

PSA Screening for Asymptomatic Prostate Cancer: Truth in Advertising

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CLINICAL ENCOUNTERS

1. *After a brief clinical visit for an unrelated problem, a patient asks why he is still having trouble controlling his urine 1 year after having a radical prostatectomy for asymptomatic prostate cancer detected by PSA screening. He relates that he recently approached his urologist with this concern and was told, "At least you're alive."*

2. *An asymptomatic man is seen for a routine preventive health visit and asks whether he should be screened for prostate cancer "with the blood test that I read about in the newspaper." The patient's physician provides a balanced discussion of the known risks and possible, but unproven, benefits of PSA screening. The patient is then invited to decide for himself whether he wants the PSA test. The patient expresses surprise that PSA testing is being publicly advertised before proven effective and declines the test.*

The review by Lynch in this issue of the Journal¹ documents that the treatment of advanced prostate cancer (stages C and D) is primarily palliative, and that cures for advanced disease are rare. In an attempt to prevent progression of early (stages A and B) asymptomatic prostate cancer to more advanced, incurable disease, some physicians and expert groups are promoting prostate-specific antigen (PSA) screening for asymptomatic prostate cancer. However, asymptomatic prostate cancer does not qualify for mass screening according to accepted criteria² because there is currently no evidence that (1) detection and treatment of prostate cancer in an asymptomatic phase significantly reduces morbidity or mortality, or that (2) treatment in the asymptomatic phase is superior to that obtained by waiting until symptoms appear.^{3,4} There is also uncertainty about the best treatment for symptomatic prostate cancer.³⁻⁶

Although all experts would agree that PSA screening for asymptomatic prostate cancer fails these criteria,

PSA screening has been recommended by the American Cancer Society, and is being heavily advertised in the media. In addition to the possible harmful effects of promoting unproven mass screening, we have concerns that enthusiasts for PSA testing may not provide patients with a complete picture of the implications of PSA testing (clinical encounter number 1). Full discussion of the risks and possible benefits of PSA testing are necessary, but take time (clinical encounter number 2).

The current controversy between advocates and skeptics of PSA screening is not likely to be resolved soon. Indirect evidence suggests that current screening techniques for prostate cancer are ineffective.⁷ Large increases (probably attributable to screening) in the reported incidence of prostate cancer, without corresponding decreases in mortality, also suggest that prostate cancer screening programs are not effective in reducing prostate cancer mortality.⁸ There is countervailing opinion, however, that prostate cancer screening with PSA might be effective.⁹ These differences of opinion, which are based more on differences of medical philosophy than on medical science (is a mass screening test innocent until proven guilty or guilty until proven innocent?) are manifested daily in primary care as illustrated by the clinical encounters cited above. How are skeptical physicians to respond when patients inquire about a PSA test? For advocates of PSA testing, what mandatory information should be provided when offering a test with known adverse consequences and unknown benefit?

"Truth in Advertising"

The answer to both these questions, and the solution with which both skeptics and advocates of PSA screening should agree, is: provide sufficient information so that the patient can make an informed decision.^{10,11} The universal application of this "truth in advertising" concept would have several beneficial effects. Most important, it would provide relevant information that some

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patients ask for, many patients want to know, and all patients should have.¹² Such information would help to inform physicians as well. There is also evidence that bringing the patient into the decision-making process may affect the number of invasive procedures performed.¹³

What Constitutes "Truth in Advertising"?

We believe that the following five areas of patient concern need to be addressed in patient-centered language before patients can be assumed to have received the "truth" about PSA testing: 1) personal relevance; 2) long-term test effectiveness; 3) short-term clinical consequences; 4) degree of reassurance inherent in a normal test; and 5) gaining perspective. Using a question-and-answer format, we have drawn upon the following sources to formulate a proposed patient information sheet concerning PSA screening (Appendix):

Question 1 (Personal relevance). *How big a problem is prostate cancer for me?* Proportions of microscopic, symptomatic, and fatal prostate cancer given in the answer are quoted from the review by Garnick.⁴ Another review of 24 studies suggests that the prevalence of histologic prostate cancer ranges from 15% to 30% in men over age 50 to approximately 60% to 70% in 80-year-old men.¹⁴ Estimates of the likelihood of death due to prostate cancer in men with "histologic" evidence of it range from less than 10%³ to 0.33%.^{7(pp 63-6)} Cumulative risk estimates of death caused by prostate cancer, other cancers, and by all cardiovascular diseases combined are derived from United States mortality statistics.¹⁵

Question 2 (Long-term test effectiveness). *Am I better off having the test, or not having it?* There is no evidence that PSA testing can preferentially detect prostate cancer likely to be symptomatic or fatal. The figures quoted in the patient information sheet assume that PSA testing detects all types of prostate cancer equally (histologic, potentially symptomatic, and potentially fatal).

Question 3 (Short-term clinical consequences). *If I do have the test, what are the immediate consequences to me if I have an abnormal test?* The proportions of PSA test results outside the normal range (values greater than 4 ng/mL, which are likely to activate further testing) were taken from reports of (1) systematic screening of men in a British general practice (14%)¹⁶ and (2) screening of American men who responded to a press release (8%).⁹ The positive predictive values of an abnormal PSA test for a recommendation for radical prostatectomy were derived from the same sources (11% for men in the British general practice and 33% for men recruited by the

press release). An overall risk estimate of a recommendation for radical prostatectomy in those agreeing to be screened may then be derived from these data. Surgical and postoperative complications of radical prostatectomy, and complications of radiation therapy, are taken from Mold et al.¹⁷

Question 4 (Degree of reassurance inherent in a normal test). *If I have a normal PSA test, will I have less chance of dying from prostate cancer, compared to someone who has an abnormal test result, or is not tested?* We have taken the estimated rate of false-negative PSA test results (25% to 45%) from Garnick.⁴

Question 5 (Gaining perspective). *What do the experts recommend? What does my own doctor think?* Groups that do not recommend any form of prostate cancer screening include the United States Preventive Service Task Force, the International Union Against Cancer, and consensus conferences in Sweden, France and Canada.⁴

Conclusions

Before any therapeutic intervention, it is standard medical practice to discuss the risks and benefits of the intervention. All too often there is no such discussion with patients about to undergo PSA screening which, in a predictable proportion of cases, will lead to radical prostatectomy or radiation therapy. Although not usually recognized by the patient at the time of initial PSA screening, test results may propel the patient down the "slippery slope" toward interventions with unknown benefits and consequences. Provision of "truth in advertising" before PSA testing is one way to restore the necessary degree of patient autonomy in deciding whether to be screened.

Physician opinion is likely to be an important influence on patients who are contemplating PSA testing. Nevertheless, the patient, not the physician, should ultimately decide whether to accept PSA testing. Patients should be given the necessary information on which to base an informed decision. This "truth in advertising" discussion is one attempt to provide such information.

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Appendix

Patient Information

PSA (prostate-specific antigen) Screening for Prostate Cancer

Before having the PSA (prostate-specific antigen) blood test, you should know the answers to the following questions:

1. **QUESTION:** How big a problem is prostate cancer for me? (How likely am I to die of prostate cancer, compared to dying of something else?)

ANSWER: Prostate cancer is common in older men, and can cause death. Current estimates indicate that a 50-year-old American man has an approximately 40% (4 in 10) chance of developing cells that look like prostate cancer under the microscope, a 10% (1 in 10) chance of having symptoms and being diagnosed with prostate cancer, and a 2% to 3% (2 to 3 in 100) chance of dying from prostate cancer.

Compared with the 2% to 3% (2 to 3 in 100) chance of dying from prostate cancer, a 50-year-old American man has a greater than 20% (2 in 10) chance of dying from other cancers and a greater than 50% (1 in 2) chance of dying from cardiovascular (heart and blood vessel) disease.

2. **QUESTION:** Am I better off having the test, or not having it? (Since I have no symptoms of prostate cancer, is there any evidence that having the screening test will increase my life expectancy, or improve my quality of life, compared to not having the test?)

ANSWER: No one knows for certain the answer to this question. At present, there is no scientific evidence that screening for prostate cancer by PSA testing, or by any other test, will increase your life expectancy, or improve your quality of life if you have no symptoms.

The PSA test can help to detect prostate cancer. However, approximately 95% (95 in 100) of the prostate cancer detected by PSA testing will not cause death, and approximately 75% (75 in 100) of the prostate cancer detected by PSA testing will never cause symptoms.

Some physicians believe that PSA screening will be beneficial because some fatal prostate cancer might theoretically be detected and treated successfully in an early stage.

Other physicians believe that PSA screening will be harmful because the majority of patients with prostate cancer found by PSA testing will be treated unnecessarily, and because there is no evidence that any treatment now available for early prostate cancer can prolong life.

All physicians agree that well-designed, scientific studies of prostate cancer treatment and PSA screening will be required to resolve this disagreement.

3. **QUESTION:** If I do have the test, what are the immediate consequences to me if I have an abnormal test?

ANSWER: If you have the PSA test, there is an 8% to 14% (8 to 14 in 100) chance that the result will be *outside the normal range*. If your PSA test result is *outside the normal range*, most urologists will recommend a test called "transrectal ultrasound" (a sound-wave test by means of a probe inserted into the rectum). Depending on the results of transrectal ultrasound, a second test called a "needle biopsy of the prostate gland" may be recommended.

If you have a test result that is *outside the normal range*, there is an approximately 11% to 33% (11 to 33 in 100) chance that you will subsequently receive a recommendation to receive a treatment for prostate cancer (either a "radical prostatectomy" or "radiation therapy"). Radical prostatectomy is a surgical procedure to completely remove the prostate gland. Radiation therapy involves the use of radiation to kill prostate cancer cells. The risks to you of radical prostatectomy and radiation therapy are shown in the Table.

4. QUESTION: If I have a normal PSA test result, will I have less chance of dying from prostate cancer, compared with someone who has an abnormal test result, or is not tested?

ANSWER: No one knows for certain the answer to this question. If you have a normal PSA test result, it is unknown whether your risk of dying from prostate cancer is different from someone who has an abnormal result, or from someone who has never had a PSA test.

Normal PSA values may be found in 25% (1 in 4 chance) to 45% (45 in 100 chance) of men with localized prostate cancer, so having a normal PSA test result does not guarantee the absence of prostate cancer. Also, a man with an enlarged prostate, but no prostate cancer, has a 33% (1 in 3) chance of having an abnormal PSA test result.

5. QUESTION: What do the experts recommend? What does my own doctor think?

ANSWER: The PSA test is recommended by some doctors and some experts, and is not recommended by other doctors and other expert groups. The American Cancer Society recommends PSA testing yearly for all men over 50 years old. This recommendation is based on the opinions of a group of experts. The United States Preventive Services Task Force, the International Union Against Cancer, and consensus conferences in Sweden, France, and Canada do not recommend PSA testing, or any other form of screening for prostate cancer. These recommendations are based on an evaluation of the available scientific evidence by other groups of experts.

Risks Associated with Radical Prostatectomy and Radiation Therapy

Risk	Likelihood	
	Radical Prostatectomy	Radiation Therapy
Death	2 in 100	0 in 100
Nonfatal thromboembolism (blood clot to the lungs)	10 in 100	0 in 100
Impotence (inability to have an erection)	20 in 100	40 in 100
Incontinence (dribbling, or uncontrollable loss of urine)	5 in 100	8 in 100
Rectal injury (radical prostatectomy) or intestinal injury (radiation therapy)	3 in 100	12 in 100
Urethral stricture (scar tissue narrowing the urine tube in the penis)	1 in 10	6 in 100
Lymphedema (swelling due to radiation damage to lymph nodes)	—	1 in 10
No complications	1 in 2	1 in 4

Overall, by *consenting to a PSA test* (even before the results are known), you should recognize that you are accepting a 0.2% (1 in 500) to 2.6% (2 to 3 in 100) chance that a urologist will recommend that you have a radical prostatectomy or radiation therapy.

Conclusion

Your decision whether to have PSA testing should be based on (1) your personal situation and (2) your understanding of the risks and benefits of PSA testing. Providing this information to you before you decide about PSA testing is part of a process called "informed consent." Despite disagreement about PSA recommendations, all experts and physicians agree that you should be fully informed about the possible benefits and known risks before you decide about PSA testing. Consider discussing PSA testing with your physician.