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HEALTH PERCEPTIONS IN PATIENTS WHO UNDERGO SCREENING AND WORKUP FOR PROSTATE CANCER

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Abstract

Background—False-positive screening tests may induce persistent psychological distress. This study was designed to determine whether a positive screening test with a negative biopsy for prostate cancer is associated with worsened mental health during short-term follow-up.

Methods—We conducted a cross-sectional telephone survey of two groups of men approximately two months after testing: 1) 109 men with an abnormal PSA test or digital rectal exam but negative biopsies for prostate cancer (group 1), and 2) 101 age-matched primary care patients with PSA screening tests in the reference range (<4 ng/ml)(group 2). Primary outcomes included state anxiety and prostate cancer-related worry. Secondary outcomes included SF-36 subscales and sexual function items. Multivariable regression techniques were used to adjust for differences in baseline covariates.

Results—Group 1 patients were more worried than group 2 patients about getting prostate cancer: mean worry = 3.9 vs. 4.5, p=.0001 (5-point scale, where 1 = extreme and 5 = none). Group 1 patients also perceived their risk of prostate cancer to be significantly greater than that of controls (p=.001). There were no significant differences across state anxiety or SF-36 subscales. Sexual bother was greater for group 1 patients, with 19% of reporting that sexual function was a moderate-big problem compared to 10% of group 2 patients (p = .0001).

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Conclusion—Men with abnormal prostate cancer screening tests report increased cancer-related worry and more problems with sexual function, despite having a negative biopsy result. Effective counseling interventions are needed prior to prostate cancer screening and during follow-up.

INTRODUCTION

Although the value of screening for prostate cancer remains controversial, such screening is popular among US men.[1] Of those men with elevated total PSA levels, 11–34% are found to have prostate cancer on biopsy.[2] Many of the remaining patients with abnormal screening results will spend time worrying about whether they have cancer. Indeed, qualitative data indicate that significant health distress and cancer-related worry can result in those with false positive screening tests.[3] In addition, false positive PSA results may reduce the likelihood that men will receive subsequent prostate cancer screening during follow-up.[4]

Prior studies of prostate cancer screening have shown mixed results with regard to health-related quality of life (HRQOL) and cancer-related anxiety. For example, in a prospective study of 626 Dutch men who attended a prostate screening program (which included PSA testing, digital rectal exam, and transrectal ultrasound), there were no clinically meaningful differences in health status during the longitudinal follow-up of screen-positive participants who were subsequently shown not to have cancer.[5] In contrast, a prospective US study of 400 men undergoing PSA screening showed that 26% of men with a benign prostate biopsy following a suspicious screening test worried “a lot” or “some of the time,” compared to 6% of men with normal PSA results, one year after testing.[6] Screening arm participants with abnormal screening test results in the Prostate, Lung, Colorectal, and Ovarian (PLCO) Screening Trial also showed a higher level of intrusive thoughts about cancer, compared to those with normal results.[7]

Because screening affects a large number of men relative to those who are expected to benefit from treatment, even a small adverse effect of apparently false positive results on HRQOL could have a substantial impact on public health. Thus, the aim of this study was to determine whether a positive screening test (abnormal PSA or digital rectal exam) in men with a negative biopsy for prostate cancer is associated with worsened mental health and increased cancer-related worry during short-term follow-up. A secondary objective was to determine the relationship between a positive screening test and self-reported sexual function, in light of prior data suggesting that some men may have residual prostate-related symptoms as long as one month following the transrectal biopsy procedure.[8]

METHODS

We conducted a cross-sectional survey approximately two months after prostate cancer screening and work-up of two comparison groups: biopsy recipients who showed no evidence of prostate cancer on microscopic examination following a suspicious screening test (group 1) and primary care patients with a PSA test in the reference range (<4 ng/ml)(group 2).

Recruitment

Group 1 patients were recruited from one university hospital and one university-affiliated community teaching hospital after being identified by the directors of surgical pathology at each study hospital. Group 2 patients were recruited from six university-affiliated primary care practices after being identified by directors of the clinical laboratory. The strategy for selection of this comparion group was to draw patients from a similar source population as those who received work-up for an abnormal screening test. Specifically, these men would have typically been referred to the urology department at either of the two study hospitals for further evaluation (including biopsy), had their PSA values been elevated. In addition, Group 2 patients

were matched on age (within five years) and the discipline of their primary care physician (internal medicine or family practice) in order to minimize differences in medical comorbidity between groups.

We excluded patients with a history of prostate cancer and those with prostate intraepithelial neoplasia or indeterminate results on prostate biopsy. In addition, we excluded patients who were unable to speak English, those unable to provide informed consent, those who were unable to communicate by telephone, and those who were unavailable for follow-up.

Approximately one month following the index test (biopsy or PSA test), all potentially eligible patients received a letter of invitation, which was signed by their urologist or primary care physician (for groups 1 and 2, respectively). All study participants provided informed consent to participate in this study. The study protocol was approved by the human subjects review committee at all participating sites.

Data collection

We contacted subjects approximately one week after the letter of invitation was sent. After obtaining telephone consent, we administered a brief 15 minute survey. All interviewers were blinded to the study hypotheses. For those patients who could not be reached by telephone, a copy of the survey with instructions was mailed to the subject's home. Patients received $10 for completing the survey. All data were entered into a Microsoft Access database and were checked for out-of-range values and missing data.

Outcomes included the following: 1) SF-36 mental health, role emotional, social, vitality, and role physical scales,[9] 2) State Anxiety Index, short-form version (SAI-6),[10] 3) two items on sexual function/bother from the UCLA Prostate Cancer Index,[11] and 4) questions pertaining to prostate cancer-related worry, perceived susceptibility to prostate cancer, and context of the index visit. We selected five of the eight SF-36 subscales based on the results of prior pilot data that suggested worsened scores across these domains in men with negative prostate biopsies.[12] We also report the results of SF-36 mental health subscales (psychological well-being and psychological distress). All subscale scores were converted to a 0–100 scale. The SAI-6 is an abbreviated version of the state component of the State Trait Anxiety Inventory (STAI), and asks subjects how they feel *right now* in terms of six adjectives (calm, tense, upset, relaxed, content, and worried) on a four-point Likert scale.[10] The STAI has been used to measure cancer-related anxiety in several studies of prostate cancer screening.[13]

As a principal feature of anxiety-provoking events in the degree to which their outcome is perceived as threatening or uncertain, we assessed prostate cancer-related worry by asking patients the following question: "Since learning the results of your biopsy/PSA test, how worried have you been about getting prostate cancer?" We assessed perceived susceptibility by asking patients: "How likely do you think it is that you will develop prostate cancer in the next five years?" Items on cancer-related worry and perceived susceptibility to prostate cancer were adapted from similar questions used in studies of breast cancer screening,[14,15] and were pre-tested in our pilot study. Both items were highly correlated (r = .33, p = .0001).

To determine the comparability of the two groups (and to identify factors that may confound the relationship between screening status and HRQOL), we collected data on demographics (age, race, education, marital status, employment), medical comorbidity (using the Seattle Index of Comorbidity[16]), self-reported history of depression or anxiety (requiring medication or counseling), and symptoms of benign prostatic hyperplasia (using the AUA Symptom Index).[17] At both hospital laboratories, the normal range for PSA was 0 – 4.0 ng/mL. At the university hospital, serum PSA values determined by the Abbott AxSYM® microparticle enzyme immunoassay (MEIA) method from Abbott Diagnostics (Abbott Park, IL). At the

community hospital, serum PSA analyses were performed using the Vitros ECi chemiluminescence immunoassay from Ortho-Clinical Diagnostics, Inc. (Raritan, NJ).

Statistical analysis

Baseline characteristics of group 1 and group 2 patients were compared using the two-independent-sample t-test or Wilcoxon rank-sum test for continuous variables (depending on whether the data were normally distributed) and the chi-squared test for dichotomous variables. To adjust for baseline differences between groups, we performed logistic regression to determine the association between having a suspicious screening test (in the absence of cancer) and dichotomized SF-36 outcomes. We dichotomized SF-36 scores at the median value for 55–64 year old men in the general population using SF-36 norms,[18] because SF-36 scores were highly skewed. Mental health subscale scores were dichotomized using the sample median (as population norms have not been reported for these measures). For those domains where the median was 100 (role-physical, role-emotional, social), scores were divided into two groups: 100 and <100. We used linear regression for the SAI-6 and ordinal logistic regression (proportional odds model) for prostate-specific outcomes (cancer worry, perceived susceptibility, and sexual function/bother). In all models, we adjusted for age (continuous), education (dichotomized at ≤12 years), marital status (married vs. unmarried), comorbidity score, prior history of depression or anxiety, AUA symptom index (dummy-coded by tertile), and family history of prostate cancer.

Statistical analyses were performed using STATA, version 7.0 (Stata Corp., College Station, TX). All tests were two sided, and a *p*-value of less than or equal to .05 was considered to indicate statistical significance.

RESULTS

During the period April 2002 through Feb, 2003, we invited 269 men to participate in the study. Of the 130 eligible group 1 patients, 84% completed the survey (21 refused or were unreachable); of 139 eligible group 2 patients, 73% completed the survey (38 refused or were unreachable). There were no significant differences between survey completers and non-completers across age, race, employment, or marital status. Of survey completers, group 1 patients had fewer years of education, more lower urinary tract symptoms, and were more likely to report an abnormal prostate exam in the doctor's office, but were otherwise comparable to group 2 patients (Table 1).

Table 2 shows that cases were more likely to have mean SF-36 scores below the population median than controls, although none of these differences were statistically significant after multivariable adjustment. Similarly, there were no significant differences between cases and controls in SAI-6 scores or SF-36 mental health subscale scores.

When patients were specifically asked about prostate cancer, however, cases were significantly more worried than controls about getting prostate cancer ($p = .0001$) (Table 2). These findings are not explained by PSA values. In cases with available PSA data, mean worry scores were 4.0, 3.7, and 4.0 in the lower, middle, and upper tertiles of PSA values, respectively ($p = .41$); similar results were observed in controls. Cases also perceived their risk of prostate cancer to be significantly greater than that of controls ($p = .001$), with only 40% of cases believing that their risk of prostate cancer was very low (1:100 or less) compared to 60% of controls.

Finally, for those subjects who reported being sexually active in the prior four weeks, 58% of biopsy recipients and 71% of PSA controls rated their ability to function sexually as very good or good ($p = .0001$). We found that sexual bother was greater for cases than controls, with only

43% of cases reporting no problems with sexual function compared to 72% of controls ($p = .002$)(Table 2).

DISCUSSION

Our findings reflect the reality of contemporary clinical practice and confirm that men with abnormal screening tests, but without prostate cancer on biopsy, show increased cancer-related worry compared to men with PSA values in the reference range, as reported by other investigators.[6] In particular, men with abnormal PSA results are often caught in a prolonged cycle of testing and re-testing, in which, "no one has found cancer, but no one can reassure [men] that they do not have it."[19] Similar results have been observed in women with false positive mammograms, who show substantial psychological distress and a heightened sense of susceptibility to breast cancer.[15,20]

Men often have inadequate knowledge about screening with PSA and are not aware of the test's limitations with regard to false-positive and false-negative test results.[21] Not surprisingly, we found that the majority of men with abnormal screening tests had distorted perceptions of their risk of developing prostate cancer (either too high or too low). Similar findings have been reported for men in primary care who are presented with elevated PSA results.[22] Indeed, it is concerning that a large proportion of cases (40%) mistakenly believed that their five-year risk of getting prostate cancer was one percent or less. The reassurance from a negative biopsy may not be entirely justified as up to 19% of these patients have been determined to have cancer on repeat biopsy.[23]

In this study, we also found that biopsy recipients reported worse sexual function and more bother with sexual function over the short-term. These findings may be related to residual pain or other troublesome side effects following the biopsy procedure, such as hematospermia; for most patients, these symptoms resolve within seven days of the biopsy.[8,24] Alternatively, increased bother with sexual function may stem from persistent worries about prostate cancer. The relationship between false-positive screening tests and sexual functioning should be explored further in prospective studies.

Although biopsy recipients showed more cancer-related worry and worsened sexual function than PSA controls, we found no significant differences in state anxiety or SF-36 scores between these groups over the short-term. Physiological stress, as measured by serum cortisol, tends to be greatest shortly after patients are informed of an abnormal PSA test result, and then drops to baseline levels once patients are informed of their biopsy results.[25] Differences in state anxiety related to screening status in the present study may have been attenuated by the time that patients were surveyed (approximately two months after the index test). Another possible explanation for the lack of difference between groups is lack of power; this is unlikely, however, given that the study sample had 85% power to detect a 3-point difference in SAI6 scores between cases and controls.

The limitations of this study deserve comment. First, this was a cross-sectional analysis and we did not collect data on the outcomes of interest prior to screening. We cannot rule out the possibility that increased cancer-related worry *predisposes* men to develop abnormal PSA results (e.g., by seeking more frequent screening).[26] Indeed, our analysis reflects the cumulative effect of serial testing and eventual biopsy for group 1 patients, several of whom were receiving surveillance of an initially abnormal PSA and who tend to receive more frequent PSA testing than group 2 patients.[6] Second, our findings could possibly be explained by the method of assembly of the case and control groups. Specifically, cases had fewer years of education and higher AUA scores; more prostate-related symptoms and abnormal DRE findings could have led cases to worry more about prostate cancer than controls (irrespective

of their test results). We note, however, that results were unchanged after extensive adjustment for demographic variables, medical and psychological comorbidity, family history, and AUA score in multivariable regression models. Third, we did not collect qualitative data to explain why biopsy recipients reported greater worry or what patients were told by their physicians following their biopsy or PSA results. Finally, the study sample had few men from minority groups. Thus, it is unknown whether our findings can be generalized to men in different racial or ethnic groups.

Our results reinforce the importance of discussing the potential benefits and harms of prostate cancer screening, including psychological effects, with patients up front.[27,28] Many men obtain reassurance after a negative PSA test.[29] To reduce patient anxiety, however, efforts should be made to expedite the work-up of men with abnormal screening tests, and counseling should be offered to those men with persistent worry despite having a negative biopsy for prostate cancer. Moreover, our results highlight the need to improve the specificity of current prostate cancer screening strategies and to provide education and feedback to primary care physicians in order to minimize the inappropriate use of prostate cancer screening.[30]

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Table 1

Characteristics of two comparison groups: Men without prostate cancer on biopsy (Group 1), and men with PSA values in the reference range (Group 2).[*]

Variable	Group 1 (n=109)	Group 2 controls (n=101)	p-value
Demographics			
Age, mean (sd)	62 (8)	60 (8)	0.10
Race (% Caucasian)	98	97	0.69
Education, mean (sd)	15.2 (3.1)	16.5 (3.4)	0.003
Employment (% retired)	35	32	0.66
Marital status (% married)	84	90	0.22
Source of primary care (% internal medicine)[†]	69	74	0.43
Comorbidity			
Seattle index of comorbidity, median[‡]	3	3	0.79
History of depression, %	12	10	0.62
History of anxiety disorder, %	6	6	0.92
Prostate items			
Family history of prostate cancer, %	23	20	0.68
AUA score, median (IQR)[§]	7.0 (4–12)	5.5 (2–10)	0.01
Abnormal prostate exam, %	46	13	0.0001
PSA value (ng/ml), mean (sd)[**]	6.6 (4)	1.4 (1)	0.0001

[*] Age, race, and PSA values were obtained from computerized records; all other variables were based on self-report.

[†] Missing for 15 biopsy group 1 patients

[‡] The Seattle index of comorbidity (SIC) is computed based on the following formula: SIC=Age (in 5-year intervals) + Prior MI + 2*(Cancer) + Lung disease + 2*(CHF) + 2*(Diabetes) + Pneumonia + 2*(Stroke) + 2*(Past smoker) + 4*(Current smoker)

[§] AUA (American Urologic Association) score ranges from 0 to 35 (higher scores indicate more symptoms of prostatism); IQR = interquartile range.

[**] Missing for 32 group 1 patients and 3 group 2 patients.

Table 2

Outcome measures

Variable	Group 1 (n=109)	Group 2 (n=101)	p-value
SAI-6, mean (sd)*	33.1 (1.9)	32.9 (1.6)	.99
SF-36, probability below median (sd)†			
Mental health	.34 (.24)	.28 (.19)	.70
Psychological distress	.36 (.18)	.30 (.13)	.18
Psychological well-being	.45 (.22)	.43 (.18)	.89
Role-emotional	.14 (.12)	.10 (.07)	.73
Social	.27 (.18)	.19 (.14)	.71
Vitality	.33 (.18)	.27 (.15)	.69
Role-physical	.29 (.18)	.26 (.16)	.84
Prostate-specific questions			
Cancer-related worry, %‡			.0001§
Not at all	26	60	
A little bit	47	31	
Somewhat	21	8	
Extremely-very much	6	1	
Perceived 5-year risk of prostate cancer, %**			.001§
Very low (≤1:100)	40	60	
Somewhat low (1:20)	27	28	
Moderate (1:10)	19	10	
High-very high (≤1:5)	13	1	
Sexual questions			
Sexual function, %††			.0001§
Very good	18	36	
Good	40	35	
Fair	28	18	
Poor-very poor	14	12	
Sexual bother, %‡‡			.002§
None	43	72	
Very small	26	12	
Small	12	6	
Moderate-big	19	10	

* SAI-6 = State Anxiety Index (short form), scored on a scale from 20–80 (where 20 is least anxiety, 80 is most anxiety). Predicted means and standard deviations were obtained using linear regression (adjusted for age, education, marital status, comorbidity score, prior history of depression/anxiety, AUA symptom index, and family history of prostate cancer).

† Predicted probability of score below median value for 55–64 year old men in the general population, using multiple logistic regression models (including variables listed above). Median values were: Mental health = 80, Role-emotional = 100, Social = 100, Vitality = 65, Role-physical = 100. Mental health subscale scores were dichotomized using the sample median (Psychological distress = 93, Psychological well-being = 80)

‡ Subjects were asked “Since learning the results of your prostate biopsy (or PSA test), how worried have you been about getting prostate cancer?” Response anchors were: extremely, very much so, somewhat, a little bit, and not at all.

§ Based on ordinal logistic regression models (including variables listed above).

** Subjects were asked “How likely do you think it is that you will develop prostate cancer in the next 5 years?” Response anchors were: very low (1 in 100 or less), somewhat low (1 in 20), moderate (1 in 10), somewhat high (1 in 5), or very high (1 in 2 or greater). Based on responses from 104 and 96 group 1 and group 2 patients, respectively.

†† Subjects were asked “Overall, how would you rate your ability to function sexually during the past 4 weeks?” Based on responses from 87 and 84 group 1 and group 2 patients who reported sexual activity within the prior 4 weeks, respectively.

‡‡ Subjects were asked “Overall, how big a problem has your sexual function been for you during the last 4 weeks?” Based on responses from 100 and 94 group 1 and group 2 patients, respectively.