Dipyridamole Thallium-201 Single-Photon Emission Computed Tomography for Prediction of Perioperative Cardiac Events in Patients With Arteriosclerosis Obliterans Undergoing Vascular Surgery

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The aim of the study was to determine whether or not dipyridamole thallium-201 single-photon emission computed tomography (^{201}Tl -SPECT) has significant additive value for predicting perioperative cardiac events in patients with arteriosclerosis obliterans (ASO) undergoing vascular surgery. Routine preoperative ^{201}Tl -SPECT was performed in 106 consecutive patients with ASO (age 68 ± 8.9 years; 91 men and 15 women). The frequency of reversible defects in a clinical high-risk group ($n=44$) was significantly higher than in a low-risk group ($n=62$; 55% vs 24%, $p<0.01$). Perioperative cardiac events occurred in 9 patients, including 4 cardiac deaths, 1 non-fatal myocardial infarction, and 4 cases of unstable angina. Although clinical risk stratification was useful in predicting cardiac events (19% in the high-risk group vs 2% in the low-risk group, $p<0.01$), the positive predictive value was low. When considering a combination of 2 or more than 2 risk factors and a large reversible defect as a predictor, the positive predictive value and specificity increased from 19% to 47% and from 64% to 91%, respectively, whereas the sensitivity remained unchanged (89%). These results suggest that the addition of ^{201}Tl -SPECT data to clinical risk-stratified patients with ASO allows better prediction of perioperative cardiac events. (*Jpn Circ J* 1998; 62: 274–278)

Key Words: Dipyridamole ^{201}Tl -SPECT; Arteriosclerosis obliterans; Cardiac event; Clinical risk factor

Ischemic cardiac events are the leading cause of morbidity and mortality in patients with peripheral vascular disease after vascular surgery^{1–3}. For this reason, assessment of the cardiac risk in patients scheduled to undergo vascular surgery is essential for avoiding perioperative cardiac complications. Recognition of the cardiac risk of vascular surgery has recently focused interest on methods of identifying high-risk patients. Although exercise ^{201}Tl scintigraphy has been used successfully for non-invasive detection of coronary artery disease (CAD), its applicability is limited in vascular patients, especially in patients with arteriosclerosis obliterans (ASO), because of claudication. Many studies have shown that dipyridamole ^{201}Tl imaging is an effective predictor of the occurrence of perioperative cardiac events and is unaffected by the patient's physical limitations^{4–16}. In contrast to the results of these studies however, other studies have failed to confirm the additive value of dipyridamole ^{201}Tl imaging for prediction of cardiac events in clinical risk-stratified patients^{17–20}.

In addition, the prevalence of CAD in patients with atherosclerotic occlusive disease is lower than in dilative disease (aortic aneurysm)^{21–23} but most previous studies^{4–20} included a mixture of patients with different types of vascular disease, even non-vascular disease. The usefulness of ^{201}Tl single-photon emission computed tomography (SPECT) for prediction of perioperative cardiac events in ASO population is not known. Although dipyridamole ^{201}Tl -SPECT appears to be superior to planar imaging for detection of myocardial ischemia and assessing cardiac prognosis, it has been used in only a few studies^{2,15,17}. The aim of this study was to estimate whether dipyridamole ^{201}Tl -SPECT has additive value for predicting perioperative cardiac events in a group of consecutive clinical risk-stratified patients with aortoiliac and/or distal ASO who routinely underwent dipyridamole ^{201}Tl -SPECT.

Materials and Methods

This study was an open and non-random study. Between January 1990 and December 1995, 113 consecutive patients with aortoiliac and/or distal ASO being considered for vascular surgery were referred to Yamanashi Medical University for routine ^{201}Tl -SPECT and clinical evaluation (Table 1). Patients with unstable angina, recent (within 3 months) myocardial infarction, or congestive heart failure were excluded. All patients gave written informed consent for the dipyridamole ^{201}Tl -SPECT study. Patients were stratified into a clinical

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Table 1 Patient Characteristics

Characteristic	Number of subjects
Age (years)	68.1 ± 8.9
≤ 60	16 (15%)
61–70	46 (43%)
71–80	33 (31%)
≥ 81	11 (10%)
Male sex	93 (88%)
History of angina	12 (11%)
Previous myocardial infarction	7 (7%)
Hypertension	58 (55%)
Diabetes mellitus	28 (26%)
Clinical risk factors	1.4 ± 1.1
0	20 (19%)
1	42 (40%)
2	28 (26%)
≥ 3	16 (15%)
Severity and types of ASO	
Fontaine class 2	69 (65%)
3	16 (15%)
4	21 (20%)
Aortoiliac occlusion	23 (22%)
Femoropopliteal occlusion	39 (37%)
Diffuse occlusion	44 (42%)

high-risk cohort if they had 2 or more than 2 of the following risk factors: age >70 years; history of myocardial infarction, angina, or congestive heart failure; diabetes mellitus; hypertension with left ventricular hypertrophy; presence of Q wave; ST-segment ischemic abnormalities during rest electrocardiogram;¹⁵ and ventricular arrhythmia class ≥4a on Holter monitoring. Clinical and scintigraphic data were derived prospectively and made available to the referring physicians. Surgery was canceled in 7 patients: in 3 because of improvement in walking distance, in 2 because of the development of serious complications (severe heart failure or multiple cancers), and in 2 because of refusal to undergo surgery. Among these 7, 6 patients had 2 or more than 2 risk factors and 4 had a reversible defect. The remaining 106 patients represented the study population, with 44 patients stratified into a high-risk group and 62 patients into a low-risk group. All patients underwent vascular surgery, except 1 who died from preoperative sudden cardiac death. Fifty patients underwent intra-abdominal aortoiliac femoral reconstruction, including 32 patients who had aortic clamping procedures and 55 patients who underwent distal vascular reconstruction under general or epidural anesthesia or a combination of both. Mainly on the basis of the clinical risk stratification and abnormal ^{201}Tl -SPECT results, 19 patients underwent preoperative coronary angiography. Two patients who subsequently underwent myocardial revascularization were excluded from the study of the prediction of perioperative cardiac events.

Dipyridamole ^{201}Tl -SPECT was performed within 1 month before the operation. Dipyridamole induces myocardial ischemia by the steal phenomenon in patients with significant coronary stenosis because it acts predominantly on small resistance vessels of the coronary bed. Intravenous dipyridamole was infused at a rate of 0.14 mg/kg per min for 4 min. A 12-lead electrocardiogram, blood pressure, and heart rate were recorded initially and every 1 min thereafter until the patient underwent imaging. Aminophylline was administered when severe ischemia or symptoms were present. Recording of initial

Fig 1. Left ventricle segmentation according to the 3 orthogonal planes.

images was started within 10 min after thallium injection, and delayed images were recorded 4 h later. A γ -camera (Toshiba GLA-9300/DI, Japan) with a low-energy, high-resolution collimator was used. The myocardial uptake of ^{201}Tl was assessed during a 180° circular movement, starting from the 45° left anterior oblique projection using 4° increments (46 projections). Transverse sections were obtained by filtered back-projection. The reconstructed tomographic data were displayed in 3 standard cardiac planes (short, horizontal long, and vertical long axis). The left ventricle was divided into 6 standard segments (Fig 1).¹⁵ Each segment was assigned to a coronary territory except for the apical segment (anterior and septal segments: left anterior descending coronary artery; lateral segment: left circumflex coronary; inferior and posterior segment: right coronary artery).⁹ The images were analyzed qualitatively, and a consensus was obtained from 2 nuclear cardiologists who were unaware of the patient's clinical data. The scintigrams were classified as normal, fixed defect (if the initial abnormality was unchanged on the delayed image), or reversible defect (if the initial abnormality was partial or showed total normalization on the delayed image). By using a simple analysis for assessing the extent of abnormal defects, a reversible defect in more than 1 coronary arterial territory was considered to be a large reversible defect.

Cardiac End Points

Perioperative cardiac events were ascertained retrospectively and classified as cardiac death (sudden death or death due to myocardial infarction or congestive heart failure), non-fatal myocardial infarction (based on standard electrocardiogram and enzymatic criteria), and unstable angina (≥2 episodes of resting chest pain with ST-segment changes within 24–48 h) during the hospitalization period up to 30 postoperative days. Major cardiac events were defined as cardiac death or non-fatal myocardial infarction.

Data Collection and Statistical Analysis

The clinical variables taken into account were age,

Table 2 Results of Dipyridamole Thallium SPECT

	All patients (n=106)	0-1 risk factor (n=62)	≥2 risk factors (n=44)	p value
Normal	24 (23%)	16 (26%)	8 (18%)	<0.01
Fixed defect	43 (41%)	31 (50%)	12 (27%)	<0.05
Reversible defect	39 (37%)	15 (24%)	24 (55%)	<0.001
Anterior	25 (24%)	6 (10%)	18 (41%)	<0.005
Large	22 (21%)	3 (5%)	19 (43%)	<0.001

Anterior: reversible defect in the area supplied by the left anterior descending coronary artery.

gender, history of myocardial infarction, angina, heart failure, or cerebral accident, hypertension, diabetes mellitus, smoking, alcohol consumption, hypercholesterolemia (total cholesterol >220 mg/dl), and electrocardiographic indices. The ASO Fontaine class, aortic clamping during operation, and the operative time were also taken into consideration. The χ^2 test with Yates' correction, or Fisher's exact test, if required, was used to compare clinical and scan variables for the patient population as they related to the occurrence of cardiac events. Continuous variables are presented as the mean $\pm$ SD. The relationship between clinical risk factors and ^{201}Tl -SPECT results and the perioperative outcome was expressed as the sensitivity, specificity, and positive and negative predictive value for the prediction of cardiac events. A p value less than 0.05 was considered to be statistically significant.

Results

Dipyridamole ^{201}Tl -SPECT

There were no serious complications (severe hypotension, respiratory failure or myocardial infarction) associated with dipyridamole ^{201}Tl -SPECT in this study population. In 3 of the 106 patients, chest pain and/or ischemic ST-segment depression occurred, and aminophylline was administered to 2 of these patients.

The results of dipyridamole ^{201}Tl -SPECT imaging are given in Table 2. Reversible defects were more common in patients with multiple clinical risk factors than no or 1 risk factor ($p < 0.001$). In contrast, the ^{201}Tl -SPECT findings were not significantly associated with the classification of ASO severity. Of 19 patients who underwent preoperative coronary angiography, severe stenosis (defined as $\geq 75\%$ diameter reduction) was found in 13 of 15 patients with a reversible defect (87%) or in 10 of 11 patients with multiple risk factors and a large reversible defect (91%). No severe stenosis was found in 1 patient with a fixed defect and 3 patients with normal SPECT results.

Perioperative Cardiac Events

Perioperative cardiac events occurred in 9 of 104 patients without antecedent myocardial revascularization (9%). The events included 4 cardiac deaths, 1 non-fatal myocardial infarction, and 4 episodes of unstable angina. Among them, 1 preoperative sudden cardiac death was regarded as a perioperative cardiac event in this study. Excluding this case did not significantly alter the present study results in a repeat analysis. The 9 clinical risk factors were not predictive of perioperative cardiac events except for arrhythmia $\geq$ class 4a in this study population. No relationship was found between the class of ASO severity and the occurrence of events. The operation, with or without aortic cross-clamping, was also not associated with the occurrence of events. Only a surgical procedure of more than 7 h was found to be more common in the patients with perioperative cardiac events. Of 9 patients with severe stenosis in coronary angiography who had multiple risk factors and a large reversible defect, no cardiac events occurred in 2 patients who had undergone preoperative myocardial revascularization, whereas 4 cardiac events occurred in the remaining 7 patients. Table 3 shows the relationship between the thallium SPECT results and perioperative cardiac events. The patients with normal or fixed defect of SPECT results never had cardiac events. Cardiac events occurred in 9

Table 3 Thallium SPECT and Perioperative Cardiac Events

	No event (n=95)	Any event (n=9)	p value	No major event (n=99)	Major event (n=5)	p value
Normal	24 (25%)	0 (0%)	NS	24 (24%)	0 (0%)	NS
Fixed defect	43 (45%)	0 (0%)	<0.01	43 (43%)	0 (0%)	NS
Reversible defect	28 (32%)	9 (100%)	<0.001	32 (32%)	5 (100%)	<0.01
Anterior	15 (15%)	7 (78%)	<0.001	19 (19%)	4 (80%)	<0.01
Large	12 (11%)	8 (89%)	<0.0001	15 (15%)	5 (100%)	<0.0001

Abbreviations are the same as in Table 2.

Table 4 Clinical and Thallium SPECT Indices for Cardiac Events

	Sensitivity (%)	Specificity (%)	Predictive value (%)		Accuracy (%)	χ^2	p value
			Positive	Negative			
One or no risk factors	89	20	10	95	26	0	NS
Two or more risk factors	89	64	19	98	66	7.6	<0.01
Reversible defect	100	71	24	100	74	14.9	<0.001
Anterior	78	83	30	98	83	14.4	<0.001
Large	89	87	40	99	88	26.1	<0.0001
Two or more risk factors with large reversible defect	89	91	47	99	90	32.3	<0.0001

Abbreviations are the same as in Table 2.

(23%) out of 37 patients with reversible defect, 7 (30%) out of 23 patients with anterior reversible defects, 8 (40%) out of 20 patients with large reversible defects.

Additive Predictive Value of ^{201}Tl -SPECT

Table 4 presents a comparison of the clinical and ^{201}Tl -SPECT indices for perioperative cardiac events in the patients with ASO. Cardiac events occurred in 8 of 42 patients with multiple risk factors and only in 1 of the 62 patients with less than 2 risk factors ($p < 0.01$, positive predictive value 19%). In contrast, 9 of 37 patients with and none of 67 patients without a reversible defect had cardiac events ($p < 0.001$), and 8 of 20 patients with and 1 of 84 patients without a large reversible defect had cardiac events ($p < 0.001$) (positive predictive value 24% and 40%, respectively). For the patients with multiple risk factors, ^{201}Tl -SPECT remains predictive of the cardiac events: cardiac events occurred in 8 of 22 patients with and none of 20 patients without a large reversible defect ($p < 0.01$), and in 8 of 17 patients with and none of 25 patients without a large reversible defect ($p < 0.001$). For all of the ASO patients in this study (except 2 patients who underwent preoperative myocardial revascularization), multiple risk factors together with a large reversible defect is the best effective index for prediction of perioperative cardiac events ($p < 0.0001$).

Discussion

An abnormal result with dipyridamole ^{201}Tl scintigraphy, both the presence and extent of a reversible defect, has generally been shown to be an effective predictor of perioperative cardiac events in patients with peripheral vascular disease in several studies^{8,9,11,14,15}. Although patients with vascular disease are at high risk of CAD, both the incidence of CAD and perioperative mortality and morbidity are relatively lower in patients with ASO than with aortic aneurysm²¹⁻²³. However, to our knowledge, all of the previous studies were based on heterogeneous patient populations. Moreover, SPECT has been developed in recent years and has improved the accuracy of detection of myocardial ischemia because of its greater resolution, but only a few studies used SPECT for stratification of the perioperative cardiac risk^{15,17,20}. Our present study indicates that dipyridamole ^{201}Tl -SPECT myocardial imaging is very useful for predicting both major and any perioperative cardiac events in ASO patients. Using a simple semiquantitative analysis, ^{201}Tl -SPECT predicted cardiac events more accurately in all study populations: major and any event rates were 25% and 40%, and 0% and 0% respectively when a large reversible defect was present or absent. Our findings confirm the results of most previous studies^{4,6,8-11} with an important distinction in study population that the cardiac risk is relatively low: the rates of previous infarction and angina were 7% and 11% in our study population compared with 18–58% and 23–54% in the previous studies. Interestingly, 2 of the more recent studies using thallium SPECT for prediction of perioperative cardiac events in patients undergoing abdominal aortic surgery drew completely different conclusions. Baron et al²⁰ used 3-h delayed redistribution imaging in a large series of 457 non-selected consecutive patients and confirmed Mangano et al's early study¹⁸ by concluding that dipyridamole ^{201}Tl -SPECT is not an accurate

screening test for the evaluation of perioperative cardiac risk. By contrast, Vanzetto et al¹⁵ performed a reinjection study in 134 clinically selected patients with high cardiac risk and found that ^{201}Tl -SPECT demonstrated significant prognostic value for cardiac events compared with the clinical variables only. Our study was similar to those studies in that we used non-selected consecutive patients. Certainly, a different study design (prospective vs retrospective study) and surgical procedures (aortic reconstruction vs distal vascular reconstruction) would influence the results. The divergent result reported by Baron et al²⁰ and Mangano et al¹⁸ may be partly explained by a difference in technique: we used 4-h delayed redistribution imaging, which may improve the sensitivity of the test. Of course, the rates of previous infarction and angina (16% and 19%, respectively) in Baron et al's study population were low, but ours were lower.

Additive Prognostic Value

Clinical evaluation is the first important step in cardiac risk stratifications for patients undergoing vascular surgery, but there is no current consensus on the optimal clinical evaluation to risk stratification²⁴. Eagle et al²⁵ showed that the presence of ≥ 2 of the 6 following clinical risk factors predicts a relatively high-risk population: a history of angina, congestive heart failure, diabetes mellitus, previous myocardial infarction, ventricular ectopia, and age > 70 years. Our study confirmed these findings but included 3 additional factors: severe hypertension and Q wave or ST-segment ischemic abnormality on the electrocardiogram. Ventricular arrhythmia was defined as $\geq$ class 4a. Although clinical risk stratification was useful for predicting perioperative cardiac events, patients with multiple risk factors had a higher incidence of cardiac events than those with fewer than 2 risk factors (19% vs 2%); the specificity and positive predictive value were low. Importantly, the combination of clinical assessment followed by ^{201}Tl -SPECT significantly improved the prediction of cardiac events in this study: patients with and without multiple risk factors and a large reversible defect had significantly different event rates (47% vs 1%), whereas the specificity and positive predictive value increased from 64% to 87% and from 19% to 47%, respectively.

Study Limitations

There are some limitations in this study. Firstly, it is a retrospective observational study. The ^{201}Tl -SPECT results were not blinded to the referring physicians, and thus the performance or extent of surgical procedures and perioperative medical therapy were potentially influenced by the scan report. In addition, perioperative medical treatment might affect the occurrence of perioperative cardiac events. Secondly, the study is relatively small in size. Finally, stepwise logistic regression was not used to analyze our data because univariate analysis showed only $\geq$ class 4a arrhythmia to be predictive of cardiac events ($p < 0.05$) among the 16 clinical variables (the operative time is not a preoperative clinical variable).

Clinical Implications

Recent studies indicate that routine use of coronary angiography before vascular surgery leads to worse outcomes, even among patients at higher than average

risk.²⁶ Moreover, perioperative cardiac events can be reduced in high-risk patients by intensifying the perioperative medical therapy when the results of non-invasive assessment are used.²⁷ Based on our findings, preoperative ²⁰¹Tl-SPECT should be performed when a patient has 2 or more than 2 risk factors. If ²⁰¹Tl-SPECT shows any reversible defect, the patient should undergo close monitoring and intensified perioperative anti-ischemic management. Further intervention, such as coronary angiography and, if required, revascularization, should be reserved for those patients who have both multiple risk factors and a large reversible defect.

In conclusion, the combination of ²⁰¹Tl-SPECT data and clinical risk factor allows better prediction of perioperative cardiac events in Japanese patients with ASO.

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