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Prostate Cancer Overdiagnosis in the United States: The Dimensions Revealed

Nick Mulcahy

Authors and Disclosures

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September 1, 2009 — More than 1 million additional men have been diagnosed with and treated for prostate cancer since the introduction of prostate-specific antigen (PSA) screening in the 1980s. And the "vast majority of these additional 1 million men did not benefit from early detection," write the authors of a new study published online August 31 in the *Journal of the National Cancer Institute*.

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"Prostate cancer screening has resulted in substantial overdiagnosis and in unnecessary treatment," Otis W. Brawley, MD, medical director of the American Cancer Society, writes in an editorial that accompanies the new study.

These new findings once again question the benefits of prostate cancer screening, says Dr. Brawley.

'Does prostate cancer screening save lives?' is still a legitimate question.

"Does prostate cancer screening save lives?' is still a legitimate question," he states.

The new study examines national prostate cancer incidence and treatment data in the United States from 1986 — the year before prostate-antigen screening (PSA) was introduced — to 2005.

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The study's conclusions stem from the idea that, for cancers detected early in a population, there should be a reduction in the number of cancers detected later in that same population.

In the United States, that offsetting reduction has not occurred in prostate cancer.

Instead, overall incidence rose rapidly after 1986, before peaking and declining in 1992 — but the decline was to levels "considerably higher than those in 1986," write the study authors, H. Gilbert Welch, MD, PhD, from Dartmouth Medical School in Hanover, New Hampshire, and Peter C. Albertsen, MD, from the University of Connecticut Health Center in Framingham.

The excess incidence — and thus overdiagnosis — has been worst in young men. The relative incidence rate (2005 relative to 1986) was 7.23 in men younger than 50 years. This rate is considerably higher than the relative incidence rates found in older men — 0.56 in men 80 years and older, 1.09 in men 70 to 79 years, 1.91 in men 60 to 69 years, and 3.64 in men 50 to 59 years.

Men Need to Be Informed

Drs. Welch and Albertsen believe that clinicians should "explicitly communicate," to men considering the screening, the relative magnitude of the number of deaths averted to the number overdiagnosed.

However, this is a difficult task, the authors admit. "Estimating the trade-off between a mortality benefit and an overdiagnosis is problematic when there is uncertainty about whether the benefit exists at all," they write.

There is uncertainty about whether the benefit exists at all.

The current study conservatively estimates that 1 death is averted for every 20 men overdiagnosed, say the authors. A recent European study suggests a 1 to 50 ratio, which is a "more plausible" estimate, write Drs. Welch and Albertsen, because it is from a randomized clinical trial (screened vs unscreened groups). "Given the European trial report that 1410 men need to be screened to avoid 1 death, this translates into a trade-off of approximately 1 death averted to 50 men overdiagnosed with prostate cancer," write the authors, referring to the study from the European Randomized Study of Screening for Prostate Cancer (*New Engl J Med.* 2009;360:1320-1328).

However, in a recent major American randomized cancer screening trial, prostate cancer screening did not provide a mortality benefit (*New Engl J Med.* 2009;360:1310-1319).

Thus, with the possibility that the true mortality benefit "approaches 0," the estimate of the ratio of deaths averted to men overdiagnosed "approaches 1 to infinity," write Drs. Welch and Albertsen

Findings Are Probably Underestimates

The investigators of the new study used data on age-specific incidence and initial course of therapy for prostate cancer from the National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER)

Program. They then used age-specific male-population estimates from the US Census to determine the excess in the number of men diagnosed and treated in each year after 1986.

Since 1986, an estimated additional 1,305,600 men were diagnosed with prostate cancer; of that number, 1,004,800 were definitively treated for the disease, say the authors.

Excess incidence does not provide an exact figuring of overdiagnosis, admit the authors. However, in time, it is still a fairly good estimate, they suggest. "Although excess incidence is only a proxy for overdiagnosis — because some of the excess may simply reflect the lead time of diagnosis — the 2 measures become increasingly equivalent with the passage of time," they write.

During the entire study period of 1986 to 2005, prostate cancer incidence rose 26% (from 119 to 150.5 per 100 000), they observe.

To calculate how many men needed to be overdiagnosed to avert 1 death from prostate cancer, the authors used "the most optimistic assumption about the benefit" that was possible — "that the entire decline in prostate cancer mortality observed during this period is attributable to screening" (and none was related to improved therapies, techniques, clinician skill, and so on). Thus, they estimated "that approximately 56,500 prostate cancer deaths had been averted and that approximately 23 men had to be diagnosed and approximately 18 treated for each man experiencing the presumed benefit" — a death averted.

These numbers related to the benefit of screening are probably an underestimate because, in addition to the fact that they ignore progress made in prostate cancer treatment, they also ignore the fact that prostate cancer would have declined after 1986 if PSA had not been introduced.

How would prostate cancer incidence have declined?

The authors explain that prostate cancer was slowly increasing, at a rate of about 2% per year, in the decade before 1986. However, this increase was almost entirely due to cancers found incidentally when men were treated surgically (with transurethral resection) for benign prostatic hyperplasia. Half of all prostate cancer in 1986 was found during this surgery. When the surgery fell out of favor, the number of prostate cancers discovered this way dropped by 50% — a drop large enough to have caused an overall decline in prostate cancer incidence had PSA screening not arrived at the same time.

In short, because the investigators used 1986 as their base year, a year in which prostate cancer incidence numbers were inflated because of a specific surgery, their estimates of the effect of PSA screening represent underestimates, they say.

Whatever the exact numbers, many men have undergone unnecessary treatment and other difficulties, say Drs. Welch and Albertson. "All overdiagnosed patients are needlessly exposed to the hassle factors of obtaining treatment, the financial implications of the diagnosis, and the anxieties associated with becoming

a cancer patient," they write

The researchers have disclosed no relevant financial relationships.

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