Preferences of Elderly Men for Prostate-Specific Antigen Screening and the Impact of Informed Consent

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Background. Use of the prostate-specific antigen (PSA) as a screening test remains highly controversial, particularly in older men. This study was undertaken to assess the impact of information on the preferences of older men for such screening.

Methods. The elderly cohort (age ≥65 years) of a larger randomized trial was studied to determine the effect of a 3-minute scripted informational intervention on primary care patients' interest in PSA screening and on potential predictors of screening interest.

Results. Informed patients were significantly less interested in screening than were uninformed patients (p = .006). Informed patients considered PSA screening to be significantly less efficacious than did uninformed patients (p = .004), but among both uninformed and informed patients, perceived efficacy correlated with interest in screening (multivariate OR 2.3, 95% CI 1.5–3.8 for uninformed patients; OR 2.2, 95% CI 1.3–3.9 for informed patients). Perceived seriousness of prostate cancer predicted interest in screening among uninformed patients (OR 1.8, 95% CI 1.3–2.6), but not among informed patients. Informed patients who were married were less interested in screening than those who were single, divorced, or widowed (OR 0.3, 95% CI .08–0.9). Marital status did not predict screening interest among uninformed patients.

Conclusions. Involving elderly patients in the decision whether to screen with the PSA by providing them with information leads to a significant reduction in interest in such screening. Factors that appear to influence the screening preferences of informed elderly patients include perceived efficacy of screening and marital status, whereas uninformed patients are more likely to weigh the perceived seriousness of prostate cancer in their screening decision.
years and over (11); however, as PSA screening is particularly controversial in elderly men, specific attention to this segment of the population is clearly warranted.

METHODS

This analysis focuses on the elderly cohort (age 65 years and older) of a randomized controlled trial that examined the impact of an informational intervention on patient interest in PSA screening. The study involved 205 men, 104 of whom were elderly, who had no history of prostate cancer and had never been screened with the PSA. They visited one of four university-affiliated primary care practices between June 1994 and March 1995 for routine appointments. The men randomly received either a scripted overview of PSA screening or a brief control message, both read aloud by a trained research assistant. The methodology of the randomized trial and the content of the informational intervention have been reported previously (11). Key elements of the information included the lifetime probability of developing and dying from prostate cancer, known risk factors for prostate cancer, likelihood and implications of an abnormal PSA result, usual evaluation of an abnormal result, and the uncertain benefits and common complications of early prostate cancer treatment.

Baseline sociodemographic information, including age, race, education, income, and marital status, was collected from both intervention and control patients prior to randomization. Family history of prostate cancer and self-perceived health status were also elicited. Following randomization and delivery of the intervention or control message, patient interest in undergoing PSA screening was determined using a 5-point Likert scale (from definitely not interested to definitely interested). In addition, patients were queried regarding potential predictors of interest derived from the Health Belief Model (12). These factors— including perceived seriousness of the underlying disease, perceived susceptibility to the disease, perceived efficacy of screening in terms of improved health outcome, and perceived barriers to screening—have been shown previously to predict other types of cancer screening behavior (13,14). Finally, both intervention and control patients were administered the following risk-benefit tradeoff question: "How willing would you be to undergo treatment for prostate cancer if the doctor thought you could be cured but wasn't sure, and the treatment had a 25% (1 in 4) chance of causing impotence (inability to have an erection) and a 5% (1 in 20) chance of incontinence (leakage of urine)?" The complication rates used in the question were based on published studies available at the time of the survey, and responses were measured on a 5-point Likert scale from very willing to very unwilling.

Baseline patient characteristics in the informed and uninformed elderly cohorts were compared using the two-tailed t-test for continuous variables and chi-square test for categorical variables. To determine the impact of the informational intervention on PSA screening interest, differences in mean interest between uninformed and informed elderly patients were analyzed using the two-tailed t-test. Differences in screening interest between elderly and nonelderly patients were examined using the two-tailed t-test and two-way analysis of variance (for differences by age group and intervention group). Potential predictors of interest in PSA screening in the entire elderly cohort were examined with chi-square testing using the Mantel-Haenszel test for linear association. Factors found to be significantly associated with screening interest from these bivariate analyses were included in a multivariate model using stepwise ordinal logistic regression, because interest in PSA (the outcome variable) was measured on a 5-point scale and was not normally distributed. Multivariate associations are reported as odds ratios (OR); ordinal logistic regression assumes a constant OR for each outcome category, in this case interest level in PSA screening.

To explore how the information affected patient preferences for screening, potential predictors of interest were sought by separately analyzing patient characteristics in the informed and uninformed cohorts, using the Mantel-Haenszel test for linear association. Results are presented for the bivariate analyses that yielded significant associations for either or both of the informed and uninformed groups. These factors were then used to develop two multivariate predictive models (one for each of the study arms) with interest in PSA as the outcome variable. Ordinal logistic regression was used to create the prediction models, and results are expressed as odds ratios with 95% confidence intervals (CI). All significance testing was two-tailed.

RESULTS

Baseline characteristics of the elderly primary care patients in this trial are shown in Table 1. There were no statistically significant differences between the informed and uninformed patients. The majority of patients did not graduate from high school, had family incomes of under $15,000, were married, and had Medicare as their only medical insurance. There was also no difference in self-perceived health status between informed and uninformed patients.

Interest in PSA screening was significantly lower among elderly patients who received the informed consent intervention than in control (uninformed) patients. As depicted in Figure 1, mean interest in screening was 2.8 on the 5-point scale among informed patients and 3.6 among uninformed patients (p = .006); this translates into a 20% diminution in interest in informed compared with uninformed patients.

Table 1. Baseline Characteristics: Uninformed Versus Informed Elderly Patients*

<table>
<thead>
<tr>
<th></th>
<th>Uninformed Patients (n = 56)</th>
<th>Informed Patients (n = 48)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, yr (SD)</td>
<td>71.5 (4.9)</td>
<td>73.2 (6.7)</td>
</tr>
<tr>
<td>Minority</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Minority</td>
<td>35.7</td>
<td>31.3</td>
</tr>
<tr>
<td>Non-high school graduates</td>
<td>64.3</td>
<td>66.7</td>
</tr>
<tr>
<td>Family income &lt; $15,000</td>
<td>72.2</td>
<td>73.9</td>
</tr>
<tr>
<td>Married</td>
<td>69.6</td>
<td>58.3</td>
</tr>
<tr>
<td>Medicare only insurance</td>
<td>76.8</td>
<td>83.3</td>
</tr>
<tr>
<td>Family history prostate cancer</td>
<td>9.1</td>
<td>10.4</td>
</tr>
</tbody>
</table>

*No differences were significant at p-value < .05.
There were no significant differences in screening interest between younger (age 50-64 years, \( n = 101 \)) and older (age 65 years and older, \( n = 104 \)) patients. Mean interest among younger patients was 3.6 on the 5-point scale, as compared with 3.2 for older patients (\( p = 0.1 \)). As shown in Figure 2, the effect of the informational intervention was similar for younger and older patients, lowering interest significantly in both groups. Two-way analysis of variance confirmed no significant interaction between age and intervention group for screening interest (\( p = 0.9 \)).

Potential predictors of interest in PSA screening in the entire elderly cohort are presented in Table 2. Informed patients, older patients, and patients who considered themselves healthier were significantly less interested in screening in the bivariate analyses. However, when these three factors were entered in a multivariate model, only the informational intervention remained a significant predictor of screening interest. To understand why better health was associated with lower screening interest, potential relationships between self-perceived health status and other patient factors were explored. There was a weak negative correlation between health and perceived susceptibility to prostate cancer (\( r = -0.17, p = .09 \)) and between health and willingness to accept treatment risks (\( r = -0.16, p = .10 \)).

Informed patients considered PSA screening to be significantly less efficacious than did uninformed patients (\( p = .004 \) for difference). There were no significant differences between uninformed and informed patients in perceived seriousness of prostate cancer, perceived susceptibility to prostate cancer, barriers to screening, and willingness to accept treatment risks.

Predictors of interest in PSA screening among uninformed (control) and informed elderly patients are shown in Table 3. Among uninformed patients, perceived seriousness of prostate cancer, willingness to accept prostate cancer treatment risks for potential cure, and perceived efficacy of screening all predicted interest in screening. Among informed patients, as with uninformed patients, perceived efficacy of screening predicted interest. In addition, perceived susceptibility to prostate cancer was positively correlated with screening interest and being married was negatively correlated. Age was not associated with screening interest in either uninformed or informed cohorts. However, in patients age 75 years and older, there was a strong trend toward decreased interest among informed patients (\( p \) for difference in mean interest .06).

Table 4 presents the results of the multivariate analyses for the uninformed and informed cohorts. Perceived efficacy
remained a significant predictor of screening interest among both uninformed and informed patients. Perceived seriousness remained a predictor among uninformed patients, whereas willingness to accept treatment risks was no longer predictive. Marital status remained predictive of screening interest in the informed cohort, with the OR of 0.3 indicating that married patients were less likely to desire PSA screening. Perceived susceptibility to prostate cancer no longer predicted screening interest among informed patients.

**DISCUSSION**

Given the great uncertainty about whether prostate cancer screening benefits elderly patients, providing these patients with information about the benefits and burdens of screening is critical. The principal finding of this study was that the provision of such information resulted in a significant decrease in interest in PSA screening. In the elderly cohort as a whole, two other factors—age and self-perceived health status—also predicted interest in screening. Advancing age was associated with a dropoff in interest, which is not surprising in that the informational intervention specifically mentioned that many physicians do not recommend screening beyond 75 years. Somewhat surprisingly, patients with better self-perceived health were less interested in screening. This may be partly explained by the finding that healthier patients perceived themselves to be slightly less susceptible to prostate cancer and were somewhat less willing to chance impotence or incontinence—the principal risks of early prostate cancer treatment—than were patients who perceived their health to be poorer. In the multivariate model, however, only the informational intervention predicted interest in screening.

Comparing the elderly and nonelderly cohorts, there was no significant difference in PSA screening interest. Moreover, the informational intervention had a similar impact on both younger and older patients, significantly diminishing interest in screening. It appears that receiving information had a greater impact than age on patients’ screening interest.

Are there any characteristics of elderly patients that predict interest in PSA screening? Based on our analysis of the uninformed (control) patients, the perception that screening is efficacious, the perception that prostate cancer is serious, and greater willingness to accept treatment risks for potential cure all predicted interest, though the latter factor was not significant in the multivariate analysis. No sociodemographic variables such as age, race, education, income, or marital status helped to predict interest.

How did the provision of information about prostate cancer and PSA screening alter these predictors? First, informed patients considered PSA screening to be significantly less efficacious than did their uninformed counterparts. This is not an unexpected finding in that the informational intervention included a discussion of the uncertainty as to whether early intervention in prostate cancer improves survival or quality of life, and discussed the risks of early prostate cancer treatment. Second, although the informed cohort, on the whole, perceived PSA screening to be less efficacious, efficacy still correlated with interest in being screened; that is, among informed patients, the more efficacious they considered the test, the more interested they were in having it. Third, the perception that prostate cancer is serious and willingness to accept treatment risks did not factor into informed patients’ interest in screening. This is likely due to the elements of the informational intervention that emphasized the highly variable natural history of prostate cancer and the risks of impotence and incontinence with treatment of early-stage disease. Fourth, informed patients who were married were less likely to be interested in screening than their single, divorced, and widowed counterparts. This may be due to concern over impotence, as one survey relating to treatment of early-stage prostate cancer found that a majority of men were willing to sacrifice extension of life expectancy for maintenance of sexual potency (15). Fifth, among informed patients, in contrast to uninformed patients, perceived susceptibility to prostate cancer was associated with interest in screening, although this relationship did not persist in the multivariate analysis. By informing patients that advancing age, family history, and Black race increase risk of prostate cancer, the intervention did provide patients with sufficient information to gauge their personal susceptibility, which may explain the association. Finally, there was a strong but statistically nonsignificant trend toward diminished interest in screening among informed patients 75 years and older. In that the informational script specifically stated that many physicians do not recommend screening with the PSA beyond age 75, this finding is not unexpected.

Most physicians have not traditionally involved their patients in decisions whether to screen for asymptomatic disease. The concept of implied consent—that patients who voluntarily present for medical care consent a priori to the care provided by their physicians—has led to a practice standard whereby screening decisions are determined almost exclusively by the physician. This concept makes sense for screening practices where the benefits have been convincingly demonstrated, such as with mammographic screening in women 50–65 years, and where the burdens of screening are known to be negligible. Such is clearly not the

<table>
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<tr>
<th>Predictor</th>
<th>Odds Ratio</th>
<th>95% Confidence Interval</th>
<th>Predictor</th>
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<th>95% Confidence Interval</th>
</tr>
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<tbody>
<tr>
<td>Perceived efficacy of screening</td>
<td>2.3</td>
<td>1.5–3.8</td>
<td>Perceived efficacy</td>
<td>2.2</td>
<td>1.3–3.9</td>
</tr>
<tr>
<td>Perceived seriousness of prostate cancer</td>
<td>1.8</td>
<td>1.3–2.6</td>
<td>Marital status</td>
<td>0.3</td>
<td>0.08–0.9</td>
</tr>
</tbody>
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*Ordinal logistic regression.*
case with prostate cancer screening in the elderly. There is no evidence to suggest that screening for early stage prostate cancer confers a mortality, morbidity, or quality of life benefit on elderly men, while there is evidence, albeit controversial, to suggest that “watchful waiting” (i.e., treating only symptomatic disease) can have a favorable outcome (16). The potential burdens of screening with the PSA are substantial, including the evaluation of a large number of false-positive results (two-thirds of abnormal PSA results are false-positives [17]), the excessive worry created by both false- and true-positive results, and the significant risk of complications caused by treatment of prostate cancer detected by PSA screening. In a survey of Medicare patients who had undergone radical prostatectomy between 1988 and 1990, over 30% reported incontinence to the point of requiring pads and 60% reported complete impotence (5); these complication rates are significantly higher than published rates for younger patients.

The potential benefits of screening elderly men for asymptomatic prostate cancer are also tempered by the effects of competing risks. Because the elderly generally have many competing risks for death compared to younger patients, the actual impact of a new diagnosis of prostate cancer on life expectancy may be very small, even discounting the risks of treatment (18). When these risks are factored in, there is a strong possibility that the survival benefit of treatment could be negligible, and that survival may, in fact, be shortened.

The current literature on elderly patients’ preferences for prostate cancer treatment is limited and offers conflicting information. One survey, which included both older and younger men, found that 68% of men were willing to trade off a 10% or greater advantage in 5-year survival to maintain sexual potency (15), while another survey of outpatient veterans found that 62% were willing to accept incontinence and 83% were willing to accept impotence for better long-term survival, although older patients were less willing to accept impotence than younger patients (19). Among elderly patients who had actually undergone radical prostatectomy for prostate cancer, fully 89% would choose surgery again, although there was significant variability in quality-of-life responses; those who developed incontinence and/or impotence had a significantly reduced quality-of-life responses; those who developed incontinence to the point of requiring pads and 60% reported complete impotence (5); these complication rates are significantly higher than published rates for younger patients.

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There are several limitations to this study. First, the study cohort was of relatively low educational and income status, limiting the generalizability of the findings. Second, the main outcome measure, patient interest in PSA, was a surrogate marker for actual screening. Third, the size of the elderly cohort analyzed in this study was small enough to raise the possibility of a type II (or β) error; that is, there may have been significant differences between informed and uninformed patients that this study was too small to detect. Fourth, as our understanding of prostate cancer and prostate cancer screening evolves, the content of the informational intervention will inevitably become outdated. Even so, it will be approximately a decade before the results of randomized trials of early intervention in prostate cancer become available (21,22); hence, uncertainty regarding efficacy of screening will persist for the foreseeable future. Moreover, the greater significance of this study is that older patients can understand information about a controversial screening test, and can utilize that information to formulate screening preferences. Finally, one might criticize the content of the control script as being too favorable and that of the intervention script as being too cautionary, hence skewing the results of the study. Indeed, there was nothing in the control script to dissuade patients from screening, while the intervention script did mention some of the potential burdens, controversies, and recommendations related to screening. However, we would argue that the control message is a reasonable surrogate for what currently happens in the majority of practice settings: either no involvement of the patient in the screening decision, or the patient offered screening without discussion. The intervention script was designed to simulate an informed consent discussion, which inherently raises both potential benefits and burdens of screening. Moreover, the intervention script was reviewed and revised by a panel of primary care physicians and urologists, who felt that it represented a reasonable facsimile of an informed consent discussion.

There is sufficient concern over the appropriateness of screening with the PSA that it would be reasonable to not offer such screening to elderly men with life expectancies of under 10 years or with significant coexisting illness. However, physicians who do offer screening should explicitly involve their patients in the screening decision by providing them with sufficient information to enable them to weigh the benefits and burdens of screening. Based on the findings of this study, such informed decision making will result in fewer elderly patients seeking PSA screening, but will target those individuals for whom screening is commensurate with their values and preferences.

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REFERENCES


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