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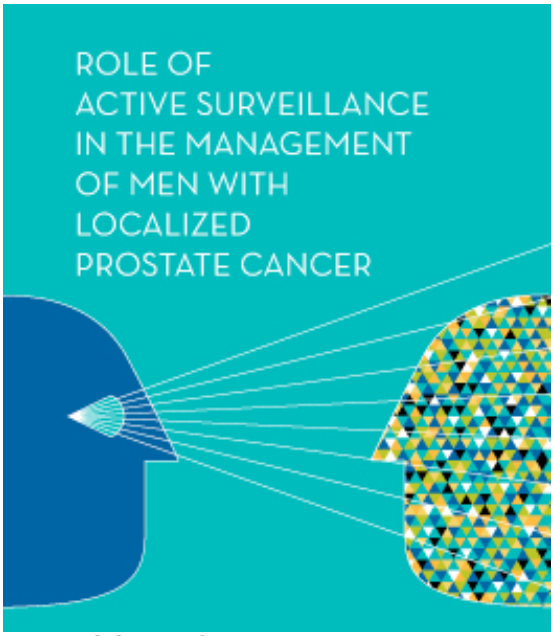
ONLINE FIRST: Independent Panel Says 100,000-Plus US Men Diagnosed Annually with Prostate Cancer Are Candidates for Active Surveillance



BY PEGGY EASTMAN

BETHESDA, MD — A multidisciplinary panel of independent experts has concluded in a draft statement that

more than 100,000 American men diagnosed each year with low-risk prostate cancer are candidates for active surveillance – proactive monitoring that delays curative treatment until it is warranted based on defined indicators of disease progression. Active surveillance is much different from watchful waiting, which the panel defined as a more passive approach that foregoes curative treatment and intervenes only for symptom relief.

The panel shared its endorsement of active surveillance here on the last day of a state-of-the-science conference held Dec. 5-7 on the grounds of the National Institutes of Health and in a news telebriefing.

In the United States, active surveillance is markedly underused. Currently, only about 10% of US men with low-risk prostate cancer -- defined as a prostate-specific antigen (PSA) value of less than 10 ng/mL and a Gleason score of 6 or less -- are placed on active surveillance, despite the fact that 50% of all prostate cancers receive a Gleason score of 6 from pathologists.

Fully 90% of these prospective active-surveillance candidates are referred for surgery or radiation therapy, due primarily to a physician's recommendation. The panel found that about a quarter of patients who do embark on active surveillance will undergo curative treatment within two to three years of diagnosis, and as many as half by five years -- for reasons that remain unclear.

There is no standardization in active surveillance protocols, and there are no randomized clinical trials to determine whether prostate cancer patients who undergo active surveillance have better or worse outcomes than those who have curative treatment immediately upon diagnosis. The panel made a number of research recommendations to fill in knowledge gaps.

The state-of-the-science conference was sponsored by the National Cancer Institute, the Centers for Disease Control and Prevention, and NIH's Office of Medical Applications of Research (OMAR). The Agency for Healthcare Research and Quality (AHRQ) was a conference partner. Panel members served without compensation, although their travel expenses were paid by NIH.

In writing its 19-page draft statement, the panel relied on presentations of data by invited speakers and published literature. The conclusions were influenced by, among others, the Prostate Cancer Intervention Versus Observation Trial (PIVOT) study, a randomized trial of 731 men comparing radical prostatectomy to observation for men with clinically localized prostate cancer. The PIVOT trial has found that in men with localized prostate cancer, radical prostatectomy produced reductions in all-cause mortality and prostate cancer mortality that were not statistically significant and were less than 3% in absolute terms through 12 years when compared with observation.

Men with low-risk prostate cancer who might be candidates for active surveillance deserve to know about this strategy as a viable option for them, said panel chair Patricia A. Ganz, MD, Director of the Division of Cancer prevention and Control Research at the Jonsson Comprehensive Cancer Center of the University of California, Los Angeles. "Anything we can do to bring this into the consultation room, so that the patient feels comfortable raising this issue with his physician" will help to create wider acceptance of active surveillance," said Dr. Ganz, who is also Professor at the Schools of Medicine and Public Health at UCLA .

She added that advocacy groups for this type of treatment strategy "will have an NIH-vetted document that describes this as an integral approach to the management of men with prostate cancer."

Dr. Ganz pointed out that the majority of men who are treated with radical prostatectomy or radiation therapy can experience side effects that include erectile dysfunction, urinary leakage, proctitis, or voiding dysfunction. Despite these potential side effects, some low-risk men may decide against active surveillance because they are anxious and fearful about a cancer diagnosis.

In fact, the panel recommended that "strong consideration" should be given to calling low-risk prostate cancer something other than the anxiety-provoking word "cancer," citing the terms ductal carcinoma in situ and cervical intraepithelial neoplasia as examples of terminology that does not use the emotion-laden word "cancer."

Another speaker, Paul F. Schellhammer, MD, Professor at East Virginia Medical School and Medical Director of the Virginia Prostate Center, said, “The word ‘cancer’ becomes the driving force in a patient’s view of his diagnosis and future.…Active surveillance is not an intuitive pathway for a patient to accept on receiving a diagnosis of cancer.”

He added, “”To convincingly discuss the active surveillance strategy/game plan will take all the counseling skills of a physician, both at diagnosis and at the follow-up intervals.”

Asked by *OT* if the panel expects its draft statement to have an effect on clinical management of low-risk prostate cancer, Dr. Ganz said the statement should give more support to the US urology centers that are currently promoting active surveillance as an accepted treatment strategy. But she noted that changes in clinical practice will likely be gradual.

The panel’s statement noted that today, active surveillance may be presented to patients in a negative way -- characterized as “doing nothing.” These unfavorable presentations may “reflect physician opinion, but also may be an unintended consequence of a specialist’s perspective and training,” states the draft statement.

“Physician recommendation is very, very powerful,” said panel member Nananda F. Col, MD, MPP, MPH, Professor of Medicine at the Center for Excellence in the Neurosciences and the Departments of Family Medicine and Geriatric Medicine at the University of New England. Dr. Col, who is President of Shared Decision Making Resources in Georgetown, Maine, noted that a urologist will typically tend to recommend surgery, while a radiation oncologist is likely to recommend radiation.

“I think over time we will probably see change; it’s not going to be immediate,” said Dr. Ganz. Asked if the panel believes its report will generate controversy, she said, “I think if there weren’t some controversy in this we wouldn’t have been doing this conference.”

Panel member John M. Barry, MD, Emeritus Professor of Surgery in the Divisions of Urology and Abdominal Organ Transplantation at Oregon Health & Science University, agreed with Dr. Ganz that the panel’s conclusions are likely to provoke controversy. With any novel concepts or expansion of older concepts in medicine there is controversy, he noted.

Also a speaker, Otis W. Brawley, MD, Chief Medical Officer of the American Cancer Society, told *OT* that he is pleased by the panel’s report and its recommendation that men who are candidates for active surveillance be fully informed about this management strategy. “I think the statement is absolutely wonderful; I hope it will cause doctors and patients to consider active surveillance as a legitimate form of treatment,” he said.

Does he think the statement will change clinical practice? “I hope it does,” he replied, “but I’m pessimistic….Many hospitals have a business plan for prostate cancer and are making money off it.”

He pointed out that most states have legislation mandating that women diagnosed with breast cancer be informed of all their treatment options, and said he would like to see the 90% of men with newly diagnosed low-risk prostate cancer who are candidates for active surveillance but don’t receive it be similarly informed of their treatment choices. For prostate cancer, “I wish we could do this without legislation,” he said.

Also at the meeting, prostate cancer survivor and advocate Jerry Sims of Pinckney, Michigan, called the panel’s statement “a big step forward.” What low-risk men need to know, he said, is that they don’t need to rush into prostate cancer treatment.

And Merel Grey Nissenberg, Esq., President of the National Alliance of State Prostate Cancer Coalitions, while agreeing with the panel that low-risk men need information on all their treatment options, including active surveillance, cautioned that it remains vitally important to identify and give curative treatment to the subset of men whose prostate cancer is potentially lethal. “Advanced prostate cancer is a terrible disease,” she said.

Posted by Editors at 10:50 AM
1 comment
12/13/2011
Merel G. Nissenberg said:
Active Surveillance is an idea whose time is coming...but not yet here. The panelists themselves could not even agree on what is truly a Low Low Risk prostate cancer patient, with a dispute over whether PSA (below or above 10) is more important than Gleason Score. There was discussion on under-staging and also missing certain higher grade lesions when performing a biopsy. Even the PIVOT trial could not be wholly relied on, as it was under-powered and the results too premature at this point. AS is a good option for only certain patients. While it is a good argument against the fear of over-treatment, it must be carefully applied to the correct patient population.

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