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ARTICLE

The Role of Carotid Arterial Intima-Media Thickness in Predicting Clinical Coronary Events

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Background: Carotid arterial intima-media thickness is used as a noninvasive surrogate end point to measure progression of atherosclerosis, but its relation to coronary events has not been fully explored.

Objective: To determine whether carotid arterial intima-media thickness predicts coronary events.

Design: Long-term follow-up (average, 8.8 years) of a previously assembled cohort of persons who completed the 2-year Cholesterol Lowering Atherosclerosis Study, a randomized arterial imaging trial designed to study the effects of lipid lowering on progression of atherosclerosis.

Setting: University-based ultrasonography laboratory.

Patients: 146 men 40 to 59 years of age who had previously had coronary artery bypass graft surgery.

Measurements: Preintrusive atherosclerosis in the common carotid artery was evaluated every 6 months with B-mode ultrasonography, and intrusive atherosclerosis in the coronary arteries was evaluated at baseline and at 2 years with quantitative coronary angiography. After the trial, the incidences of coronary events (nonfatal acute myocardial infarction, coronary death, and coronary artery revascularization) were documented.

Results: For each 0.03-mm increase per year in carotid arterial intima-media thickness, the relative risk for non-fatal myocardial infarction or coronary death was 2.2 (95% CI, 1.4 to 3.6) and the relative risk for any coronary event was 3.1 (CI, 2.1 to 4.5) ($P < 0.001$). Absolute intima-media thickness was also related to risk for clinical coronary events ($P < 0.02$). Absolute thickness and progression in thickness predicted risk for coronary events beyond that predicted by coronary arterial measures of atherosclerosis and lipid measurements ($P < 0.001$).

Conclusion: Noninvasive B-mode ultrasonographic measurement of progression of intima-media thickness in the distal common carotid artery is a useful surrogate end point for clinical coronary events.

Carotid arterial intima-media thickness measured with B-mode ultrasonography is used as a noninvasive end point (that is, an outcome) in epidemiologic studies and clinical trials to gauge progression and regression of atherosclerosis [1-3]. As such, carotid arterial intima-media thickness, expressed as a single measurement (in millimeters) or a rate of change (in millimeters per year), is used as a surrogate end point for atherosclerosis of the coronary artery. However, its relation to coronary events has not been fully explored.

It is well established that progression of atherosclerosis of the coronary artery determined by sequential coronary angiography is predictive of coronary events [4-6]. A close histologic relation between carotid and coronary atherosclerosis has been seen in autopsy studies [7], and the two arterial beds share many risk factors that contribute to the progression of atherosclerosis [8, 9]. Furthermore, carotid arterial intima-media thickness has been a good indicator of the presence and extent of coronary artery disease in observational studies [10, 11].

The Cholesterol Lowering Atherosclerosis Study [12] was a clinical arterial imaging trial designed to study the effects of colestipol-niacin therapy on progression of atherosclerosis in the coronary, femoral, and carotid arteries. We have reported that treatment is beneficial for all three arterial beds [3, 13-16]. In addition, long-term follow-up of the study cohort indicated that progression of coronary artery disease was predictive of coronary events [4].

The objectives of this long-term follow-up of the Cholesterol Lowering Atherosclerosis Study cohort are 1) to determine whether carotid arterial intima-media thickness [expressed as a single measurement or as a rate of change] predicts coronary events, 2) to compare the relative prognostic utility of the two carotid arterial intima-media thickness measures; and 3) to compare the relative prognostic contribution of the two carotid arterial intima-media thickness measures with an angiographic measure of coronary artery disease progression and lipid levels.

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Study Design

In the Cholesterol Lowering Atherosclerosis Study, 188 nonsmoking men 40 to 59 years of age who had previously had coronary artery bypass graft surgery were randomly assigned to receive colestipol-niacin therapy plus dietary therapy (target diet, <125 mg of cholesterol per day and 22% of energy as fat, 10% as polyunsaturated fat, and 4% as saturated fat) or placebo plus dietary therapy (target diet, <250 mg of cholesterol per day and 26% of energy as fat, 10% as polyunsaturated fat, and 5% as saturated fat) [12]. In addition to the primary end point provided by coronary angiograms at baseline and after 2 years of treatment, B-mode ultrasonography of the carotid artery was done at baseline and every 6 months during the 2-year treatment period. The cohort for this study consisted of patients who had completed the 2-year treatment period and had evaluable coronary and carotid arterial end points.

Baseline and 2-year coronary artery films were processed by quantitative coronary angiography in tandem; frames were matched for orientation and degree of contrast filling [17]. For each evaluable arterial segment, three sequential frames were processed in end diastole. For each coronary lesion, percent diameter stenosis was obtained as the average over the three sequential frames. For each patient, the change in percent diameter stenosis over 2 years was averaged for all evaluable coronary artery lesions.

B-mode ultrasonographic images of the carotid artery were obtained with a Diasonics CV400 system with a 7.5-MHz probe (Diasonics, Milpetas, California). Longitudinal views of the far wall of the right distal common carotid artery were recorded with the minimum gain necessary for clear visualization of structures. Common carotid arterial intima-media thickness was measured with an automated computerized edge-detection algorithm [18]. The distance between the echoes arising from the blood-intima interface and the media-adventitia interface was taken as the measure of intima-media thickness. Distal common carotid arterial intima-media thickness was the average of approximately 80 intima-media thickness measurements made over 1 cm. Measurements were made by persons blinded to treatment assignment and the occurrence of clinical coronary events.

Follow-up for Coronary Events

After completion of the 2-year treatment period, the occurrence of major medical events and information on all medications (including lipid-lowering agents) was determined for all patients by a clinic visit (59% of all follow-ups) or a mailed questionnaire (41%) at annual follow-up points through 30 June 1994. No ascertainment bias was associated with method of follow-up.

Coronary events were nonfatal acute myocardial infarction, coronary death, and need for coronary artery revascularization [percutaneous transluminal coronary angioplasty or coronary artery bypass graft surgery] because of recurrence or worsening of angina pectoris. For all patient-reported events, hospital records were obtained for confirmation, and all causes of death were confirmed by hospital records and death certificates. Myocardial infarction was diagnosed by a cardiologist who was blinded to treatment assignment and ultrasonographic and angiographic end point measures. Myocardial infarction was confirmed if two of the following three criteria were substantiated: typical chest pain, positive creatine phosphokinase-MB, and a new Q wave on electrocardiogram. In order to include only events that were clearly related to clinical symptoms, we did not count 1) coronary artery revascularizations that were related to the reading of the 2-year coronary angiogram or 2) silent myocardial infarctions noted on electrocardiograms at annual follow-up examinations as clinical coronary events.

Statistical Analysis

The two dependent variables were time from completion of the trial to nonfatal myocardial infarction or coronary death and time from completion of the trial to the first coronary event (nonfatal myocardial infarction, coronary death, or coronary artery revascularization). The two independent variables were the absolute carotid arterial intima-media thickness (in millimeters), measured at the end of the 2-year trial, and the annual rate of change in carotid arterial intima-media thickness (in millimeters per year), evaluated over the 2-year trial. The intima-media thickness change rate was computed for each patient by fitting a least-squares regression line relating intima-media thickness measurements to time in the study. The average number of ultrasonographic examinations per patient was 2.8 ± 0.4. The absolute carotid arterial intima-media thickness is a cumulative measure of carotid atherosclerosis, whereas the intima-media thickness change rate represents the speed with which atherosclerosis of the carotid artery is changing.

Univariate and multivariate proportional hazards models were used to test for relations (overall and within each treatment group) between the intima-media thickness variables and coronary event rates. Covariates included the baseline value for intima-media thickness (for analyses of intima-media thickness change rates) and treatment group (for analyses of the total sample). Because patients had the option to continue their randomized, blinded treatment in a 2-year extension of the Cholesterol Lowering Atherosclerosis Study, an additional covariate indexed whether a given patient was treated in the 2-year extension period. Likelihood ratio tests for trend in coronary event rates used each intima-media thickness variable as continuous data. Hazard ratios (as estimators of relative risks) and 95% CIs were expressed per SD (0.03 mm/year for the carotid arterial intima-media thickness change rate and 0.13 mm for the absolute carotid arterial intima-media thickness). Absolute carotid arterial intima-media thickness values were categorized by quartiles based on the distribution of the baseline intima-media thickness for all patients; carotid arterial intima-media thickness change rates were categorized by quartiles based on the distribution of changes in the placebo group. Hazard ratios were then computed for each of the upper quartiles relative to the first.

Because earlier analyses of the study cohort showed a significant relation between progression of coronary artery disease (assessed by the change in percent diameter stenosis using quantitative coronary angiography) and coronary events [4], we also evaluated the relative prognostic contributions of this angiographic measure of coronary artery disease progression and the ultrasonographic measure of carotid arterial intima-media thickness progression. For the change in percent diameter stenosis, hazard ratios and 95% CIs were expressed per 10% change in percent diameter stenosis. The cutoff of 10% change is double the measurement error for percent diameter stenosis on short-term repeated angiography. The joint prognostic contribution of the carotid artery and coronary artery measures of atherosclerosis with lipid levels that were found to be significantly different between patients with and without coronary events was also evaluated.

Values given are the mean ±SD unless otherwise indicated.

Role of the Funding Source

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Characteristics of the Cohort at Baseline and after Treatment

Of the 188 patients randomly assigned to treatment, 42 (22%) were excluded from the study: Eleven did not have a baseline ultrasonogram, 13 had no ultrasonographic follow-up, and 18 had no ultrasonogram evaluable for intima-media thickness. No differences were seen in baseline characteristics or changes on coronary angiography at 2 years between these 42 patients and the remaining 146 patients (78%) who had sufficient data to allow us to compute a carotid arterial intima-media thickness change rate. At baseline, the age of the study cohort was 54.2 ± 4.5 years; the systolic blood pressure was 121.5 ± 13.0 mm Hg; the diastolic blood pressure was 79.3 ± 8.7 mm Hg; the total cholesterol level was 6.30 ± 0.87 mmol/L; the low-density lipoprotein (LDL) cholesterol level was 4.38 ± 0.78 mmol/L; the high-density lipoprotein (HDL) cholesterol level was 1.14 ± 0.24 mmol/L; the triglyceride level was 1.70 ± 0.97 mmol/L; the carotid arterial intima-media thickness was 0.66 ± 0.14 mm; and the coronary artery percent diameter stenosis was 36.0 ± 7.2. Sixty-nine percent of patients were former smokers. Of the 146 patients, 73 were assigned to drug treatment and 73 were assigned to placebo.

During the 2-year treatment period, the drug produced significant benefit for all lipid levels ($P < 0.01$) and blood pressure ($P < 0.05$). The average outcomes at 2 years for the drug group and the placebo group were 0.64 ± 0.13 mm and 0.68 ± 0.13 mm, respectively, for the common carotid arterial intima-media thickness ($P = 0.06$); –0.024± 0.031 mm per year and 0.021 ± 0.021 mm per year, respectively, for the common carotid arterial intima-media thickness change rate ($P < 0.001$); and 0.47 ± 6.10 and 2.83 ± 5.79, respectively, for the change in percent diameter stenosis ($P = 0.02$). Sixty-three patients in the drug group (86%) and 54 patients in the placebo group (74%) continued into the optional 2-year extension.

Coronary Events

During an average of 8.8 years of follow-up (range, 0.7 to 12.3 years) after angiography at 2 years, 68 of 146 patients (47%) (27 in the drug group and 41 in the placebo group) had at least one coronary event. The first coronary event was percutaneous transluminal coronary angioplasty in 6 patients in the drug group and 9 patients in the placebo group, coronary artery bypass graft surgery in 12 patients in the drug group and 9 patients in the placebo group, nonfatal myocardial infarction in 8 patients in the drug group and 20 patients in the placebo group, and coronary death in 1 patient in the drug group and 3 patients in the placebo group. The rate of total coronary events was 6.3 per 100 person-years (4.7 per 100 person-years in the drug group and 8.0 per 100 person-years in the placebo group; $P = 0.05$). Of these 68 patients, 38 (12 in the drug group and 26 in the placebo group) ultimately had a nonfatal myocardial infarction (9 in the drug group and 22 in the placebo group) or died of coronary disease (3 in the drug group and 4 in the placebo group). The rate of myocardial infarction and coronary death was 3.1 per 100 person-years (1.9 per 100 person-years in the drug group and 4.5 per 100 person-years in the placebo group; $P = 0.03$).

Table 1 shows the clinical characteristics, at baseline and during the trial, of patients with and without coronary events. Patients with coronary events were more likely to have been assigned to placebo, had lower HDL cholesterol levels during treatment, had greater absolute common carotid arterial intima-media thicknesses, and had more common carotid arterial intima-media thickness progression and coronary artery disease progression. The correlations between the change in

percent diameter stenosis and the two measures of carotid arterial intima-media thickness were 0.21 for absolute carotid arterial intima-media thickness (*P* = 0.03) and 0.28 for carotid arterial intima-media thickness change rate (*P* = 0.02). The correlation between the two carotid arterial intima-media thickness measures was 0.15 (*P* = 0.11).

View this table: [in this window] [in a new window]	Table 1. **Clinical Characteristics of the Study Cohort (*n* = 146) at Baseline and during the Trial, Stratified by Occurrence of Clinical Coronary Events***

Common Carotid Arterial Intima-Media Thickness Change Rate and Risk for Coronary Events

Carotid arterial intima-media thickness progression was significantly related to risk for subsequent myocardial infarction or coronary death (Table 2) (relative risk, 2.2 per 0.03 mm/year; *P* < 0.001). The relative risk for myocardial infarction or coronary death in the highest quartile of intima-media thickness change rate (≥ 0.034 mm/year) was 2.8 relative to the lowest quartile (<0.011 mm/year). In analysis by treatment group, relative risks of similar magnitude were found in the placebo group (relative risk, 2.1 per 0.03 mm/year; *P* = 0.02) and the drug group (relative risk, 2.4 per 0.03 mm/year; *P* = 0.007). Analyses of the relation between the carotid arterial intima-media thickness change rate and subsequent risk for any coronary event yielded results similar to those for myocardial infarction and coronary death (Table 2).

View this table: [in this window] [in a new window]	Table 2. **Common Carotid Arterial Intima-Media Thickness Change Rate and Risk for Clinical Coronary Events***

Absolute Common Carotid Arterial Intima-Media Thickness and Risk for Coronary Events

The absolute carotid arterial intima-media thickness was significantly related to risk for myocardial infarction or coronary death (Table 3) (relative risk, 1.4 per 0.13 mm; *P* = 0.02). The relative risk for myocardial infarction or coronary death in the highest quartile of absolute intima-media thickness (≥ 0.733 mm) relative to the lowest quartile (<0.566 mm) was 7.7. In analysis by treatment group, absolute common carotid arterial intima-media thickness was significantly related to risk for myocardial infarction or coronary death in the drug group (relative risk, 1.9 per 0.13 mm; *P* = 0.009) but not in the placebo group. Analyses of the relations between absolute carotid arterial intima-media thickness and subsequent risk for any coronary event yielded results similar to those of myocardial infarction or coronary death (Table 3). Although absolute carotid arterial intima-media thicknesses in the placebo group were not significantly related to coronary events, the relative risks in the upper quartiles were elevated (≥ 3.8).

View this table: [in this window] [in a new window]	Table 3. **Absolute Common Carotid Arterial Intima-Media Thickness and Risk for Clinical Coronary Events***

Coronary Angiography, Carotid Arterial Intima-Media Thickness Progression, Lipids, and Risk for Coronary Events: Multivariate Analyses

In evaluations of both measures of common carotid arterial intima-media thickness (Table 4, model 1), both the intima-media thickness change rate and the absolute intima-media thickness were independent predictors of coronary events ($P < 0.05$). In models evaluating measures of carotid and coronary atherosclerosis (Table 4, models 2 and 3), each carotid arterial intima-media thickness measure contributed significantly to prediction of the event risk beyond that provided by the coronary measure of change in percent diameter stenosis ($P < 0.05$). All three measures contributed significantly to the prediction of any coronary event (Table 4, model 4).

View this table: [in this window] [in a new window]	Table 4. **Multivariate Associations of Lipid Levels and Coronary Arterial and Common Carotid Arterial Measures of Atherosclerosis with Risk for Clinical Coronary Events***

Because HDL cholesterol levels during treatment were related to any coronary event (Table 1) and because HDL cholesterol was the only lipid significantly related to risk for coronary events in Cox regression analyses (data not shown), the predictive contribution of this variable was also evaluated. Each carotid arterial intima-media thickness measure contributed significantly to prediction of the event risk beyond that provided by measurements of HDL cholesterol levels alone (Table 4), models 5 and 6; $P < 0.05$), and all measures of carotid or coronary atherosclerosis contributed significantly to prediction of the event risk beyond that provided by HDL cholesterol levels alone (Table 4), model 7; $P < 0.05$).

Because of the demonstrated prognostic utility of the two carotid arterial intima-media thickness measurements and the apparent correlation of the change rate with treatment, we evaluated the independent contribution of treatment group to the prediction of the definitive clinical outcome of nonfatal myocardial infarction or coronary death. Considered univariately, assignment to the drug group decreased the relative risk for nonfatal myocardial infarction or coronary death by 0.41 (95% CI, 0.20 to 0.80) ($P = 0.01$). After adjustment for the absolute intima-media thickness, the relative risk was unchanged: 0.45 (CI, 0.23 to 0.90) ($P = 0.02$). In contrast, after adjustment for the intima-media thickness change rate, the treatment effect on nonfatal myocardial infarction or coronary death was no longer apparent (relative risk, 1.1 [CI, 0.4 to 2.6]; $P > 0.2$).

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The rate of change of preintrusive carotid atherosclerosis determined by measurement of the intima-media thickness of the distal common carotid arterial far wall was predictive of coronary events. For each 0.03-mm increase per year in common carotid arterial intima-media thickness, the relative risk for nonfatal myocardial infarction or coronary death was 2.2 and the relative risk for nonfatal myocardial infarction, coronary death, or a revascularization procedure was 3.1 (Table 2). This relation with coronary events was similar in the placebo group and the drug group (Table 2).

In addition, the absolute measurement of the intima-media thickness of the distal common carotid arterial far wall was predictive of coronary events. For each 0.13-mm increment in common carotid arterial intima-media thickness, the risk for coronary events increased (relative risk, 1.4 for myocardial infarction or coronary death and for any coronary event) (Table 3). Patients in the highest quartile had a very elevated risk for coronary events (Table 3). In analysis by treatment group,

absolute carotid arterial intima-media thickness was significantly related to risk for myocardial infarction or coronary death or any coronary event in the drug group but not in the placebo group (Table 3). These findings show an overall gain in the prediction of coronary events in an untreated group of patients by using multiple measurements of intima-media thickness rather than a single determination. In addition, after adjustment for the intima-media thickness change rate, the effect of treatment on nonfatal myocardial infarction or coronary death was no longer apparent. This finding indicates that the effect of treatment on coronary events was mediated through the measurement of the intima-media thickness change rate.

Although previous studies have examined the relation between a single measure of carotid artery atherosclerosis and coronary events, none have examined the relation of progression of common carotid arterial intima-media thickness and coronary events. On the basis of a categorical system describing carotid artery structural changes (including intrusive lesions), Salonen and Salonen [19] reported that a one-time measurement of the maximal common carotid arterial intima-media thickness greater than 1.0 mm was predictive of acute myocardial infarction over a 1-month to 3-year period (relative risk, 2.2 [CI, 0.7 to 6.7]). Using a categorical system describing the severity of atherosclerosis at the carotid and femoral artery bifurcations, Belcaro and colleagues [20] also reported that a one-time intima-media thickness measurement greater than 1.0 mm in asymptomatic patients was predictive of a cardiovascular event over a 6-year period. In both studies, early preintrusive atherosclerosis intima-media thickness values less than 1.0 mm were considered the "normal" referent category. Despite differences in end point definitions, our risk relationships of coronary events and absolute intima-media thickness are consistent with findings from these previous studies.

Our results indicate that measures of atherosclerotic progression from two arterial beds are independent predictors of coronary events (Table 4, models 2 to 4). The relation between common carotid arterial intima-media thickness and angiographic presence and extent of coronary artery disease has been reported elsewhere [10, 11], and many risk factors that contribute to the progression of atherosclerosis are shared by the two arterial beds [8, 9, 13, 16, 21-24]. In addition, we have shown that treatment with LDL-cholesterol-lowering drugs significantly reduces common carotid arterial intima-media thickness [3, 16, 22]. The independence of these two measures is probably due to the fact that each assesses different phases of the atherosclerotic process: Carotid arterial intima-media thickness assesses early atherosclerosis still limited to the arterial wall, whereas quantitative coronary angiography assesses advanced atherosclerosis when intrusive lesions are present. It is generally acknowledged that the magnitude of reduction in coronary events is out of proportion to the magnitude of reduction in coronary stenosis, thereby supporting plaque stabilization as an underlying mechanism. Our data indicate that carotid arterial intima-media thickness incorporates additional, independent information on prediction of coronary events beyond the angiographic measurement of luminal narrowing.

The association of advanced coronary atherosclerotic lesions with risk factors and risk for coronary events has been determined by serial coronary angiography [4-623, 24]. However, progression of the early preintrusive phases of atherosclerosis cannot be determined by angiography because this method allows visualization of the arterial lumen only. Screening and treatment strategies that use angiography are not feasible. On the other hand, measurement of carotid arterial intima-media thickness is noninvasive and can easily be deployed as a low-cost surrogate end point for the progression of coronary artery atherosclerosis. The demonstration that progression of carotid arterial intima-media thickness is predictive of coronary events has important implications for clinical research as well as for clinical assessment and treatment of risk factors for atherosclerosis.

Because almost all persons in affluent societies develop atherosclerosis but not all develop clinical symptoms [25], screening and treatment strategies that use clinical risk factor assessment to identify persons at high risk for the development of symptoms have been recommended. However, guidelines that attempt to apply risk assessment determined from population studies to preventive interventions of an individual person are limited because the causes of atherosclerosis are multifactorial [26]. Although risk factors are etiologically important for atherosclerosis, they are not ideal for screening a population at high risk for coronary events [27]. Traditional lipid and nonlipid clinical markers of risk for atherosclerosis do not necessarily reflect the atherosclerotic process at the level of the arterial wall.

Measurement of carotid arterial intima-media thickness progression, the result of each individual person's response to his or

her own risk factor burden, removes inferences about the atherosclerotic process derived from traditional risk factor assessment by providing direct information about the progression of atherosclerosis at the level of the arterial wall. A screening strategy based on the rate of intima-media thickness progression is a more rational approach to prevention of coronary artery disease [2] that may improve our ability to decide who should receive antiatherosclerotic therapy to reduce risk for development of clinical symptoms. As we have shown, each carotid arterial intima-media thickness measure contributed significantly to the prediction of coronary events beyond that predicted by HDL cholesterol alone (Table 4, models 5 and 6). To the extent that common carotid arterial intima-media thickness progression is associated with risk for coronary events, a potentially enormous clinical significance is linked to the noninvasive assessment of the progression of early preintrusive atherosclerosis.

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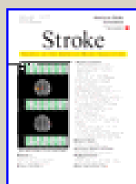

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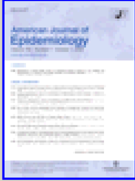

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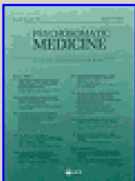

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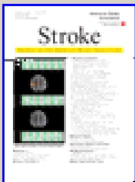

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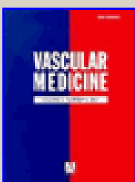

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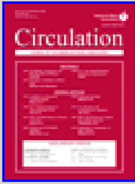

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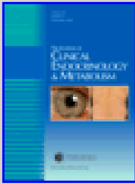

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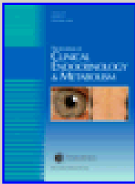

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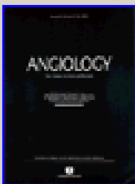

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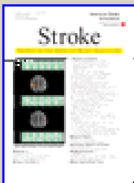

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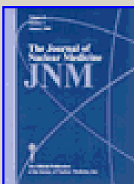

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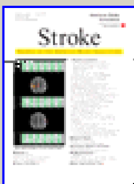

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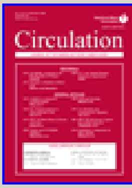

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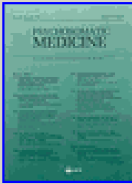

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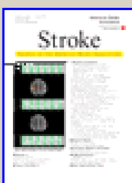

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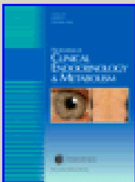

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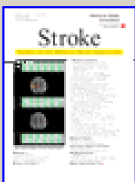

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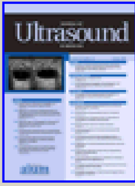

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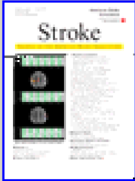

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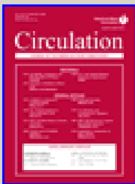

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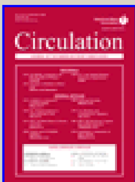

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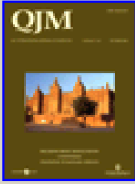

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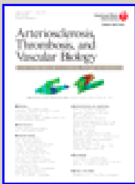

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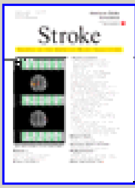

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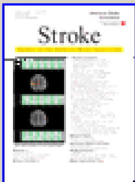

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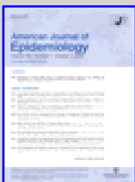

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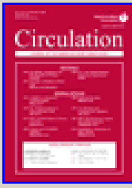

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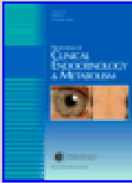

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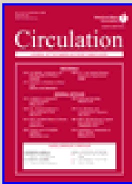

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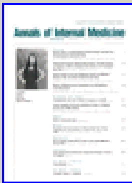

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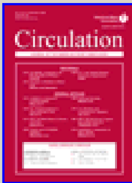

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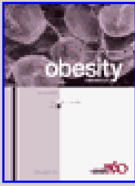

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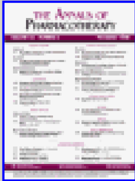

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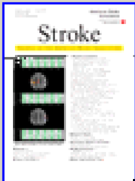

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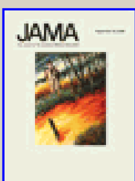

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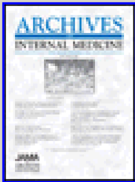

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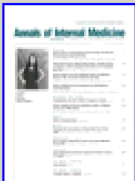

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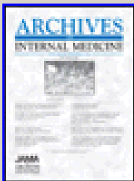

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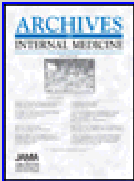

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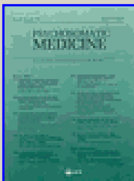

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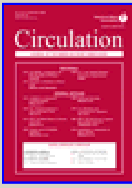

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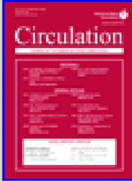

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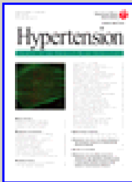

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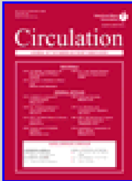

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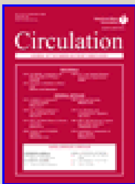

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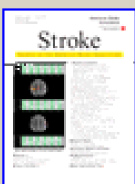

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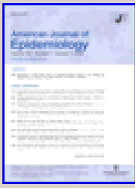

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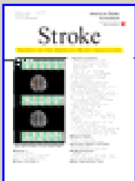

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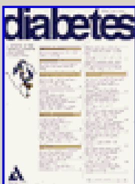

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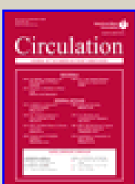

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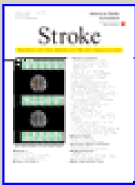

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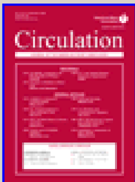

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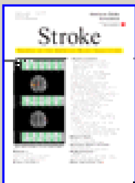

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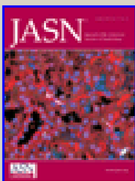

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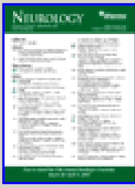

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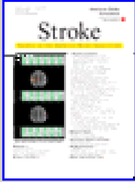

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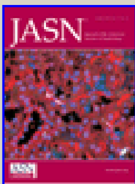

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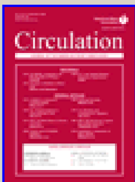

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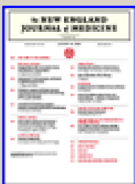

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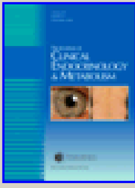

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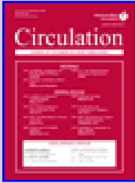

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