Impact of Electron Beam Tomography, With or Without Case Management, on Motivation, Behavioral Change, and Cardiovascular Risk Profile

A Randomized Controlled Trial

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Context Although the use of electron beam tomography (EBT) as a motivational tool to change behavior is practiced, its efficacy has not been studied.

Objective To assess the effects of incorporating EBT as a motivational factor into a cardiovascular screening program in the context of either intensive case management (ICM) or usual care by assessing its impact over 1 year on a composite measure of projected risk.

Design Randomized controlled trial with a 2 × 2 factorial design and 1 year of follow-up.

Setting and Participants A consecutive sample of 450 asymptomatic active-duty US Army personnel aged 39 to 45 years stationed within the Washington, DC, area and scheduled to undergo a periodic Army-mandated physical examination were enrolled between January 1999 and March 2001 (mean age, 42 years; 79% male; 66 [15%] had coronary calcification; mean [SD] predicted 10-year coronary risk, 5.85% [3.85%]).

Interventions Patients were randomly assigned to 1 of 4 intervention arms: EBT results provided in the setting of either ICM (n=111) or usual care (n=119) or EBT results withheld in the setting of either ICM (n=124) or usual care (n=96).

Main Outcome Measure The primary outcome measure was change in a composite measure of risk, the 10-year Framingham Risk Score (FRS).

Results Comparing the groups who received EBT results with those who did not, the mean absolute risk change in 10-year FRS was +0.30 vs +0.36 (P=.81). Comparing the groups who received ICM with those who received usual care, the mean absolute risk change in 10-year FRS was –0.06 vs +0.74 (P=.003). Improvement or stabilization of cardiovascular risk was noted in 157 patients (40.2%). In multivariable analyses predicting change in FRS, after controlling for knowledge of coronary calcification, motivation for change, and multiple psychological variables, only the number of risk factors (odds ratio, 1.42; 95% confidence interval, 1.16-1.75 for each additional risk factor) and receipt of ICM (odds ratio, 1.62; 95% confidence interval, 1.04-2.52) were associated with improved or stabilized projected risk.

Conclusions Using coronary calcification screening to motivate patients to make evidence-based changes in risk factors was not associated with improvement in modifiable cardiovascular risk at 1 year. Case management was superior to usual care in the management of risk factors.

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CARDIOVASCULAR RISK FACTOR modification programs for primary prevention traditionally have been implemented through the use of cardiovascular risk prediction to target risk-reduction strategies.[1] Although conventional risk prediction can explain up to 75% of the risk of clinical coronary heart disease,[2] there is a need for both improved methods of risk detection and increasing motivation to modify risk. Evidence exists that cardiovascular risk screening—and its feedback—has mild but nonsustained beneficial effects on serum cholesterol levels, diet, and predicted risk.[3-8] However, concerns also exist that such interventions may have adverse consequences, such as the effects of disease labeling on quality of life.[9-11] The dilemma is that given the scope of global illness burden due to cardiovascular disease,[12,13] there is a need for new strategies to improve both risk prediction and primary prevention of coronary artery disease.

The use of diagnostic screening tests for the purpose of enhancing motivation toward healthy behavioral modification is widely practiced, but its effectiveness is not well studied. Electron beam tomography (EBT) is a

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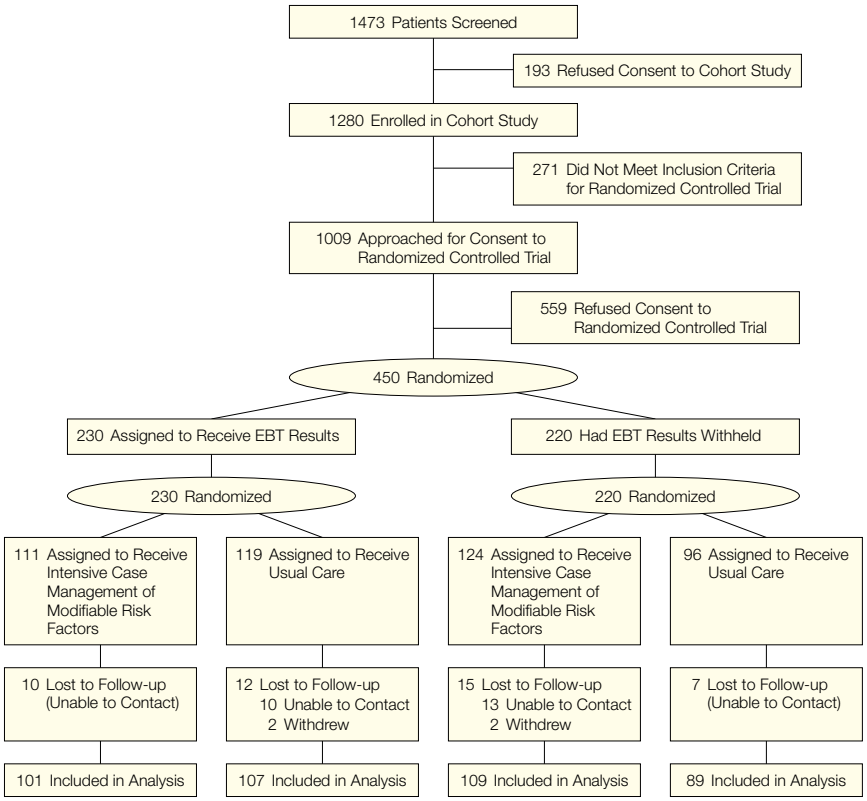
Figure. Flow of Participants Through the Randomized Controlled Trial



EBT indicates electron beam tomography.

new technology used for the detection of subclinical coronary artery disease that has been validated as a tool to predict cardiovascular risk, although its incremental value is controversial.[14] There may also be utility for EBT in improving motivation for cardiovascular risk factor modification by capitalizing on the "teachable moment" of visualizing coronary calcification, as suggested by a retrospective survey study.[15]

We conducted a randomized controlled trial to test the added efficacy of anatomically based coronary heart disease detection with EBT compared with conventional risk prediction alone in the context of either intensive risk factor modification or usual care. We hypothesized that showing patients a picture of their coronary anatomy with EBT, whether with or without evidence of underlying coronary calcification, would generally enhance motivation to modify risk factors to reduce risk of developing clinical coronary heart disease.

METHODS

Study Design

We undertook a randomized controlled trial of 2×2 factorial design comparing anatomically based cardiovascular risk prediction with conventional risk prediction with or without intensive risk factor management in a consecutive sample of participants undergoing a periodic screening physical examination. This protocol was approved by the Department of Clinical Investigation and the Human Use Committee of Walter Reed Army Medical Center (Washington, DC) and was federally funded. Our report follows the CONSORT statement on reporting parallel-group randomized trials.[16] The methods of the Prospective Army Coronary Calcium (PACC) project have been previously published.[17]

Study Patients

Eligible patients included all active-duty US Army personnel aged 39 to 45 years stationed within the Washington, DC, area and scheduled to undergo a periodic Army-mandated physical examination. Participation in the protocol was entirely voluntary. Eligible patients who were approached for consent were explicitly informed that nonparticipation in the study protocol would in no way affect their future medical care or military career. Patients with a history of coronary heart disease or who indicated a history of angina pectoris on the questionnaire of Rose et al[18] were ineligible.

All patients underwent a health risk appraisal, already part of the routine Army physical examination, then were asked to participate in the PACC cohort study, which included an EBT and once-yearly telephone contact for at least 5 years. At the same time that participants enrolled in the cohort study (before an EBT was performed), they were asked to also voluntarily participate in a 1-year randomized controlled trial to assess the impact of knowledge of EBT results on risk factor modification and other behavioral factors.

Between January 1, 1999, and March 14, 2001, 1473 eligible patients were screened, of whom 1280 enrolled in the cohort study; from this group, 450 provided written informed consent to undergo EBT in addition to the required physical examination procedures (FIGURE). Of those enrolled in the cohort study who were excluded from the randomized trial, 271 were not eligible because they were not expected to be in the local area for at least 1 year and the remainder (n=559) were nonconsenters. Those who did not consent to the randomized trial were similar to the randomized trial participants with respect to age, sex, education, motivation to change lifestyle, and cardiovascular risk factors.

Randomization

We randomly assigned the 450 participants to 1 of 4 intervention arms us-

ing a random-numbers table in a 2-stage fashion: EBT results provided in the setting of intensive case management (ICM); EBT results provided in the setting of usual care; EBT results withheld in the setting of ICM; and EBT results withheld in the setting of usual care. Sealed enrollment packets (opaque and stamped with the log number) were centrally located with the data manager and were not accessible by research nurses, who approached patients for consent to the study. Only after participants completed the consent process were they officially enrolled with a log number, after which research nurses obtained the packets from the data manager. The allocation sequence was concealed to all research personnel. After participants were enrolled, they completed a series of surveys, an electrocardiogram, biometric measurements, and an EBT scan. After EBT, the radiologist printed out a picture of the scan results and calculated a score. These results were concealed in the information systems of the health care system and placed in a sealed envelope until participants met with a research nurse to discuss the results or completion of the trial, depending on study group assignment. Among those assigned to receive EBT information, research nurses met with participants and discussed the results of the EBT in a standardized fashion. Patients randomized to withholding of EBT results received this information after completing the 1-year follow-up of their initial examination.

Measurements

Each participant provided details of his/her medical history, smoking status, and family history of premature coronary heart disease. Biometric variables were measured in standard fashion as previously described.[17] Measured cardiovascular risk variables were used to calculate the predicted cardiovascular risk using the 10-year Framingham Risk Score (FRS) equations.[19] We measured several dimensions of physical, social, and emotional functioning using the Short Form-36,[20] anxiety scores using the Taylor Anxiety Score and the PRIME-MD self-reported Patient Health Questionnaire,[21,22] stage of behavioral change using a ladder score,[23,24] as well as physical activity,[25] medication use, dietary intake,[26] and hostility level.[27] All of these tools have been validated in prior studies and are widely used.

One year after study enrollment, we repeated measurement of all variables and again assessed the FRS to analyze the 1-year change in these variables.

Assessment of Subclinical Atherosclerosis

The presence and quantification of subclinical atherosclerosis was determined from a single baseline examination through measurement of coronary artery calcification by EBT using the scoring method of Agatston et al.[28] Electron beam tomography was performed using an Imatron C-150LXP scanner (GE Imatron, South San Francisco, Calif). Images were obtained using a 40- to 50-slice (3-mm thickness) protocol with image acquisition gated to 70% to 80% of the electrocardiographic R-R interval while respirations were held. Scans were scored and interpreted by an experienced radiologist (I.M.F.) who was blinded to the clinical status and intervention group of participants. This scoring system has been demonstrated to correlate well with histologic and angiographic plaque burden.[29-34]

Interventions

The results of the EBT (a representative picture of the coronary anatomy with focus on any abnormalities and the coronary calcification score) were presented to each participant in a standardized fashion with the statement that calcification specifically identifies underlying atherosclerotic coronary artery disease and is predictive of heart disease risk (full script of presentation available from the authors). The counseling was coupled with risk factor identification and advice with the intent of capturing the "teachable moment" in those who had coronary calcification, modeling the success of other interventions in the setting of objective disease, such as acute myocardial infarction.[35,36] Those who did not have coronary calcification were given cautious reassurance about their heart disease risk and counseled about risk factor management according to national treatment guidelines. All modifiable risk factors were targeted for intervention, including hypertension, obesity, hyperlipidemia, sedentary lifestyle, smoking, high-fat diet, and glucose intolerance.

Further counseling depended on assignment to either ICM or usual care. Usual care risk factor modification involved general counseling by a research nurse. The counseling consisted of dietary, smoking cessation, and exercise counseling. Participants with modifiable risk factors also received referrals to their primary care physician, a dietitian, and a smoking cessation program as appropriate. When a potential need for risk-reducing medications was identified according to national guidelines, the prescription and follow-up were deferred to participants' primary care physicians.

Intensive case management was defined as an integrated approach of research nurses and dietitians providing frequent contact tailored to participants' stages of behavioral change.[23,24,37,38] This consisted of an initial counseling session at the time of randomization that focused on achievable goals based on the individual's stage of change and hostility level. Reinforcement was provided through follow-up contacts at 2 weeks by telephone, at 4 weeks by mail, at 8 weeks through a visit (at which time repeat measurements were performed to guide the counseling session and provide feedback), at 12 weeks by mail, at 16 weeks through a visit (with the same repeat measurements), and at 24 weeks through a visit (with repeat measurements). At 24 weeks, if a participant's low-density lipoprotein cholesterol goal (based on National Cholesterol Education Program guidelines) was not achieved, a cholesterol-lowering medication was prescribed in accordance with standard of care. If coronary calcification was present, this

was incorporated into case management as an objective sign of subclinical coronary artery disease to activate the individual to modify behaviors. When a potential need for risk-reducing medications was identified (according to national guidelines), these were prescribed either by the study team or the patient's physicians according to the participant's preference.

Table 1. Baseline Characteristics of 450 Consecutive Asymptomatic Participants Presenting for Periodic Physical Examination Involving a Cardiovascular Screening Program*

Variables	EBT Information (n = 230)	No EBT Information (n = 220)	*P* Value
Sex, male	185 (80.4)	172 (78.2)	.56
Age, mean (SD), y	41.9 (1.9)	42.0 (1.9)	.58
Completed college	187 (81.7)	162 (75.0)	.11
Married	186 (80.9)	180 (81.8)	.81
Race			
Black, non-Hispanic	51 (22.4)	47 (21.6)	.56
White, non-Hispanic	156 (68.4)	140 (64.2)	
Medical history			
Current cigarette use	18 (7.8)	20 (9.2)	.50
Diabetes	1 (0.4)	2 (1.8)	.21
Hypertension	25 (10.9)	25 (11.4)	.88
Family history of CAD	34 (15.6)	39 (17.8)	.61
Hypercholesterolemia	44 (19.1)	40 (18.2)	.81
Depression or anxiety disorder	32 (13.9)	32 (14.1)	.99
Medication use			
Statins	11 (4.8)	6 (2.8)	.33
Hypertensive agents	11 (4.8)	14 (6.5)	.54
Antidepressants	15 (6.5)	8 (3.7)	.20
Biometric and behavioral measures, mean (SD)			
Systolic blood pressure, mm Hg†	121.7 (12.3)	120.7 (12.4)	.38
Diastolic blood pressure, mm Hg†	76.4 (9.0)	75.4 (8.9)	.24
Body mass index‡	27.1 (3.3)	27.2 (3.7)	.89
Physical activity§	3.0 (0.85)	2.9 (0.87)	.62
Dietary fat intake, kcal‖	37.2 (0.09)	38.2 (0.19)	.60
Motivation to change¶	8.3 (1.3)	8.3 (1.5)	.99
Laboratory variables, mean (SD)			
Fasting glucose, mg/dL	89.2 (10.4)	91.0 (13.5)	.12
Hemoglobin A_{1C}, %	5.5 (0.5)	5.6 (0.6)	.06
Lipids, mg/dL			
Total cholesterol	199.8 (36.6)	202.3 (33.5)	.45
LDL-C	126.7 (34.1)	130.2 (33.9)	.27
HDL-C	54.3 (14.6)	53.9 (15.6)	.78
Triglycerides	113.6 (63.9)	113.4 (57.8)	.97
Coronary calcification	41 (17.8)	25 (11.5)	.08
Coronary calcification score, mean (SD)	7.9 (27.7)	3.7 (17.8)	.06
≥1 Risk factor	171 (77.8)	176 (76.7)	.52
Framingham Risk Score, mean (SD), %#	5.78 (3.84)	5.91 (3.87)	.72

Abbreviations: CAD, coronary artery disease; EBT, electron beam tomography; HDL-C, high-density lipoprotein cholesterol; LDL-C, low-density lipoprotein cholesterol.
SI conversion factors: To convert total, HDL, and LDL cholesterol to mmol/L, multiply values by 0.0259; to convert glucose to mmol/L, multiply values by 0.0555; to convert triglycerides to mmol/L, multiply values by 0.0113.
*Data are expressed as number (percentage) unless otherwise noted.
†Systolic and diastolic blood pressures are the average of 3 measurements taken while seated and after 5 minutes of rest.
‡Body mass index was calculated as weight in kilograms divided by the square of height in meters.
§Physical activity was measured using the validated Baecke Physical Activity questionnaire.[25] Number represents a sports index ranging from 0 to 5.
‖Dietary fat intake was assessed using the Block Dietary Intake questionnaire.[26]
¶Motivation to change was based on a visual ladder score from 1 to 10 to measure overall behavioral stage of change.[23,24]
#The Framingham Risk Score denotes the 10-year probability of cardiovascular disease (myocardial infarction, coronary heart disease death, angina pectoris, stroke, congestive heart failure, and peripheral vascular disease); values were obtained using the logistic function derived from data in the Framingham Heart Study.[19]

Outcome Measures

The primary outcome variable was change in 10-year predicted event rate (FRS) at 1 year after enrollment. The FRS was calculated using the continuous measure of risk from the logistic function derived from the Framingham Heart Study.[19] It is a standard assessment of the probability of cardiac death or nonfatal myocardial infarction and has been validated as a predictive tool in several cohort studies.[1,2]

Secondary outcomes included change in individual risk factor variables (blood pressure, body mass index, and glucose and cholesterol levels), behaviors (exercise and dietary fat intake), functional status, motivation to change lifestyle, and emotional factors (anxiety, depression, and stress).

Statistical Analysis

The sample size determination (n=450) for this study was based on the primary end point of change in predicted risk based on cumulative risk factors. Assuming an SE of change in 10-year FRS predicted risk of 0.55%, $\alpha = .01$, and $\beta = .10$, a sample size of 100 patients per arm would be required to detect a 0.3% between-group difference in change in 10-year predicted risk. For those lost to follow-up, multiple analyses were performed to assess the sensitivity of our findings to the absence of these data, whereby data on these participants were excluded or either a change in FRS of 0 or an average change in FRS for study group assignment was imputed. Two-tailed χ^2 analysis and the *t* test or the Mann-Whitney rank sum test were used for univariate comparisons of categorical and continuous variables, respectively. Multivariable models predicting change in FRS (with tests of main effects and interactions, as well as controlling for stage of change, psychological variables, and baseline differences with $P<.20$) were calculated using logistic regression. Model fit was assessed using the Hosmer-Lemeshow goodness-of-fit test. Data were analyzed by an intention-to-treat approach. There were no crossovers; thus, patients who completed the 1-year as-

sessment were analyzed according to initial treatment assignment. A 2-tailed *P* value of .05 or less was considered to indicate statistical significance. All analyses were performed with SPSS version 11 (SPSS Inc, Chicago, Ill).

RESULTS

Patient Characteristics

Of the 450 randomized participants, 406 (90%) completed the 1-year follow-up. Baseline characteristics and risk factor profiles of the participants are shown in TABLE 1 by assignment to receipt vs withholding of EBT information. The cohort as a whole (mean age, 42 years; 79% male; 15% prevalence of coronary calcification) had a mean (SD) predicted coronary risk (10-year FRS) of 5.85% (3.85%). The overall projected risk was low to intermediate, but more than 75% of the cohort had at least 1 modifiable risk factor. No significant baseline differences between the groups were found, though there was a trend toward a higher prevalence of calcification among those who received EBT information compared with those who did not (17.8% vs 11.5%; *P*=.08).

Primary Outcome

Comparing the group who received EBT results with those who did not, the mean change in FRS after 1 year of follow-up was 0.30% (95% confidence interval [CI], –0.05% to 0.64%) vs 0.36% (95% CI, –0.04% to 0.76%) (*P*=.81) (TABLE 2). Comparing the group who received ICM with those who did not, the mean change in FRS was –0.06% (95% CI, –0.43% to 3.1%) vs 0.74% (95% CI, 0.37%-1.10%) (*P*=.003) (TABLE 3). The mean 1-year changes in FRS were –0.057% (95% CI, –0.53% to 0.41%) for EBT information with ICM; 0.63% (95% CI, 0.13%-1.13%) for EBT information without ICM; –0.058% (95% CI, –0.63% to 0.52%) for ICM without EBT information; and 0.86% (95% CI, 0.33%-1.40%) for usual care without EBT information (*P*=.03 by analysis of variance) (TABLE 4). These analyses included data only for participants who completed follow-up at 1 year. Informed imputations for loss to follow-up and missing data did not significantly change the results.

One year after follow-up, 157 (40.2%) had an improvement in their predicted risk (defined as ≤0 change in 10-

Table 2. Primary and Secondary Outcome Measures After 1 Year of Follow-up by Receipt of EBT Information*

Outcomes	EBT Information (n = 208)	No EBT Information (n = 197)	*P* Value†
Change in 10-year Framingham Risk Score (primary outcome measure), mean (SD), %	0.30 (0.18)	0.36 (0.20)	.81
Change in secondary outcome measures, mean (SE)			
Motivation to change	0.27 (0.09)	0.38 (0.12)	.48
Systolic blood pressure, mm Hg	0.96 (0.80)	1.65 (0.79)	.54
Diastolic blood pressure, mm Hg	2.3 (0.3)	0.90 (0.28)	.67
Body mass index	0.38 (0.12)	0.35 (0.11)	.84
LDL-C, mg/dL	–6.38 (1.51)	–5.77 (1.94)	.81
Physical activity	0.02 (0.05)	–0.08 (0.05)	.23
Proportion who quit smoking	5/13	4/17	.63
Fasting glucose, mg/dL	1.19 (0.76)	0.27 (1.30)	.53
Hemoglobin A_{1C}, %	–0.15 (0.03)	–0.21 (0.05)	.25
Depression score‡	–0.04 (0.21)	–0.13 (0.22)	.75
Anxiety score‡	–0.19 (0.18)	–0.38 (0.21)	.50
Stress score§	–0.51 (0.19)	–0.62 (0.17)	.67
Mental health functional status‖	0.44 (0.55)	1.01 (0.48)	.44

Abbreviations: EBT, electron beam tomography; LDL-C, low-density lipoprotein cholesterol.
*Analysis included data only for participants who completed follow-up at 1 year. Informed imputations for loss to follow-up and missing data did not significantly change the results. See Table 1 footnotes for conversion factors and descriptions of outcome measures.
†Calculated from analysis of variance for between-group comparisons of change after 1 year of follow-up.
‡Continuous scores for depression and anxiety were obtained using the PRIME-MD[22] based on the number and severity of symptoms reported in each domain. Higher scores indicate worse mental health.
§Stress was measured by the number and severity of responses to measures of 9 different domains of life (work, finances, relationships, caregiving burden, body image, sexuality, psychological support, health, and traumatic life experiences).
‖Mental health functional status was measured with the Short Form-36.[20]

Table 3. Primary and Secondary Outcome Measures After 1 Year of Follow-up by Receipt of ICM or Usual Care*

Outcomes	ICM (n = 209)	Usual Care (n = 196)	*P* Value†
Change in 10-year Framingham Risk Score (primary outcome measure), mean (SD), %	–0.06 (0.19)	0.74 (0.18)	.003
Change in secondary outcome measures, mean (SE)			
Motivation to change	0.58 (0.10)	0.06 (0.11)	.001
Systolic blood pressure, mm Hg	0.75 (0.79)	1.89 (0.81)	.31
Diastolic blood pressure, mm Hg	–0.03 (0.61)	0.72 (0.69)	.41
Body mass index	–0.31 (0.11)	–0.42 (0.12)	.53
LDL-C, mg/dL	–7.85 (1.88)	–4.19 (1.53)	.14
Physical activity	–0.06 (0.83)	0.01 (0.05)	.41
Proportion who quit smoking	8/21	1/9	.30
Fasting glucose, mg/dL	0.26 (1.16)	1.25 (0.91)	.50
Hemoglobin A_{1C}, %	–0.15 (0.04)	–0.21 (0.04)	.21
Depression score	–0.19 (0.21)	0.03 (0.22)	.46
Anxiety score	–0.39 (0.18)	–0.17 (0.21)	.43
Stress score	–0.59 (0.18)	–0.54 (0.18)	.86
Mental health functional status	1.15 (0.49)	0.27 (0.55)	.23

Abbreviations: ICM, intensive case management; LDL-C, low-density lipoprotein cholesterol.
*Analysis included data only for participants who completed follow-up at 1 year. Informed imputations for loss to follow-up and missing data did not significantly change the results. See Tables 1 and 2 footnotes for conversion factors and descriptions of outcome measures.
†Calculated from analysis of variance for between-group comparisons of change after 1 year of follow-up.

Table 4. Primary and Secondary Outcome Measures After 1 Year of Follow-up by 2 × 2 Factorial Grouping*

Outcomes	EBT Information (n = 208)		No EBT Information (n = 198)		P Value†
	ICM (n = 101)	Usual Care (n = 107)	ICM (n = 109)	Usual Care (n = 89)	
Change in 10-year Framingham Risk Score (primary outcome measure), mean (SD), %	−0.057 (0.24)	0.63 (0.25)	−0.058 (0.29)	0.86 (0.27)	.03
Change in secondary outcome measures, mean (SE)					
Motivation to change	0.49 (0.11)	0.07 (0.14)	0.65 (0.17)	0.05 (0.16)	.006
Systolic blood pressure, mm Hg	0.40 (1.04)	1.50 (1.21)	1.07 (1.17)	2.36 (1.03)	.69
Diastolic blood pressure, mm Hg	−0.06 (0.77)	−0.06 (0.86)	0.41 (0.74)	0.90 (0.79)	.82
Body mass index	0.39 (0.17)	0.37 (0.18)	0.24 (0.14)	0.47 (0.17)	.80
LDL-C, mg/dL	−6.21 (2.1)	−6.53 (2.17)	−9.36 (3.05)	−1.38 (2.11)	.16
Physical activity	0.05 (0.08)	−0.01 (0.07)	−0.16 (0.08)	0.03 (0.07)	.20
Proportion who quit smoking	5/10	0/3	3/11	1/6	.21
Fasting glucose, mg/dL	1.68 (0.91)	1.14 (0.92)	−1.05 (2.05)	1.88 (1.42)	.43
Hemoglobin A_{1C}, %	−0.09 (0.04)	−0.20 (0.03)	−0.20 (0.06)	−0.23 (0.07)	.30
Depression score	−0.37 (0.27)	0.27 (0.32)	−0.04 (0.33)	−0.26 (0.28)	.46
Anxiety score	−0.47 (0.22)	0.07 (0.28)	−0.32 (0.30)	−0.46 (0.30)	.47
Stress score	−0.43 (0.28)	−0.60 (0.25)	−0.76 (0.26)	−0.48 (0.26)	.82
Mental health functional status	1.09 (0.69)	−0.16 (0.85)	1.20 (0.70)	0.78 (0.63)	.53

Abbreviations: EBT, electron beam tomography; ICM, intensive case management; LDL-C, low-density lipoprotein cholesterol.
*Analysis included data only for participants who completed follow-up at 1 year. Informed imputations for loss to follow-up and missing data did not significantly change the results. See Tables 1 and 2 footnotes for conversion factors and descriptions of outcome measures.
†Calculated from analysis of variance for between-group comparisons of change after 1 year of follow-up.

year FRS despite a 1-year increase in age). There was no difference in this proportion among the groups who received EBT information compared with those who did not (39.9% vs 40.4%; $P=.92$). However, there was a higher proportion of improvement among those who received ICM compared with those who did not (46.0% vs 33.9%; $P=.02$).

Secondary Outcomes

Table 4 shows the effect of EBT information, with or without ICM, on multiple factors. There was no association between the receipt of EBT information and positive changes in cardiovascular health outcomes, but there was also no evidence of adverse effects, such as increase in depressive, anxiety, stress, or mental health functional status scores. Intensive case management was associated with an improvement in overall motivation for change. The mean change in motivation in those receiving ICM was 0.58 (95% CI, 0.37-0.78) vs 0.06 (95% CI, −0.15 to 0.27) ($P=.006$). Change in motivation was inversely correlated with an increase in FRS ($r=-0.12$; $P=.02$), indicating internal validity of the tool to assess motivation.

Multivariable Analyses

In multivariable analyses using baseline variables to predict change in 10-year FRS at 1 year of follow-up, controlling for knowledge of coronary calcification (ie, those who received EBT results and had calcification) or calcification score, sex, age, education, activity level, and depressive, anxiety, hostility, stress, baseline motivation for change, and baseline between-group differences with $P<.20$, only the number of risk factors (odds ratio, 1.42; 95% CI, 1.16-1.75 for each additional risk factor) and receipt of ICM (odds ratio, 1.62; 95% CI, 1.04-2.52) were associated with improved projected risk by FRS. The results did not change when those lost to follow-up were assumed to have a change in FRS of 0, when an average change in FRS for each group was imputed, or when baseline differences (eg, statin use, antihypertensive use) were controlled for. Further analysis exploring potential interaction with the interventions failed to show any evidence of interaction between study group assignments themselves, or with sex, change in motivation to change lifestyle, baseline risk, or knowledge of coronary calcification or a score of 0.

In multivariable analyses exploring which factors accounted for the change in predicted risk as a dichotomous outcome, changes in systolic blood pressure, low-density lipoprotein cholesterol, and quitting smoking (in that order of relative contribution) explained the majority of variance in change in risk.

Subgroup Analysis

Subgroup analysis (n=388 with complete data for this analysis) involving only those with calcification on EBT (n=59) showed a trend toward a smaller increase in risk associated with receiving the EBT information at baseline (mean change, 0.21%; 95% CI, −0.97% to 1.39%) compared with those from whom EBT information was withheld (1.52%; 95% CI, 0.40%-2.63%; $P=.13$). More participants who received the information had stable or reduced cardiovascular risk but this was not statistically significant (41.7% vs 26.1%; $P=.27$). Conversely, analysis involving only those without calcification (n=329) showed similar changes in risk among those who received EBT information at baseline compared with those who did not (mean change,

0.31%; 95% CI, –0.03% to 0.66% vs 0.21%; 95% CI, –0.22% to 0.63%; *P*=.70). There were also similar proportions that showed improvement in risk among the groups without calcification who either did or did not receive the EBT information (39.5% vs 42.6%; *P*=.58).

COMMENT

Our findings show that in an asymptomatic population at an appropriate age for cardiovascular risk screening, the addition of anatomically based subclinical coronary disease diagnosis using EBT does not substantially affect coronary risk profile. We measured change in modifiable behaviors at 1 year, a reasonable period after attempting to activate a patient to change lifestyle. We also found that this lack of effect was not modified by the setting in which the information was given (ICM of risk factors or usual care). To our knowledge, this is the first study to assess the value of subclinical coronary disease diagnostic testing to enhance cardiovascular behavioral modification in a randomized controlled fashion.

It has been hypothesized that presenting objective evidence of disease (in this case, an image of one's coronary arteries) has an activating effect on the patient in a more emotive way than simply alerting a patient to his/her risk of an adverse outcome. Interacting with patients in such a state of readiness to change has also been called "the teachable moment" and such motivational strategies have been shown to be efficacious in improving modification of risk factors (particularly smoking cessation) in the setting of acute myocardial infarction.[35-37] Once the patient is primed for intervention on modifiable behaviors, it is intuitive that a rigorous proactive process to facilitate such change would be a necessary component of a cardiovascular risk reduction program. Although it is rational to extrapolate this to a primary prevention setting in which objective subclinical disease is presented to a patient, it has not been tested in a systematic fashion for the primary prevention of cardiovascular disease.

Adverse effects of anatomically based risk prediction are often not adequately considered—whether that someone with considerable risk factors for disease who has no evidence of preclinical disease might be falsely reassured or that someone with positive results might have adverse psychological or quality-of-life effects.[8-11] There is some evidence that presenting test information (eg, bone densitometry) for other disease states has a beneficial effect on medical interventions.[39,40] However, these trials only showed improvement in the prevalence of an intervention; they did not show improvement in clinical outcomes. In a systematic review of the psychological impact of predicting individuals' risks of illness, receiving a positive test result was associated in the short term with anxiety, depression, poorer perceptions of health, and psychological distress.[41] In our study, we did not find any differences in 1-year stress, mental health functional status, anxiety, or depressive status among those who received EBT information, ICM, or usual care. Also reassuring is that among participants with scores of 0, those who received the EBT information did not have higher increases in projected risk than those who did not, indicating evidence that a score of 0 does not convey false reassurance resulting in adverse behavioral outcomes. However, we and others have found a rate of incidental findings of 8%, one third of which were considered major findings requiring expensive and invasive testing.[42,43]

We did find that ICM had an effect on mitigating the progression of projected risk. The absolute reduction in projected 10-year risk was 0.8% (17% relative risk change), amounting to 8 cardiovascular events prevented (at 10 years) per 1000 patients treated for 1 year (number needed to treat, 125). This calculation involves several critical assumptions, including stability and durability of the risk factor changes. This change in risk associated with ICM is supported by and may be mediated by the improvement in motivation to change. Although there is little evidence that risk factor interventions for primary prevention are associated with improved all-cause and coronary artery disease mortality, such data are plagued by the lack of long-term follow-up.[44] While there is substantial evidence for the use of intensive risk factor management in secondary prevention, more research is required to definitively prove the efficacy of primary prevention programs for the reduction of cardiovascular risk over longer periods. In the meantime, it is appropriate to continue to focus primarily on risk factors for the prevention of cardiovascular disease, especially given the large proportion of variance that is explained by conventional risk factors in large cohorts.[2]

Our study has several important limitations. It is possible that we were unable to show an effect on behavior because this cohort did not have a sufficient prevalence of modifiable risk factors or coronary calcification, especially since the motivating factor is presumably the presence of disease. This is supported by the trend in higher proportion of change among those who had calcification and received this information when looking only at the subgroup with calcification. However, these subgroup analyses, while interesting and provocative, should be interpreted with caution and require further study. A study is needed that specifically addresses the motivational impact of EBT among patients with high FRS, in whom a higher prevalence of calcification would be expected. However, it is notable that our study population was not without substantial prevalence of risk factors. Almost 40% of our cohort was not at low risk by conventional standards,[45] and 4 of 5 participants had at least 1 modifiable risk factor, consistent with national data on the high prevalence of risk factors in the United States.[45] The prevalence of calcification was only 15% in this cohort; however, this is not dissimilar to the prevalence of cases among other screen-

ing initiatives, such as bone mineral density for osteoporosis and mammography for breast cancer.

It is also possible that the consent process excluded patients who might be more or less likely to respond to a motivational intervention. This issue of generalizability of conclusions from randomized trials is a methodological problem of all trials that require consenting participation, thereby excluding a population of patients for whom trial conclusions may not be applicable. Finally, there may be other legitimate reasons for incorporating EBT into prevention programs, such as for improved prognostication. Some recent data suggest that there is incremental prognostic value of coronary calcification, though the clinical significance of this remains to be determined.[46,47]

Further study should be undertaken to assess the motivational effect of atherosclerosis imaging in higher-risk cohorts with higher prevalence of coronary calcification. Most cardiovascular screening programs that incorporate atherosclerosis imaging currently do not discriminate on baseline risk as a determinant of imaging. While the fifth decade of life may be a reasonable time to initiate cardiovascular screening programs, the average absolute risk in this population is still low, as is the prevalence of coronary calcification. It is possible that atherosclerosis imaging for motivational effect could be effective if used only in those who exceed a threshold of predicted risk based on conventional risk prediction.[45] However, more randomized controlled trials with clinical end points are needed before noninvasive tests are routinely implemented in intermediate-risk populations.

Even if use of a diagnostic technology were motivational, it is unlikely to be optimally used without the clinical expertise to interpret the significance of the results. The current widespread use of a model of self-referral for atherosclerosis screening does not formally couple such decision making and interpretation with a regular health care practitioner and, thus, may be largely ineffectual as an intervention to incrementally alter cardiovascular risk.[48,49] Until there is evidence that adding coronary imaging with conventional risk assessment adds incremental value in improving risk, primary prevention programs should preferentially focus on the detection and intensive management of modifiable risk factors and not anatomic case finding for motivational effect.

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Analysis and interpretation of data: O'Malley, Taylor.
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Without *speculation* there is no good and original observation.
—Charles Darwin (1809-1882)