $\pm$  s.d.) which were analyzed using Student's t-test for paired samples. Also analyzed were severity scores for Day 1 and Day 2 data (see Table 3).

# RESULTS

Exercise performance results from two separate days are presented in Table 1.

For 16 patients, exercise levels and symptoms were comparable. Of the four whose exercise levels (duration and/or heart rate achieved) and/or presence of angina (two patients) differed between their two studies, three also showed some differences on their thallium images (Table 2).

# **Electrocardiographic Exercise Test**

Exercise time differed in three patients by more than 1 min: 2.3 min for Patient 5, 1.3 min for Patient 19 and 1.5 min for Patient 14 with exercise-induced left bundle branch block (LBBB) for 1 min on both studies.

Mean values of the maximal heart rate for Days 1 and 2 were  $155.8 \pm 15$  versus  $156 \pm 14.9$  bpm. Mean values of the



FIGURE 1. Example of reproducible study. Large defects are nonreversible on the 3-hr delayed study in LAD and RCA territories for both Day 1 and Day 2. Also seen is inferoseptal partial redistribution reproduced on both Day 1 and Day 2. On Days 1 and 2, exercise-induced LBBB at 1 min was noted. The patient (no. 14) is a 52-yr-old male who had coronary bypass surgery in 1989.

exercise times for Days 1 and 2 were  $10.4 \pm 3.2$  versus  $10.7 \pm 2.9$  min.

Eleven patients reproduced significant ST-segment depression (1-3 mm) and six patients did not show any ST changes. One failed to reproduce significant ST-segment change (Patient 9); one reproduced exercise-induced LBBB after 1 min of exercise (Patient 14); and one had ECG machine malfunction (Patient 15).

Two patients (nos. 7, 15) reproduced typical angina on both studies and two patients (nos. 5, 6) had angina described only in one of the two studies.

#### **Thallium Scintigraphic Images**

Thallium results were identical (Fig. 1) in 15 of 16 patients (94%) with reproducible ECG exercise and symptoms (Table 2).

Three of 20 (15%) thallium scan pairs differed in the degree of redistribution, although all showed redistribution. One patient showed a second stress defect on one study only (Fig. 2).

In three of the four patients whose studies showed some difference between two exams, there were differences in exercise: presence of angina on one of the two studies for Patients 5 and 6 or difference in the duration of exercise and maximal heart rate achieved (Patients 5 and 19).

# Statistical Analysis of Defect Severity and Extent

Results of extent, severity and reversibility scores are presented in Tables 3 and 4. The large standard deviations shown in the tables reflect differences between patients, i.e., varying degrees of perfusion defects and ischemia, which were measured using student's paired t-test, and not differences between studies.

The mean  $\pm$  s.d.s for the 20 patient bull's-eye pixel stress scores (extent scores and severity scores) were not statistically significantly different on Day 1 compared to Day 2 (repeat exam). Likewise, the mean 3-hr delay scores on Days 1 and 2 were also not statistically significantly different.

In contrast, as expected, there were significant differences in the comparison of stress extent (p < 0.0015) and severity (p < 0.0028) scores to 3-hr delayed scores for both Day 1 and Day 2 studies. These data confirm expected differences in scores between stress and delayed data because of ischemia in some patients, as well as statistical broadening of normal file standard deviation values on delayed data compared to stress.

# **Reversibility Score**

Reversibility scores (Table 4) were calculated for 40 studies (20 patients) after image assessment by the readers. Ten patients had zero reversibility on both studies, three patients reproduced a reversibility score greater than 0 on both studies and seven showed reversibility on only one study. Four of those seven patients were visually assessed as different in the degree of redistribution or presence of a second defect; three of those four showed differences in exercise performance between both studies. The remaining three patients (nos. 3, 7 and 10) were visually assessed as fixed, implying a discrepancy between the visual and quantitative readings on one of the two thallium tests. Two of these patients (nos. 7 and 10) had small defects and minimal reversibility, but one (Patient 3) had large perfusion defects in two vascular territories. The stress score on Day 1 was 1935 and the reversibility score was 286; the Day 2 stress score was 1582 and the reversibility score was zero. The study for the first day was quantitatively positive for reversibility, but visual assessment was fixed for both days. This probably represents a significant discrepancy between the visual and quantitative data.

		TAB	LE 1		
Clinical	and	Exercise	Stress	Treadmill	Data

		Study 1				Study 2			
Patient no.	Sex/Age	EX duration (min)	ST mm	Max HR	A	EX duration (min)	St mm	Max HR	A
1	M/52	12.9	2	166	_	12.9	3	164	
2	M/54	9.0	1	159		9.0	1	154	_
3	M/63	7.7	2	161		7.6	2	148	
4	M/47	15. <del>9</del>	2	137		15.1	2	163	
5	M/65	5.6	1	134	_	7.9	2	134	y
6	M/39	13.8	0	173	y	14.3	0	176	-
7	M/64	6.3	3	137	ý	6.3	3	131	у
8	M/61	13.9	2	170	_	14.2	2	168	_
9	M/49	16.1	2	173		15.7	0	169	_
10	M/63	10.0	1.5	151		10.8	1.5	146	_
11	F/48	12.0	0	174	_	12.6	0	176	_
12	M/64	12.3	0	133		12.0	0	133	_
13	M/63	9.8	0	166	_	9.7	0	161	_
14	M/52	9.0	*	145		10.5	*	154	
15	M/42	8.8	1.5	145	v	9.0	+	148	v
16	M/64	10.75	0	180	_	11.0	0	160	_
17	F/75	9.7	1.5	149		9.7	1.0	148	_
18	M/61	12.6	1.0	168		12.5	1.0	176	_
19	F/50	7.0	3.0	153	_	8.3	2.0	174	
20	M/79	5.6	0	143	_	6.3	0	138	_
Mean ± 1 s.d.		10.43 ± 3.18		155.8 ± 15.0		10.75 ± 2.86		156.0 ± 14.9	

\*Exercise-induced LBBB at 1 min.

<sup>†</sup>ECG machine malfunction.

A = angina during exercise on treadmill; EX duration = time of exercise on treadmill; STmm = ST-segment decrease on ECG test; Max HR = maximum heart rate achieved during ECG test.

#### Interobserver Validation

The studies were read in several sessions by two experienced observers blinded to results of the other study on each patient. Reprocessing of two studies based on physician review of the quality control data was performed in an effort to render data from different cameras and different hospitals more uniform. For location of perfusion defect, there was 100% agreement; for defect size, there was agreement in all cases except one patient (no. 15), a 5% disagreement; for degree of redistribution there was 100% agreement. There was total agreement between the two readers on size, degree of redistribution and location in 19 pairs of the 20 matched studies (Table 5).

# DISCUSSION

The data substantiate a high level of intrapatient reproducibility of treadmill exercise SPECT thallium myocardial perfusion imaging and quantitative bull's-eye testing for patients with stable CAD. The data also demonstrate the correlation of image and quantitative analysis with levels of stress achieved in patients with CAD. The results indicate that reproducibility requires equivalence of treadmill exer-

TABLE 2
Combined Results From Electrocardiographic Testing and Thallium Scintigraphy

	Positive <sup>201</sup> TI Reproducibility	Lacking <sup>201</sup> TI Reproducibility*
Reproduced exercise ECG and	15	1
symptoms on both studies:	(Patients 1, 2, 3, 4, 7, 8, 10,	(Patient 15)
	11, 12, 13, 14, 16, 17, 18, 20)	
Ex. ECG and symptoms on both	1	3
studies not reproduced	(Patient 9)	(Patients 5, 6, 19)



FIGURE 2. Example of nonreproducible study. First exam (Day 1) showed only an anteroseptal defect (arrowhead). The second exam (Day 2) showed the anteroseptal defect and a new inferior defect (curved arrow). The patient did not reproduce angina on the second exam. The patient (no. 6) is a 39-yr-old man with documented coronary artery disease (LAD mid 60%, RCA 100%).

cise performance on the part of the patient. When this requirement is met, reproducibility of  $^{201}$ Tl results was seen in 94% of the patients studied. Interobserver agreement for two experienced readers working in the same department was 95%.

Importance of exercise at the same level was demonstrated in a study by McLaughlin et al. (3) in which reproducibility was achieved in 91% of subjects when maximal exercise was reproduced, and in only 53% when submaximal levels of exercise in a subgroup of patients with ischemic defects were compared to their maximum exercise scan results. The results reported here and those of McLaughlin et al. are particularly important for establishing the necessity to compare similar exercise <sup>201</sup>Tl studies when <sup>201</sup>Tl is used to follow a patient over time for assessment of new symptoms.

Given the complexities of SPECT stress <sup>201</sup>Tl imaging, 94% reproducibility is quite remarkable. This result, however, reflects reproducibility within this institution. Comparison of two <sup>201</sup>Tl studies done at different centers on the same patient may not generate reproducibility rates as high as those achieved at this center. Wackers et al. (5) recently reported on factors affecting uniformity of interpretation of planar <sup>201</sup>Tl imaging in a multicenter trial. They found suboptimal reproducibility and poor interlaboratory agreement in the interpretation of <sup>201</sup>Tl stress planar images. For 24 clinical centers, the agreement on 556 planar thallium imaging studies compared with the core laboratory's interpretation was poor (kappa values 0.27-0.36). Use of SPECT quantitative techniques (i.e., the bull's-eye) and standardization of terminologies to describe extent and severity of perfusion defects as presented here are important factors in minimizing variabilities which contribute to nonreproducibility. Wackers et al. (5) pointed out that lack of standardization in image display and lack of objective criteria for interpretation were major factors in the poor reproducibility of interpretations in their study.

Many factors impact potential nonreproducibility of SPECT <sup>201</sup>Tl studies. Excluding technical errors, variable incidences and degrees of exercise-induced coronary vascular spasm may accompany different levels of exercise. The influence of dietary intake hours prior to the study, mental and emotional stress at the time of the study and other potential factors which may affect the relative severity of coronary artery flow impairment or vessel abnormality are speculative and remain undocumented.

 TABLE 3

 Reproducibility Severity of Standard Deviations

Patient no.	Study 1 (Stress)	Study 1 (Delay)	Study 2 (Stress)	Study 2 (Delay)
1	551	113	829	40
2	433	437	187	329
3	1935	1246	1582	1871
4	798	453	577	354
5	693	305	613	711
6	77	18	101	88
7	464	233	422	142
8	54	77	111	158
9	176	139	242	137
10	154	43	118	145
11	92	28	17	78
12	24	43	41	63
13	156	13	321	96
14	1794	1254	1593	933
15	700	182	631	316
16	624	799	458	628
17	108	66	160	304
18	284	317	247	334
19	100	40	420	70
20	49	0	10	0
Mean ± 1 s.d.	467.0 ± 538.9	435.4 ± 456.3	<b>290.3 ± 384.2</b>	339.9 ± 436.3

The <sup>201</sup>Tl results presented here are valid for tests performed with minimal technical errors of acquisition and processing. Each study was carefully reviewed for potential processing errors by two physician readers. Reprocessing by an experienced technologist to ensure comparability of SPECT images between Day 1 and Day 2 studies was performed at the request of the readers in two cases.

In an interinstitutional study of observer variability for agreement in interpretation between two institutions (2), investigators reported "complete or essential" agreement

<u></u>		Reproducibility	Reversibility score			
	Study 1 (Stress)	Study 1 (Delay)	Study 2 (Stress)	Study 2 (Delay)	Day 1	Day 2
1	123	39	204	15	177	483
2	118	110	60	97	0	0
3	284	229	260	352	286	0
4	162	100	118	90	77	64
5	206	97	182	210	44	0
6	24	7	31	28	23	0
7	131	74	136	48	19	0
8	19	23	35	51	0	0
9	56	46	71	48	0	0
10	49	16	40	47	15	0
11	30	10	7	25	0	0
12	9	16	15	21	0	0
13	49	5	90	32	0	0
14	332	264	309	237	11	23
15	179	58	152	93	0	95
16	188	221	124	167	0	0
17	33	22	48	85	0	0
18	81	94	73	93	0	0
19	31	14	89	24	0	159
20	17	0	4	0	0	0
Mean ± 1 s.d.	106.1 ± 93.7	72.3 ± 79.9	106.2 ± 83.5	92.3 ± 91.1	32.6 ± 72.9	41.2 ± 112.0

TABLE 4Statistical Analysis

 TABLE 5

 Interobserver Agreement on Defect Size, Defect Location and Level of Redistribution for the Two Studies (S1 and S2) for Each Patient

		Reader 1 Reproducibility between $S_1$ and $S_2$			Reader 2 Reproducibility between $S_1$ and $S_2$			
Patient Defect	Size	Degree of redistribution	Location	Defect	Size	Degree of redistribution	Location	
1	L	Y	Y	Y	L	Y	Y	Y
2		Y	Y	Y		Y	Y	Y
3	L	Y	Y	Y	L	Y	Y	Y
4		Y	Y	Y		Y	Y	Y
5	L	Y	Ν	Y	L	Y	N	Y
6*	L	N	N	N	L	N	Ν	N
7		Y	Y	Y		Y	Y	Y
8		Y	Y	Y		Y	Y	Y
9		Y	Y	Y		Y	Y	Y
10		Y	Y	Y		Y	Y	Y
11	NL	Y	Y	Y	NL	Y	Y	Y
12	NL	Y	Y	Y	NL	Y	Y	Y
13	NL	Y	Y	Y	NL	Y	Y	Y
14		Y	Y	Y		Y	Y	Y
15 <sup>†</sup>	м	Y	N	Y	L	Y	Ν	Y
16		Y	Y	Y		Y	Y	Y
17		Y	Y	Y		Y	Y	Y
18		Y	Y	Y		Y	Y	Y
19	м	Ν	Ν	Y	м	N	Ν	Y
20	NL	Y	Y	Y	NL	Y	Y	Y
Agreer	nent	90%	80%	95%		90%	80%	95%

\*New second perfusion defect.

<sup>†</sup>Disagreement only on size of defect (M vs. L) between Reader 1 and Reader 2.

Y = yes; N = no; L = large defect with complete or nearly complete redistribution; M = moderate defect with complete or nearly complete redistribution; NL = normal.

in 70%, minor disagreement in 8% and major disagreement in 13% for four readers. This study was reported in 1978, and involved planar <sup>201</sup>Tl images without quantitative analvsis. Another study of planar <sup>201</sup>Tl (exercise and dipyridamole) examined reproducibility of quantitative planar <sup>201</sup>Tl (6) focusing on processing by seven technologists. Results indicated that reproducibility was inversely related to the size of the perfusion defects. Using that variability, a quantitative circumferential program for defining reversibility was created, resulting in concordance of 83% between subjective analysis of planar images and objective quantitative criteria for identifying reversibility of defects. Development of quantitative SPECT <sup>201</sup>Tl reversibility programs at Emory (7,8) utilized a similar approach for identifying reversibility. In the current study, there were three patients (nos. 3, 7 and 10) who achieved equivalent exercise on Day 1 and Day 2 studies, but had a zero reversibility score on one study day and a positive reversibility score on the other study day. All three were visually assessed as fixed defects on both studies. Only one of the subjects (Patient 3) showed a substantial defect reversibility score, while the others were small (Patients 15 and 19).

Thus, visual and quantitative data generally correlated well except in one subject where there was a discrepancy.

A high degree of correlation was evident between variances in stress-exercise performance and minor nonreproducibility of the <sup>201</sup>Tl study, (i.e., in the degree of redistribution seen in three patients rather than presence or absence of redistribution). In only one patient was significant nonreproducibility seen (i.e., failure to reproduce a second perfusion defect). The question of whether pharmacologic stress would diminish such nonreproducibility incidences by minimizing stress performance variances certainly deserves investigative consideration. Whether stress and delayed redistribution or stress and reinjection delayed imaging is performed, the reproducibility data shown here are relevant, since stress is the first component of both approaches and the component with the inherently largest number of intrapatient variables.

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