Effects of False-Positive Prostate Cancer Screening Results on Subsequent Prostate Cancer Screening Behavior

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Abstract

Objectives: **Little is known about screening behavior following a false-positive prostate cancer screening result, which we have defined as a screening result with ''abnormal/suspicious'' labeling that did not result in a prostate cancer diagnosis within 14 months. The purpose of this analysis was to examine whether age, race, education, or previous false-positive prostate cancer screening results via prostate-specific antigen or digital rectal exam predict decision to obtain subsequent prostate cancer screening.**

Methods: **Data were drawn from the Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial. The study sample consisted of 2,290 older men (mean age, 62.8 years; range, 55-75 years) who had false-positive (n = 318) or negative (n = 1,972) prostate-specific antigen or digital rectal exam baseline prostate cancer screening results. Multivariable logistic regression was used to assess the effect of false-positive results on subsequent prostate cancer screening behavior, adjusting for all covariates.**

Results: **The multivariable model showed that being African American (P = 0.016), and having a high school education or less (P = 0.007), having a previous false-positive prostate cancer screening result (P < 0.001), were predictive of not returning for prostate cancer screening in the following screening trial year.**

Conclusion: **The study results highlight the importance of shared decision making between patients and their providers regarding the risks and benefits of prostate cancer screening, and follow-up options for abnormal prostate cancer screening results. Shared decision making may be especially important for African American men, whom prostate cancer disproportionately affects.** (Cancer Epidemiol Biomarkers Prev 2005;14(1):190–4)

Introduction

Impact of Prostate Cancer in the United States. Among men in the United States, prostate cancer is the second most common cause of cancer mortality (1, 2). African American men have the highest incidence and mortality rates of prostate cancer of any other racial or ethnic group, and this disparity continues to increase (1, 3-10).These mortality differences are related to the fact that African Americans seem to have more pathologically locally advanced prostate cancer upon presentation to a physician, including higher preoperative prostate-specific antigen (PSA) levels, than Caucasian men (5, 9, 10). Mean PSA levels even seem to differ significantly by race among men not yet diagnosed with prostate cancer, with African Americans showing higher PSA values than Caucasians across age groups (11-15).

PSA and DRE Screening Procedures. 7Tests of PSA concentrations are commonly used to screen for prostate cancer. Abnormal/suspicious PSA results are defined as having a PSA level greater than 4.0 ng/mL. However, PSA screening tests tend to yield a fairly high rate of false-positive results, as total elevated level of PSA is not a unique indicator of prostate cancer but may also indicate prostatitis or benign prostatic hyperplasia (16-18).Although Pearson et al. (19) note that PSA has a high positive predictive value for cancer, the majority of men with elevated PSA levels do not have cancer. Only 30% of men with total elevated PSA levels are found to have prostate cancer after biopsy (20). In particular, the optimal management of patients with intermediately elevated total PSA levels (4.1-10.0 ng/mL) is uncertain (20).

PSA has been found to detect more cancer than digital rectal examinations (DRE) among African American and Caucasian men, a difference more pronounced among African American men (6). The digital rectal exam is a fairly insensitive test that misses most early-stage tumors (21). The rate of false-positive results is reduced when the PSA and DRE screenings are combined (2).

Purpose of the Present Study. Previous studies have shown that being younger, being African American, and having less than a high school education are significant predictors of not getting screened for prostate cancer (22-26). However, little is known about screening behavior after a false-positive prostate cancer screening result. The purpose of this analysis was to examine prostate cancer screening behavior subsequent to false-positive screening results for PSA and DRE. Data were drawn from the Prostate, Lung, Colorectal, and Ovarian Cancer Screening (PLCO) Trial at the Henry Ford Health System (Detroit, MI) site.

Methods

Study Sample. The PLCO Trial is a 23-year, multisite randomized trial funded by the National Cancer Institute (27, 28). The primary objective of the PLCO Trial is to

Received 4/28/04; revised 7/22/04; accepted 8/4/04.

Grant support: Department of Defense grant DAMD17-99-1-9005, Centers for Disease Control and Prevention/National Cancer Institute contract NO1-CN-25512, and National Institute on Aging grant P 30 AG 5286, and Department of Veterans affairs, Veterans Health Administration, Health Services Research and Development Service, Project no. RES 02-235, METRIC Resource Center.

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Note: Presented in part at the 55th Annual Meeting of the Gerontological Society of America in Boston, Massachusetts. on November 24, 2002, and at the Health Disparities Summit sponsored by the University of Pittsburgh and the VA Pittsburgh Healthcare System, January 8-9, 2004.

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Table 1. Demographic characteristics of sample (*N* = 2,290)

Demographic characteristics	*N* (%)
Race	
African American	324 (14.1)
Caucasian	1,966 (85.9)
Mean age (SD), y	62.8 (5.4)
Post high school education*	
Yes	1,636 (71.6)
No†	650 (28.4)

*Four study participants were missing data on this variable.
†Of the 650 participants who provided this response, 57.4% had completed high school, 36.0% had completed grades 8 to 11, and 6.6% reported having less than an 8th-grade level of education.

determine whether screening for the four PLCO Trial cancers decreases mortality due to these cancers in adults ages 55 to 74 at trial entry. Participants in the PLCO Trial, who must be asymptomatic for any of the study cancers at entry into the study, are randomized to an intervention arm (receiving cancer screening) or to a control arm (usual care).

The research protocol was approved by the relevant institutional review boards or ethics committees. Upon enrollment, all participants gave written informed consent for their study data to be analyzed.

The number of male participants in the screening arm of the PLCO Trial from January 1994 to April 1999 at the Henry Ford Health System site was 4,093. Of this number, 318 participants had false-positive PSA and DRE results at first screening; 1,972 participants had negative screening results. We excluded the 1,803 remaining PLCO Trial enrollees who did not show up for the PSA/DRE screening, had inadequate screening results, had abnormal screening results not suspicious for cancer, or were diagnosed with prostate cancer as a result of their baseline exam. Individuals of Hispanic ethnicity were excluded due to the small sample size. The study sample therefore consists of 2,290 self-identified African American and Caucasian males with at least a 14-month follow-up period from their baseline prostate cancer screening via PSA test or DRE.

Screening Procedures and Diagnostic Outcomes. Prostate cancer risk is ascertained in the PLCO Trial via two methods; the PSA test and the DRE. Participants in the intervention arm are screened at baseline post randomization for prostate cancer via PSA test and DRE and approximately 12 months later each year, for a total of 6 years of screening. Possible outcomes of prostate cancer screening were as follows: negative for prostate cancer risk, inadequate result, abnormal/suspicious for prostate cancer risk, abnormal/not suspicious for prostate cancer risk, and ''test not done.'' The follow-up and outcomes of individuals with positive screening results were ascertained by medical record abstraction and survey.

Abnormal/suspicious PSA results are defined as having a PSA level greater than 4.0 ng/mL. Abnormal/suspicious DRE results are defined as nodularity or induration of the prostate or an indication by the examiner that the prostate is judged to be suspicious for cancer in the absence of nodularity or induration. Abnormal/suspicious results lead to referral to patients' own physicians. For the purpose of the present study, a false-positive result is defined as a screening result with ''abnormal/suspicious'' labeling that did not result in a prostate cancer diagnosis within 14 months. Thus, when the time came for the next round of screening, study participants knew that they did not have prostate cancer, and were eligible to be screened again.

In the analyses, the primary independent variable is a false-positive or negative result at baseline screening, and the dependent variable is participation in the subsequent annual screening.

Most study participants (98.8%) completed both the PSA and DRE screening exams at baseline. Therefore, the phrase ''PSA and DRE screening'' is used in the article.

Analytic Approach. Individuals who died from unknown causes during the follow-up period, before the next exam, were excluded from the sample. Screening behavior, the outcome variable, was measured as ''yes'' versus ''no,'' that is, expected PSA and DRE screening not done versus expected PSA and DRE screening done in the subsequent screening year. Univariate relationships between each of the categorical covariates and screening behavior were examined using χ^2 tests, odds ratios (OR) and 95% confidence intervals (95% CI). Age was examined as a continuous covariate and univariate logistic regression was used to evaluate its relationship with screening behavior.

Multivariable logistic regression was used to assess the effect of false-positive result with screening behavior, adjusting for all other covariates (age, race, educational level, and false-positive results on other PLCO Trial screening exams). Educational level was dichotomized into post high school education versus high school education or less. Other PLCO Trial screening exams included chest X-ray for lung cancer and flexible sigmoidoscopy for colon cancer. Interactions between each covariate and the primary independent variable (baseline prostate cancer screening result) were

Table 2. Risk factors associated with returning for PLCO Trial prostate cancer screening (*N* = 2,290)

	Returned for prostate cancer screening		OR (95% CI)	*P*
	No, *n* (%)	Yes, *n* (%)		
Baseline PSA and DRE Screening result			1.96 (1.36-2.83)	<0.001
False positive	42 (13.2)	276 (86.7)		
Negative	142 (7.2)	1830 (92.8)		
Race			1.78 (1.23-2.59)	0.002
African American	40 (12.3)	284 (87.7)		
Caucasian	144 (7.3)	1822 (92.7)		
Mean age (SD)	63.4 (5.9)	62.8 (5.4)	1.02 (0.99-1.05)	0.10
Education level completed			1.71 (1.25-2.34)	<0.001
High school or less	72 (11.1)	578 (88.9)		
Post high school	111 (6.8)	1525 (93.2)		
False-positive result on nonprostate cancer screens in PLCO Trial			1.33 (0.99-1.80)	0.06
Yes	88 (9.3)	858 (90.7)		
No	96 (7.1)	1248 (92.9)		

Table 3. Multivariable logistic regression model screening behavior results (*N* = 2,290)

	OR (95% CI)	*P*
False-positive result on previous prostate cancer screening	1.91 (1.31-2.77)	<0.001
African American	1.60 (1.09-2.34)	0.016
High school education or less	1.56 (1.13-2.16)	0.007
False-positive result on previous nonprostate cancer screening	1.33 (0.98-1.80)	0.07
Age	1.00 (0.98-1.03)	0.76

assessed. Given our sample size of 2,290 screening exams, at least 90% power was available to detect a 6% difference in estimated probability of screening rates between those with previous false-positive prostate cancer screening results and those with previous negative prostate cancer screening results (assuming two-sided testing and an α of 0.05).

Results

Subject Characteristics. The study sample, which included more Caucasians than African Americans, had a mean age of approximately 63 years (Table 1). The sample also included a higher percentage of individuals with post high school education than those with a high school education or less (Table 1).

Univariate Results Related to Screening Behavior. There was a significant univariate relationship (OR, 1.96; 95% CI, 1.36-2.83) between having had a baseline false-positive PSA and DRE prostate cancer screening result and subsequent prostate cancer screening behavior. In particular, individuals with baseline false-positive prostate cancer screening results were nearly twice as likely not to return for further prostate cancer screening, compared with individuals with negative baseline prostate cancer screening results (13.2% versus 7.2% nonadherence rate, respectively; $P < 0.001$, Table 2).

African American race was significantly related to not returning for further prostate cancer screening (OR, 1.8; 95% CI, 1.2-2.6). Table 2 also shows that individuals who did not return for further prostate cancer screening in the subsequent PLCO Trial screening year had significantly lower levels of education ($P < 0.001$) than did individuals who returned for prostate cancer screening.

Multivariable Results Related to Screening Behavior. A multivariable logistic regression model was built that included false-positive status and the four baseline covariates. Interactions between false-positive status and each baseline covariate were tested. None of the interactions reached statistical significance at the $P > 0.20$ level, so these terms were dropped from the model.

Table 3 shows that individuals who had a false-positive result on their baseline prostate cancer screening were almost twice as likely not to receive subsequent screening, compared with individuals with a negative baseline prostate cancer screening result (OR, 1.9; 95% CI, 1.3-2.8; Table 3). African American race (OR, 1.6; 95% CI, 1.09-2.34) and having less than a high school education (OR, 1.5; 95% CI, 1.13-2.16) were also predictors of not returning for further screening. Having a false-positive result for another PLCO Trial exam was associated with a moderately increased likelihood of not returning for further screening, with borderline statistical significance.

Among the 175 individuals (95% of the 184 individuals who did not return for further screening) who gave a rationale for not returning for further screening, the main reasons were refusals (n = 107, 61%), not being able to be scheduled during the window of time required by study protocol (n = 51, 29%), having an illness that prevented returning for screening (n = 7, 4%), and being out of the geographic area of the Henry Ford Health System PLCO Trial screening clinics at the time of the requested screening (n = 10, 6%). The remaining 5% did not return for unknown reasons.

Strengths and Limitations of the Study

Strengths of the present analyses include a sufficient number of African American participants (n = 324, 14% of the study sample) to allow meaningful comparisons with Caucasian participants and the ability to monitor the screening practices of a defined population. Longitudinal screening intervention studies such as the PLCO Trial offer a unique opportunity to explore the dynamics of factors associated with cancer screening behavior.

A limitation of this study is that the information gained provides insight regarding these issues among individuals who have agreed to participate in a long-term cancer screening trial. These individuals are likely not representative of the general population in that they may be more involved in health promotion activities than nonparticipants. In addition, it is possible that because of variations in populations with regard to cultural factors and health beliefs, these results are not generalizable to other geographic locations.

Despite these limitations, the study outcomes point to a need to better understand decision making by patients and their providers regarding follow-up of abnormal prostate cancer screening results. As Taylor et al. (29) note, the utility of prostate cancer screening in asymptomatic men such as those screened in the present study has not yet been shown in the United States by means of a randomized trial. Consequently, dialogue between patients and their providers regarding the risks and benefits of various follow-up options is critical.

Discussion

This article has addressed the important question of whether prostate cancer screening behavior is affected by a false-positive result on a previous prostate cancer screening. The study sample consisted of a large cohort (n = 2,290) of PLCO Trial participants at the Henry Ford Health System site in Detroit, Michigan, with a sufficient number of African Americans to make meaningful racial comparisons.

The study results show a significant decrease in prostate cancer screening rates following a previous false-positive prostate cancer screening result. In fact, study participants with false-positive baseline prostate cancer screening results were nearly twice more likely not to return for further prostate cancer screening, compared with participants with negative baseline prostate cancer screening results. Other significant predictors of not receiving further prostate cancer screening were African American race and having less than a high school education. It is important to note that study participants who received a negative biopsy following their abnormal PSA tests may have later been diagnosed with prostate cancer, thus not truly having ''false-positive'' screening results. However, these

participants made their subsequent follow-up decisions based on the previous clinical results they had been provided, which indicated that they had received a negative biopsy. The study outcomes point to a need to better understand health decision-making processes regarding the decision to receive subsequent prostate cancer screening after receiving a previous false-positive prostate cancer screening result.

Health decision making refers to the process of choosing among specific health care options (30). Several components that could be included in shared decision-making discussions between patients and providers regarding prostate cancer screening are (*a*) the likelihood that prostate cancer will be diagnosed, (*b*) the meaning of possible false-positive results, (*c*) the anxiety that may occur as a result of having an abnormal prostate cancer screening result, and (*d*) the clinical uncertainty in the relationship between prostate cancer screening and the subsequent likelihood of reduced mortality due to prostate cancer (31).

One of the implications of having a false-positive PSA and DRE prostate cancer screening result is the subsequent risk of being exposed to unnecessary invasive medical procedures such as biopsies and surgeries and their associated morbidity and mortality (32-35). These procedures could in turn lead to impotence, incontinence, or (rarely) death following surgical procedures, and at the least could cause undue anxiety on the part of patients (18, 33, 34). Having a false-positive result on a PSA and DRE prostate cancer screening test may negatively affect a sense of well-being among the men receiving this result (21).

The most likely risk associated with a false-positive prostate cancer screening result is a needless, often painful biopsy. Men who have abnormal/suspicious results during the initial screening and who undergo biopsy may find the experience unpleasant. For this reason, men with this type of previous medical experience may choose not to be screened a subsequent time. At the same time, these men are at higher risk than other men to have a false-positive result for the subsequent screening, as the risk of having a false-positive result each time men are tested is nonindependent. Therefore, from a decision-analytic perspective, it is not surprising that men who have had an adverse outcome from screening (a false-positive result) and personal experience with the implications of that outcome (a prostate biopsy) seem to be less likely to choose screening a second time than men who do not have that experience.

In the current study, shared health decision making could be construed accurately at multiple levels or steps. First, patients would have to make a decision to make an appointment with their personal physicians to discuss follow-up of an abnormal/suspicious PLCO Trial screening result. Second, patients and their physicians would have to decide among several different types of follow-up. Third, patients and their physicians would have to decide whether the patients would return for subsequent PLCO Trial prostate cancer screening.

During the shared decision-making process, patients' attitudes and perceptions of the false-positive screening results could be ascertained, as well as patients' preferences for future prostate cancer screening behavior. This process could assist clinicians in ensuring that patients make informed choices about subsequent prostate cancer screening.

Additional research is needed regarding factors that influence patients' decision making and the role of their health care providers in the decision-making process. Some promising work has already begun in this area. For example, the work of Hall et al. (30) suggests that investigators ascertain (*a*) the reasons and motivation for patients choosing certain types of follow-up procedures, (*b*) the source of information used by patients in making their decisions, (*c*) the roles of health care providers such as urologists and primary care physicians, and (*d*) the roles of personal influences in patients' lives, such as spouses and other relatives, in patient's health care decision making.

Future research could evaluate the attitudes toward continued prostate cancer screening of patients with previous false-positive results. Future interventions could focus on increasing shared decision making between patients and their physicians, once a false-positive result has been found.

Acknowledgments

We thank Danica Dixon Macklin for her assistance with the manuscript preparation.

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Cancer Epidemiol Biomarkers Prev 2005;14:190-194.