Effects of Baseline Comorbidities on Cancer Screening Trial Adherence among Older African American Men

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Abstract

Background: **The purpose of this study was to examine the effects of baseline comorbidities on screening adherence in a sample of older African American men (ages ≥55 years) enrolled in a case management intervention in a cancer screening trial.**
Methods: **Baseline comorbidity data were obtained from 683 African American men who were randomly assigned to a case management intervention group (n = 344) or to a case management control group (n = 339). The effects of comorbidities on the screening adherence rates of each group were then assessed.**
Results: **No statistically significant interactions were found between each health history characteristic and the intervention. Therefore, analyses were not stratified by intervention status. In general, participants with comorbidities were no less likely to adhere to trial screening than participants without comorbidities. Exceptions were current smokers and participants with chronic bronchitis. Current smokers were less likely than others to adhere to the prostate-specific antigen test (P = 0.02) and the digital rectal examination for prostate cancer screening (P = 0.01), to the chest X-ray for lung cancer screening (P < 0.01), and to the flexible sigmoidoscopy for colorectal cancer screening (P = 0.04). Participants with chronic bronchitis had lower rates of adherence to the chest X-ray (P = 0.06). Having a relative with cancer positively influenced adherence to the digital rectal examination (P = 0.05).**
Conclusions: **Overall, older African American men with comorbidities appear to be very good candidates for participation in longitudinal cancer screening trials. However, smoking had a statistically significant and deleterious effect on adherence to all types of screening.** (Cancer Epidemiol Biomarkers Prev 2008;17(5):1234–9)

Introduction

The research literature describes chronic illness factors associated with the initial decision to enroll in clinical trials (1-3). For example, Jacobsen et al. (4), who examined the characteristics of participants and nonparticipants (ages ≥45 years) in a cardiac ventricular function study, found no differences in participation rates based on past history of coronary heart disease, congestive heart failure, or other cardiovascular disease. In contrast, patients with a history of chronic obstructive pulmonary disease were found to be less likely than others to participate.

Increasing attention is also focused on factors affecting adherence to clinical trial protocols. These factors include age, race, gender, and psychosocial influences (1, 4-9). However, considerably less attention has been given to the effects of baseline health history characteristics on trial adherence and many of these studies included predominantly Caucasian participants (10, 11). Questions remain about the effect of baseline health history characteristics on trial adherence in diverse population groups. African American men tend to participate in cancer screening trials at low rates despite having higher rates of cancer incidence and mortality than their Caucasian counterparts (5, 6, 12-15). Previous studies show that African Americans may be more likely than others to experience attrition when enrolled in clinical trials, although this finding appears to be confounded with income rather than related directly to race (16, 17). These higher rates of attrition in cancer screening trials lead to less screening data obtained from African American men. Without adequate numbers of African American men included in cancer screening trials, it is difficult to evaluate intervention effects on this population subgroup. The purpose of this study was to examine the effects of baseline comorbidities on screening adherence in a sample of older African American men (ages ≥55 years) enrolled in a case management intervention in a cancer screening trial. We hypothesize that participants with comorbidities might be less likely than those without comorbidities to continue to participate in a screening trial for a condition (cancer) with which they have not been diagnosed.

Materials and Methods

Study Sample. The study sample was composed of 683 African American men ages ≥55 years who were

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participating in an adherence trial that was conducted within the context of the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, a 22-year, multisite randomized cancer screening trial funded by the National Cancer Institute (5, 15, 18-20). The primary objective of the PLCO Cancer Screening Trial is to determine whether screening for the four PLCO cancers, which account for 48% of all cancer-related deaths in the United States, decreases mortality from these cancers in adults ages 55 to 74 years at entrance to the trial. At enrollment, PLCO Cancer Screening Trial participants had no previous diagnosis for any of the four study cancers and were not currently undergoing treatment for other cancers.

The 3-year randomized adherence trial was designed to test the efficacy of a case management strategy in retaining African American men in the PLCO Cancer Screening Trial. The Henry Ford Health System, one of the 10 sites involved in the trial contributing ~25,000 of the nearly 155,000 total study participants, served as the location for this study. The Henry Ford Health System Institutional Review Board approved the research protocol for the case management study.

Baseline health history (comorbidity) data were obtained from 683 African American men in the intervention arm of the PLCO Cancer Screening Trial who were then randomly assigned to the case management intervention group (n = 344) or to the case management control group (usual care group; n = 339). The case managers received a listing of the 344 men assigned to the intervention group as well as their PLCO Cancer Screening Trial screening status. The screening status included the following information: the date, time, and location of their next PLCO Cancer Screening Trial screening appointment, whether they had kept their previous screening appointment, and the type of screening they were scheduled to have (whether it was a baseline screening or a follow-up screening).

Case managers contacted intervention group participants at least monthly by telephone and provided information and referral services to participants, their spouses, and other relatives/friends. The case managers also linked these individuals with community-based resources to help them overcome challenges that could have served as barriers to screening participation, such as lack of transportation, lack of food, or lack of heat in their homes. Participants in the usual care group received the usual PLCO Cancer Screening Trial procedures, which included being contacted to schedule their annual screening examinations and receiving an annual mailed survey.

In a previous paper, we reported the results of the adherence trial among African American participants with low income. In particular, we found that among participants with low income, those in the intervention group had higher screening adherence rates than did participants in the control group for (a) prostate-specific antigen (PSA) test for prostate cancer (74.3% versus 53.0%; P = 0.001), (b) digital rectal examination (DRE) for prostate cancer (66.2% versus 46.1%; P = 0.011); and (c) chest X-ray for lung cancer (70.9% versus 51.3%; P = 0.012). In contrast, among participants with moderate to high income, we found no statistically significant differences in adherence rates between intervention and control group participants for any of the screening tests (21).

Measures

Outcome Variables. Adherence was defined as completion of all scheduled PLCO Cancer Screening Trial screening procedures over the retention trial period (postrandomization to the retention trial). Participants in the PLCO Cancer Screening Trial intervention arm are screened for 6 consecutive years following their randomization to this study arm. Screening for prostate cancer is conducted via two methods: blood draw for the PSA test and the DRE. Participants in the screening arm undergo PSA and DRE testing at baseline (time of randomization) and annually for 3 additional years. The PSA test alone is conducted for an additional 2 years, for a total of 6 years of prostate cancer screening.

Lung cancer screening is conducted in the PLCO Cancer Screening Trial via chest X-ray. The original protocol consisted of a single view posterior-anterior chest X-ray at baseline, year 1, year 2, and year 3 for a total of four chest X-rays. The chest X-ray examination schedule was modified in December 1998 to vary by lung cancer risk of subjects. Ever smokers in the PLCO Cancer Screening Trial screening arm continued to receive chest X-rays at baseline, year 1, year 2, and year 3. The fourth chest X-ray (year 3) was eliminated from the screening examination protocol for never smokers.

Colorectal cancer screening used flexible sigmoidoscopy at baseline and year 3 in the original study plan. A protocol change was initiated in December 1998 to extend the interval between the baseline and subsequent flexible sigmoidoscopy. The revised protocol for colorectal screening consisted of flexible sigmoidoscopy at baseline and year 5.

Predictor Variables. Health history data were drawn from a mailed, self-administered baseline questionnaire completed by participants in the PLCO Cancer Screening Trial. All health history information was based on self-report. The 49-item baseline questionnaire was on Office of Management and Budget approved form number 0925-0407. Participants were asked to report whether a doctor ever told them that they had any of the following conditions (multiple conditions could be selected): high blood pressure (hypertension), coronary heart disease/heart attack, stroke, emphysema, chronic bronchitis, diabetes, colorectal polyps, ulcerative colitis, Crohn's disease, familial polyposis, arthritis, osteoporosis, Gardner's syndrome, hepatitis, cirrhosis, diverticulitis/diverticulosis, gallbladder stones, or inflammation.

Participants were also asked whether they had ever been diagnosed as having cancer. They were also asked whether they had ever smoked. An ''ever smoker'' was defined as anyone who has ever smoked cigarettes for ≥6 months in his or her lifetime or who has ever smoked pipes or cigars. Current smokers were defined as participants who smoke cigarettes regularly now. Participants were also asked whether their parents, children, brothers, sisters, half-brothers, or half-sisters had ever been diagnosed as having any type of cancer.

Age, educational attainment, marital status, and work status were measured by participant self-report (see Table 1). To assess income level, the home addresses of the 683 study participants were geocoded using census block group methods. Census data were used to assign each study participant the average household income in the block group of his residence [a subdivision of a

Table 1. Baseline characteristics of the participants in the randomized trial

	Case management intervention group (n = 683), n (%)
Mean (SD) age at randomization	63.1 (5.5)
Education	
Less than high school	168 (24.7)
High school graduate	146 (21.5)
Some college	237 (34.8)
College graduate/postgraduate	129 (19.0)
Income	
Low	199 (30.4)
Moderate to high	455 (69.6)
Marital status	
Married	460 (67.5)
Not married*	221 (32.5)
Work status	
Currently working	243 (35.8)
Retired †	378 (55.7)
Extended sick leave/disabled/ unemployed	58 (8.5)
Baseline history	
High blood pressure	353 (55.2)
Coronary heart disease	87 (15.8)
Stroke	34 (6.5)
Chronic bronchitis	30 (5.8)
Diabetes	134 (23.9)
Arthritis	248 (43.0)
Gallbladder stones (or inflammation)	26 (5.0)
Relative ever diagnosed with cancer	276 (40.4)
Ever smoked	493 (72.2)
Currently smoke	168 (24.6)

*This category includes separated, widowed, divorced, and never married participants.
†This category includes two homemakers.

census tract roughly representing a city block (22, 23)]. Low-income level was defined as an annual household income less than 1.5 times the poverty level, adjusted for household size, and moderate to high income level was defined as an annual income greater than or equal to 1.5 times the poverty level, adjusted for household size. The poverty index levels were based on Federal Register data for 1996, which corresponded with the 1990 Census data available for the geocoding procedure.

Study Hypotheses. We hypothesized that participants with comorbidities would show lower rates of adherence to PLCO Cancer Screening Trial screenings than participants without comorbidities. Among participants with at least one comorbidity, we hypothesized that those with more comorbidities would show lower rates of adherence than participants with fewer comorbidities.

Analysis. The relationship between baseline health history variables and adherence rate for each screening test was formally assessed using logistic regression (24). Age of participant, income, educational level, and intervention status were included as covariates in the multiple logistic regression. Descriptively, adherence rates and 95% confidence intervals were calculated within each disease status group. Taking into account the varying rates of disease status and sample size available within each of the four screening outcomes, the study had at least 80% power, at the 5% significance level, to detect an absolute difference of 10% to 35% in adherence rates (25). Additionally, the relationship between number of comorbidities and adherence was examined using a Maentel-Haenszel test for trend. All statistical analyses were done with SAS statistical software version 9.1 (26).

Results

No statistically significant interactions were found between each health history characteristic and the case management intervention. Therefore, analyses were not stratified by intervention status.

Table 1 shows the demographic characteristics of the study participants. The mean (SD) age of the participants was 63.1 (5.5) years. Most (75.3%) of the 683 study participants had at least a high school education, and ~30% of the participants were of low income. The majority of participants were married (67.5%). Most were retired or on extended sick leave/disabled/unemployed (64.2%).

The baseline comorbidities of the participants are also included in Table 1. These include high blood pressure, coronary heart disease, stroke, chronic bronchitis, diabetes, arthritis, gallbladder stones (or inflammation), having a relative diagnosed with cancer, ever smoking, and currently smoking.

Table 2 shows the effects of baseline health history characteristics on adherence to PSA test, chest X-ray, DRE, and flexible sigmoidoscopy conducted in the PLCO Cancer Screening Trial. Specifically, being a current smoker was the only comorbid condition that was statistically significant in predicting adherence. Current smoking had a statistically significant negative effect on adherence to the PSA test, the DRE, the chest X-ray, and the flexible sigmoidoscopy. Participants with a relative diagnosed with cancer had higher rates of adherence to the DRE than others. None of the other baseline comorbidities were statistically associated with adherence. Finally, we examined the relationship between number of comorbidities and adherence to test whether participants with increasing numbers of comorbidities showed progressively lower rates of adherence. Our analyses showed that there was no increasing or decreasing trend in adherence rate associated with the number of comorbidities (all $P > 0.30$).

Discussion

Our results suggest that, contrary to our initial hypothesis, baseline health history characteristics had minimal effects on PLCO Cancer Screening Trial adherence among the older African American men who comprised the study sample. The exceptions were current smoking, which negatively affected adherence, and family history of cancer, which positively affected adherence.

Thus, in our study, not only were current smokers less likely to receive lung cancer screening, they were also less likely to receive prostate cancer screening and colorectal cancer screening. In the future, it will be important to discover ways to motivate smokers to engage in cancer screening because their smoking status puts them at risk for developing many types of cancer.

Participants with a family history of cancer were more likely than other participants to be adherent to prostate cancer screening and lung cancer screening. This finding is corroborated by the work of other investigators who examined the association between family history of

cancer and adherence to screening for other types of cancer. For example, Halbert et al. (27) assessed self-reported screening adherence in a sample of 65 African American women in Pennsylvania at risk for hereditary breast cancer and found fairly high levels of adherence to mammography (75% adherent), clinical breast examination (93% adherent), and breast self-examination (41%).

Positive family history of cancer appears to be related to perceived risk of getting the disease (28) and subsequent increased vigilance in self-monitoring via participation in cancer screening activities. In future studies promoting adherence to evidence-based cancer screening guidelines, it will be important to understand participants' risk perceptions so that effective interventions to improve risk communication can be developed (29, 30).

In summary, our data show that, in a longitudinal cancer screening trial conducted with adults ages 55 to 74 years at enrollment, baseline comorbidities had little or no effect on likelihood of adherence to trial screenings. Overall, older African American men with comorbidities appear to be very good candidates for participation in longitudinal cancer screening trials, as they are generally as likely as other people to adhere to cancer clinical trial screenings.

The study findings highlight the importance of including people with comorbidities in cancer clinical trials rather than excluding them *a priori*. Based on our data, there appears to be no reason to exclude older African American men with comorbidities unless the comorbid condition(s) will confound the study outcome.

Study Limitations. Study participants were older African American men living in a metropolitan area who were asked to participate in a clinical trial to evaluate the effectiveness of cancer screening tests. The findings need to be replicated before they can be generalized to clinical trials of other cancer-related outcomes such as treatment. Because the study population was restricted to older African American men, we do not know whether similar findings would be seen in a sample of women, men of other racial/ethnic groups, or among younger African American men. Another limitation is the fact that the baseline questionnaire from which baseline comorbidity data were drawn did not include information pertaining to psychiatric comorbidities (such as anxiety and alcohol/drug abuse).

Despite these limitations, this study had several strengths. First, it focused on older African American men who as a group are more likely than others to be affected by prostate, lung, and colorectal cancers. Second, it took advantage of a large national clinical trial, the PLCO Cancer Screening Trial, to address an important behavioral science research question related to adherence

Table 2. Effect of comorbidities on adherence to screens

	PSA adherence			DRE screen adherence		
	n	Rate (95% CI)	Adjusted OR* (95% CI)	*n*	Rate (95% CI)	Adjusted OR* (95% CI)
High blood pressure						
Yes	347	67.4 (62.2-72.3)	1.1 (0.8-1.6)	235	60.9 (54.3-67.1)	0.9 (0.6-1.4)
No	284	64.8 (58.9-70.3)		222	62.6 (55.9-69.0)	
Coronary heart disease						
Yes	87	64.4 (53.4-74.4)	1.0 (0.6-1.7)	60	60.0 (46.5-72.4)	1.2 (0.6-2.2)
No	459	67.3 (62.8-71.6)		365	61.9 (56.7-66.9)	
Stroke						
Yes	34	67.7 (49.5-82.6)	1.2 (0.5-2.6)	29	55.2 (35.7-73.6)	1.0 (0.4-2.1)
No	483	67.1 (62.7-71.3)		382	62.6 (57.5-67.4)	
Chronic bronchitis						
Yes	30	50.0 (31.3-68.7)	0.5 (0.2-1.1)	25	44.0 (24.4-65.1)	0.5 (0.2-1.2)
No	485	68.0 (63.7-72.2)		384	63.5 (58.5-68.4)	
Diabetes						
Yes	133	63.9 (55.1-72.1)	0.9 (0.6-1.4)	96	61.5 (51.0-71.2)	1.1 (0.6-1.8)
No	422	67.3 (62.6-71.8)		335	62.1 (56.7-67.3)	
Arthritis						
Yes	245	66.1 (59.8-72.0)	1.1 (0.7-1.5)	175	60.6 (52.9-67.9)	1.0 (0.7-1.6)
No	326	66.9 (61.5-72.0)		266	62.8 (56.7-68.6)	
Gallbladder stones (or inflammation)						
Yes	25	72.0 (50.6-87.9)	1.3 (0.5-3.2)	18	61.1 (35.7-82.7)	1.0 (0.4-2.7)
No	485	67.2 (62.8-71.4)		386	62.4 (57.4-67.3)	
Relative ever diagnosed with cancer						
Yes	271	69.4 (63.5-74.8)	1.2 (0.8-1.7)	194	68.0 (61.0-74.5)	1.5 (1.0-2.2) †
No	404	64.4 (59.5-69.0)		290	57.9 (52.0-63.7)	
Ever smoker						
Yes	488	64.6 (60.1-68.8)	0.8 (0.5-1.2)	366	59.6 (54.3-64.6)	0.7 (0.4-1.2)
No	187	71.1 (64.1-77.5)		118	69.5 (60.3-77.6)	
Current smoker						
Yes	167	58.7 (50.8-66.2)	0.6 (0.4-0.9) †	137	52.6 (43.8-61.1)	0.6 (0.4-0.9) ‡
No	508	68.9 (64.7-72.9)		347	65.7 (60.4-70.8)	

NOTE: The reference group was the group responding "no" to the presence of a comorbidity. 95% CI, confidence interval.
§$P < 0.001$.
*Adjusted for age, income, education, and intervention status.
†$P < 0.05$.
‡$P < 0.01$.

Table 2. Effect of comorbidities on adherence to screens (Cont'd)

Chest X-ray adherence			Flexible sigmoidoscopy screen adherence		
n	Rate (95% CI)	Adjusted OR* (95% CI)	*n*	Rate (95% CI)	Adjusted OR* (95% CI)
235	64.3 (57.8-70.4)	1.0 (0.7-1.6)	138	55.1 (46.4-63.5)	1.0 (0.6-1.7)
221	63.4 (56.6-69.7)		124	61.3 (52.1-69.9)	
60	61.7 (48.2-73.9)	1.1 (0.6-2.0)	41	51.2 (35.1-67.1)	1.1 (0.5-2.4)
364	64.6 (59.4-69.5)		187	62.6 (55.2-69.5)	
28	64.3 (44.1-81.4)	1.4 (0.6-3.2)	16	56.2 (29.9-80.3)	1.4 (0.4-4.5)
382	64.7 (59.6-69.5)		200	63.0 (55.9-69.7)	
25	44.0 (24.4-65.1)	0.4 (0.2-1.0)	14	50.0 (23.0-77.0)	0.6 (0.2-1.9)
383	66.1 (61.1-70.8)		200	64.0 (56.9-70.7)	
95	66.3 (55.9-75.7)	1.2 (0.7-2.0)	58	56.9 (43.2-69.8)	1.4 (0.7-2.8)
335	64.5 (59.1-69.6)		178	61.2 (53.7-68.4)	
175	64.0 (56.4-71.1)	1.2 (0.8-1.8)	87	51.7 (40.7-62.6)	1.0 (0.5-1.8)
265	64.2 (58.1-69.9)		147	65.3 (57.0-73.0)	
18	55.6 (30.8-78.5)	0.7 (0.2-1.7)	7	71.4 (29.0-96.3)	2.5 (0.4-15.8)
385	65.2 (60.2-70.0)		203	63.0 (56.0-69.7)	
192	70.3 (63.3-76.7)	1.4 (0.9-2.2)	120	62.5 (53.2-71.2)	1.3 (0.7-2.1)
291	60.8 (55.0-66.5)		162	54.9 (46.9-62.8)	
366	62.0 (56.8-67.0)	0.7 (0.4-1.1)	200	57.5 (50.3-64.4)	0.7 (0.4-1.2)
117	72.7 (63.6-80.5)		82	59.8 (48.3-70.4)	
138	54.4 (45.7-62.9)	0.5 (0.3-0.8) ‡	70	51.4 (39.2-63.6)	0.5 (0.3-1.0) †
345	68.7 (63.5-73.6)		212	60.4 (53.4-67.0)	

to trial protocols. Because the Detroit metropolitan area is sociodemographically representative of other large, urban areas, it is likely that our study results are generalizable to older African American male cancer clinical trial participants in these other, similar areas.

Disclosure of Potential Conflicts of Interest

No potential conflicts of interest were disclosed.

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