Routine Perioperative Dipyridamole ^{201}Tl Imaging in Diabetic Patients Undergoing Vascular Surgery

Is it necessary?

STUART W. ZARICH, MD
MYLAN C. COHEN, MD, MPH
STEPHEN E. LANE, MD
MURRAY A. MITTLEMAN, MD, MPH, DRPH
RICHARD W. NESTO, MD
THOMAS HILL, MD
DAVID CAMPBELL, MD
STANLEY M. LEWIS, MD

OBJECTIVE — To assess the utility of dipyridamole thallium testing in symptomatic and asymptomatic patients with diabetes undergoing vascular surgery.

RESEARCH DESIGN AND METHODS — Dipyridamole ^{201}Tl myocardial scintigraphy was performed preoperatively in 93 consecutive patients with diabetes undergoing peripheral vascular procedures. The utility of clinical and thallium variables in predicting cardiovascular complications was assessed.

RESULTS — Two groups of patients were identified: group A (36 patients) without clinical evidence of cardiac disease and group B (57 patients) with clinical evidence of cardiac disease. Dipyridamole thallium scans were abnormal in 21 of 36 (58%) of group A patients compared with 53 of 57 (93%) of group B patients ($P < 0.0001$). Compared with group B patients with perfusion defects, group A patients with perfusion abnormalities tended to have fewer defects per scan (2.7 ± 1.5 vs. 3.6 ± 1.9, $P = 0.05$). No perioperative cardiac complications occurred in group A patients while perioperative cardiac complications occurred in 9 of 57 (16%, 95% CI 7–28%) group B patients ($P = 0.01$). For the entire study population, the complication rate was 10%.

CONCLUSIONS — Diabetic individuals without clinical markers for coronary artery disease appear to be at low risk for adverse postoperative cardiac events after vascular surgery. Preoperative myocardial perfusion imaging may add little to cardiovascular risk assessment in this subgroup of patients with diabetes.

Thallium perfusion abnormalities on dipyridamole myocardial scintigraphy identifies patients at particularly high risk for postoperative myocardial infarction and cardiac death (1–4) after noncardiac vascular surgery. Peripheral vascular and coronary artery disease frequently coexist, especially in diabetic patients (5–9). Several studies (10–14) have indicated that diabetes is an independent risk factor for adverse postoperative cardiac events, leading some investigators to advocate routine preoperative assessment using dipyridamole ^{201}Tl myocardial scintigraphy for all diabetic individuals undergoing noncardiac vascular surgery (11,14). However, these studies involved relatively small numbers of patients with diabetes, and other studies (15,16) have failed to confirm diabetes as an independent risk factor.

To examine the role of routine myocardial perfusion imaging in diabetic patients undergoing vascular procedures, we performed dipyridamole thallium myocardial scintigraphy preoperatively in 93 consecutive diabetic individuals undergoing noncardiac vascular procedures. The utility of clinical and thallium variables in predicting cardiovascular complications was assessed.

RESEARCH DESIGN AND METHODS

Study population

We prospectively performed preoperative dipyridamole thallium scintigraphy on 133 consecutive diabetic individuals being evaluated for peripheral vascular surgery. Diabetes was defined as a hyperglycemic state requiring treatment with insulin or oral hypoglycemic agents. The type of surgical procedures performed, anesthesia administered, intraoperative hemodynamic monitoring used, and use of intravenous nitroglycerin were noted. The majority of procedures (>90%) were performed for limb-threatening ischemia (continuous rest pain, gangrene, or ischemic ulceration). Patients undergoing emergency surgery were excluded. All patients met the following inclusion criteria: *1*) absence of myocardial infarction within the previous 6 months; *2*) absence of severe chronic obstructive pulmonary disease; *3*) creatinine level <228 μmol/l (3.0 mg/dl); *4*) absence of congestive heart failure at the time of surgery; and *5*) absence of unstable angina. All patients were seen pre- and postoperatively by the cardiology consulting service. The patients' medical regimen for coronary disease was not specifically changed or influenced by dipyridamole thallium scanning. The results of thallium imaging were not blinded. The study protocol was approved by the Institutional Committee on Human Research, and all patients gave written informed consent.

From the Cardiovascular Division, Department of Medicine, Department of Radiology, and Department of Surgery, Deaconess Hospital, Harvard Medical School, Boston, Massachusetts.

Address correspondence and reprint requests to Stuart W. Zarich, MD, Cardiovascular Division, Deaconess Hospital, 185 Pilgrim Rd., Boston, MA 02215.

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ECG, electrocardiogram.

A total of 40 patients were subsequently excluded from this analysis. Twenty-one patients were excluded from analysis for noncardiac reasons (failure to undergo vascular surgery within 4 weeks of thallium imaging because of continued medical therapy [$n = 12$], failure to consent to surgery [$n = 1$], and failure to have peripheral vascular anatomy suitable for revascularization [$n = 8$]). Eight patients subsequently underwent percutaneous transluminal angioplasty and were excluded from further analysis. Ten patients underwent coronary angiography at the request of their primary physician based on their clinical risk profile (presence of active angina, heart failure, or prior myocardial infarction) and were excluded from further analysis. All 10 patients had positive dipyridamole thallium scans. Of these patients, five underwent coronary revascularization before uneventful vascular surgery. The remaining five patients undergoing cardiac evaluation had vascular surgery canceled or deferred to a later date. An additional person died from sepsis before undergoing surgery. The remaining 93 diabetic individuals who underwent elective peripheral vascular surgery within 4 weeks of thallium imaging form the study population.

A thorough history and physical examination to assess the cardiovascular system were performed along with a routine chest roentgenogram and resting electrocardiogram (ECG). Clinical evidence of cardiovascular disease was defined as *1*) a prior history of angina pectoris, orthopnea, paroxysmal nocturnal dyspnea, or dyspnea on exertion; *2*) abnormal cardiovascular physical examination (jugular venous distension, pulmonary rales, pathological murmurs, S_3 gallop, or peripheral edema); *3*) abnormal (>0.5) cardiothoracic ratio on chest roentgenogram; or *4*) evidence of prior myocardial infarction by history or by the presence of pathological Q waves on the ECG (17).

The duration and treatment of diabetes, as well as the presence of diabetic retinopathy, neuropathy, or nephropathy, were noted. Retinopathy was defined as the presence of retinal hemorrhages, exudates, or microaneurysms. Neuropathy was defined as diminished vibratory sensation and absent patellar or ankle reflexes. Nephropathy was defined as proteinuria in association with a serum creatinine level >114 μmol/l (1.5 mg/dl). Age, sex, history of cigarette smoking, and the presence of hypertension (systolic pressure >140 mmHg or diastolic pressure >90 mmHg) were recorded for each patient.

Dipyridamole thallium scintigraphy

All patients underwent dipyridamole thallium scanning a mean of 6 days (range 1–26 days) preoperatively using a standard protocol (18,19). Dipyridamole (0.56 mg/kg body wt) was infused intravenously over 4 min followed by infusion of 74 MBq (2 mCi) of ^{201}Tl. Initial and 3-h postinfusion images were obtained in the anterior, left lateral, and 45° left anterior oblique projections. Delayed imaging was not performed. Analog thallium images were acquired with a small field-of-view gamma camera equipped with a low-energy all-purpose collimator (Technicare Sigma 420, GE Medical Systems, Milwaukee, WI), with ~500,000 counts obtained per view. Digitized images were simultaneously constructed using an NIC 2000 computer and were analyzed with commercially available software based on the method of Wackers et al. (20). Thallium images were interpreted in a blinded manner by three experienced readers (S.E.L., S.M.L., and T.H.), who arrived at a consensus using visual analysis of planar analog images as well as by quantitative analysis of the digitized images. Thallium scans were scored according to a 10-segment scoring system (21), with each segment described as a fixed, reversible, or mixed thallium defect or as normal thallium uptake, based on comparison of the initial and delayed postdipyridamole images. An abnormal scan was defined by the presence of any single fixed, mixed, or reversible defect.

Study endpoints were *1*) myocardial infarction, defined as creatinine kinase level greater than two times normal with ≥5% MB fraction and the appearance of either new Q waves, ST segment elevation, or ST segment depression of at least 1 mm in two contiguous leads and *2*) in-hospital cardiovascular death. All patients were monitored postoperatively with serial ECGs and cardiac enzymes for 48 h and when otherwise clinically indicated. Endpoints were assessed by the study physician blinded to thallium results.

Statistical analysis

All results are expressed as means ± SD. Significance was established at $P < 0.05$ and the 95% CI is presented. Continuous variables were compared using a two-tailed unpaired *t* test. Categorical variables were analyzed using Fisher's exact test. Multivariate logistic regression analysis was performed to assess clinical and thallium predictors of adverse outcomes. In all logistic analyses, the generalized likelihood ratio test was used to assess statistical significance (22). Covariates that were considered in the multivariate model were age, sex, number of thallium defects per scan, presence of reversible defects in the left anterior descending artery territory, prior myocardial infarction, history of angina, history of congestive heart failure, hypertension, insulin use, and presence of pathological Q waves.

RESULTS — The clinical and scintigraphic characteristics of the 93 study patients compared with the 40 excluded patients are summarized in Table 1. Two groups of patients were identified within the study group: group A (36 patients) without clinical evidence of cardiac disease and group B (57 patients) with clinical evidence of cardiac disease (Table 2). There was no difference between the groups in the proportion of men, age, duration of diabetes, anesthesia administered, duration of anesthesia, placement of pulmonary arterial catheters, and administration of intravenous nitroglycerin. The mean duration of diabetes was 16 ± 10 years, and 62% of patients were insulin dependent. The distribution of procedures was similar for group A compared with group B: abdominal aortic aneurysm repair, 6 (17%) vs. 3 (5%); peripheral bypass graft procedure, 27 (75%) vs. 43 (75%); amputation and other procedures, 3 (8%) vs. 11 (18%).

Dipyridamole thallium scans were abnormal in 21 of 36 (58%) of group A patients compared with 53 of 57 (93%) of group B patients ($P < 0.0001$) (Table 3). There was no difference between groups in sex, age, duration of diabetes, use of insulin, history of hypertension, or duration of anesthesia. Compared with group B patients with perfusion defects, group A patients with perfusion abnormalities tended to have fewer defects per scan (2.7 ± 1.5 vs. 3.6 ± 1.9, $P = 0.05$). Although group A patients tended to have fewer re-

Table 1—*Clinical and scintigraphic variables in the study group and excluded patients*

	Study cohort	Excluded patients	*P* value
n	93	40	
Age (years)	66 ± 10	65 ± 11	0.57
Men (%)	66	68	1.00
Diabetes			
Duration (years)	16 ± 9	17 ± 8	0.69
Insulin usage (%)	62	67	0.82
History of			
MI (%)	36	50	0.19
Angina (%)	44	71	0.02
CHF (%)	20	36	0.13
HTN (%)	60	71	0.37
ECG Q waves	39	54	0.19
Thallium defects			
Any Defect	74/93 (80%)	34/40 (85%)	0.63
Total Defects	109	248	
Defects/patient	3.4 ± 1.7	3.2 ± 1.8	0.56
R (%)	55	56	1.00
R or M (%)	88	85	0.76
F (%)	12	18	0.55
R in LAD (%)	31	41	0.38

Data are means ± SD. Percentages for clinical variables and any thallium defect refer to the entire group. Other percentages refer to the proportion of patients with abnormal thallium scans. MI, myocardial infarction; CHF, congestive heart failure; HTN, hypertension; ECG Q waves, Q waves present on preoperative ECG; R, reversible defects; M, mixed defects; F, fixed defects; R in LAD, reversibility in the left anterior descending artery territory.

versible defects in territory supplied by the left anterior descending coronary artery (19 vs. 36%), this difference was not statistically significant. Among patients with abnormal scans, there were no differences between groups in the distribution of reversible, mixed, and fixed defects. Overall, group A patients had fewer reversible and mixed defects (50 vs. 83%, $P < 0.001$) compared with group B patients.

In-hospital perioperative cardiac complications occurred in nine patients (10%). There were three (5.3%) deaths (all cardiac) and six (10.5%) myocardial infarctions. Additionally, one episode of unstable angina with ECG changes and one episode of congestive heart failure were documented. No postoperative cardiac complications occurred in the 36 group A patients while postoperative cardiac complications occurred in 9 of 57 (16%, 95% CI 7–28%) group B patients ($P = 0.01$) (Table 2). There were no statistically significant differences in the proportion of men, age, duration of diabetes, insulin use versus oral hypoglycemic agents, or cardiac risk factors in patients with cardiac complications compared with patients without such complications. Multiple logistic regression analysis including clinical and thallium variables was subsequently performed to predict adverse cardiac outcomes.

On multivariate analysis, the presence of angina was the only clinical parameter that was an independent predictor of cardiac complications in the entire study population ($P < 0.03$). Upon consideration of thallium parameters, the total number of defects per scan was highly predictive of outcome ($P < 0.004$), while the presence of angina was of only borderline significance ($P = 0.07$). As all of the nine perioperative complications occurred in the subset of patients with clinical or electrocardiographic evidence of cardiac disease (group B), multiple logistic regression analysis was also performed in this subset of patients. The only independent predictor of perioperative complications in patients with a history of cardiac disease was the total number of thallium defects per scan (both fixed and reversible defects) ($P = 0.01$).

CONCLUSIONS— Patients undergoing vascular surgery frequently have associated coronary artery disease (24) and are at high risk for perioperative myocardial infarction and cardiac death (25). Certain clinical characteristics may be predictive for these adverse cardiac events (25). Boucher et al. (1) and others (2–4) have demonstrated the utility of dipyridamole ^{201}Tl myocardial scintigraphy for risk stratification of patients undergoing vascular surgery. Despite the impressive sensitivity (95–100%) of dipyridamole thallium scanning for detection of coronary disease in this population, it has a limited positive predictive value (33–55%) for assessing cardiovascular outcome (1,10). More recently, investigators have combined both clinical criteria and dipyridamole ^{201}Tl myocardial scintigra-

Table 2—*Summary of clinical variables for the study patients*

	Group A	Group B	*P* value
n	36	57	
Age (years)	65 ± 11	67 ± 9	0.38
Men	24 (67)	37 (65)	1.00
Diabetes			
Duration (years)	15 ± 10	17 ± 9	0.40
Insulin usage	22 (61)	36 (63)	0.81
History of			
MI	0	33 (58)	
Angina	0	41 (72)	
CHF	0	19 (33)	
HTN	23 (64)	33 (58)	0.83
ECG Q waves	0	36 (63)	
Complications	0	9 (16)	<0.01

Data are means ± SD or *n* (%). See text for description of groups A and B. Complications refers to perioperative cardiac complications. MI, myocardial infarction; CHF, congestive heart failure; HTN, hypertension.

Table 3—*Thallium scan profiles of the study patients*

Thallium defects	Group A	Group B	*P* value
n	36	57	
Any defect	21 (58)	53 (93)	<0.001
Total defects	57	191	
Defects/patient	2.7 ± 1.5	3.6 ± 1.9	0.05
R	13 (62)	28 (53)	0.60
R or M	18 (86)	47 (89)	0.71
F	3 (14)	6 (11)	0.71
R in LAD	4 (19)	19 (36)	0.18

Data are means ± SD or *n* (%). Thallium scan profiles for the two groups are shown. Percentages for any defect are calculated for the entire group. Other percentages refer to the proportion of patients with an abnormal scan. R, reversible defects; M, mixed defects; F, fixed defects; R in LAD, reversibility in territory supplied by the left anterior descending coronary artery.

phy to risk stratify vascular patients (11) with improved results.

Several studies (10–14) have suggested that diabetes is an independent risk factor for adverse cardiac events after vascular surgery, prompting some to advocate routine preoperative dipyridamole ^{201}Tl myocardial scintigraphy for all diabetic patients undergoing noncardiac vascular surgery (11,14). However, these studies were retrospective (11,13,14) and involved relatively small numbers of patients with diabetes (10–14). Others (15,16) have failed to demonstrate diabetes as an independent risk factor in their analyses. Therefore, the recommendation that all diabetic individuals undergo myocardial perfusion imaging should be scrutinized.

In the current investigation, 93 patients with diabetes were prospectively evaluated by a cardiology consultation service and with quantitative dipyridamole ^{201}Tl planar myocardial scintigraphy before noncardiac vascular procedures. Adverse cardiac events occurred in nine patients, with myocardial infarction in six patients and death in three patients. This rate of cardiac complications is comparable to that reported in the literature (1–16), although postoperative outcomes appear to be improving (26).

No adverse perioperative cardiac events occurred in diabetic individuals without clinical markers for coronary artery disease (defined as history of angina, congestive heart failure, myocardial infarction, or presence of pathological Q waves) despite a 58% prevalence of abnormal dipyridamole ^{201}Tl scans. Thus, the positive predictive value of any abnormal dipyridamole ^{201}Tl finding is limited in an asymptomatic diabetic patient without other markers of significant coronary artery disease. However, among those with clinical markers of coronary disease, the number of defects on dipyridamole thallium scanning was an independent risk factor for postoperative events consistent with the findings of Eagle et al. (11,12). The lack of blinding to scan results possibly influenced physicians to perform less extensive procedures in patients with markedly abnormal scans. However, despite similar vascular procedures and similar anesthetic techniques, all adverse perioperative cardiac events occurred in group B patients. Additionally, there was no statistically significant difference in the perioperative use of intravenous nitroglycerin or hemodynamic monitoring.

Patients without clinical evidence of coronary artery disease but with abnormal dipyridamole thallium scans had fewer defects per scan (2.7 vs. 3.6) than those with clinical evidence of coronary artery disease and tended to have fewer reversible defects in territory supplied by the left anterior descending coronary artery (19 vs. 36%). Thus, diabetic patients without clinical evidence of coronary artery disease seem to have less extensive coronary artery disease by dipyridamole thallium scanning. Conversely, the presence of angina was associated with cardiovascular complications likely due to more significant coronary artery disease. In light of the high incidence of silent myocardial ischemia in diabetic individuals, the presence of angina is of particular concern. Positive dipyridamole thallium scans were frequently found in diabetic individuals with multiple concomitant coronary artery disease risk factors as previously described (23).

Study limitations

These findings are provocative; however, our study has several limitations. First, this represents an observational study as physicians were not blinded to scan results. There may have been subtle immeasurable differences in treatment that may have influenced outcomes. However, no statistical differences were noted in perioperative or intraoperative care between the two groups. Second, the size of the asymptomatic group was small (as was the number of cardiac events), but we believe this report contains the largest number of diabetic individuals followed prospectively through vascular surgery. Third, 10 clinically high-risk patients with abnormal scans underwent preoperative coronary angiography at the request of their primary physicians, and five of these patients underwent subsequent coronary artery revascularization preoperatively. These patients were excluded from analysis because preoperative revascularization may improve cardiac outcome (27,28). Consideration of these patients in our analysis yields a 15% event rate in group B ($P = 0.024$). Therefore, inclusion of these clinically high-risk patients does not alter our results.

Since this study was performed, ^{99m}Tc sestamibi has become widely available as a myocardial perfusion agent. Compared with thallium, technetium has a higher energy emission and a shorter half-life, which results in greater image quality with less soft tissue attenuation (29). Whether these superior imaging characteristics make ^{99m}Tc sestamibi a preferable agent for use in preoperative risk assessment remains untested. However, the predictive accuracy of dipyridamole perfusion imaging with ^{99m}Tc sestamibi in patients undergoing vascular surgery is comparable to published reports using thallium (30).

In conclusion, our findings challenge the appropriateness of the recommendation that all patients with diabetes undergo myocardial perfusion imaging before vascular surgery. Recent studies and editorials have similarly questioned the routine preoperative use of dipyridamole thallium scanning in the general population undergoing vascular surgery (31–35). Diabetic individuals without evidence of coronary artery disease clinically or electrocardiographically appear to be at low risk for adverse perioperative cardiac events after vascular surgery. Pre-

operative myocardial perfusion imaging may add little to cardiovascular risk assessment in asymptomatic patients with diabetes without significant resting Q waves. Therefore, our data suggest that despite a significant prevalence of abnormal dipyridamole thallium scans, diabetic individuals without any clinical markers for coronary artery disease may safely undergo elective vascular procedures. The fact that routine preoperative dipyridamole thallium scanning in all patients with diabetes may be unnecessary has potentially important implications for medical care cost containment and requires further study.

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