'Watchful Waiting' Proves the Path Less Traveled

BY FRAN LOWRY Orlando Bureau

ORLANDO — Men with very-low-risk prostate cancer are reluctant to choose active surveillance, or "watchful waiting," as a strategy to manage their disease, according to a review of a large prostate cancer database presented at a symposium on prostate cancer sponsored by the American Society of Clinical Oncology.

Just 9% of men who were eligible for active surveillance chose to be so managed. The vast majority instead opted for a more active treatment approach, said Dr. Daniel A. Barocas of New York-Presbyterian Hospital-Weill Cornell Medical College, New York.

Active surveillance of men with very-lowrisk prostate cancer involves follow-up every 6 months with a digital rectal exam and a

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prostate-specific antigen (PSA) test, as well as biopsies at certain intervals. Treatment interventions are warranted if and when there are signs that the disease is progressing. Because of the long interval between prostate cancer diagnosis

and the symptoms of localized cancer or metastases, the benefit of treatment vs. active surveillance is a matter of debate.

Dr. Barocas and his colleagues sought to determine the proportion of men presenting with very-low-risk disease who would be potential candidates for surveillance, and then calculated the percentage of these men who actually would select surveillance as their form of management. They analyzed the Cancer of the Prostate Strategic Urologic Research Endeavor (CaPSURE) database, a large, longitudinal observational prostate cancer disease registry that drew information from 41 community and academic practices across the United States from 1999 to 2004.

Criteria for very-low-risk disease that are highly predictive of indolent tumors include a PSA level less than 10 ng/mL; PSA density of less than 0.15; clinical T1- or T2a-stage disease; nonpalpable tumor on the digital rectal exam; Gleason score of 6 or less; and less than one-third of biopsy cores are positive.

Overall, 1,886 patients met all parameters, and 310 (16%) met the criteria for active surveillance. Patients who met the criteria for active surveillance were significantly more likely to be younger, privately insured, had higher education and income levels, and were white.

Only 28 patients (9%) chose active surveillance. Asked to speculate about why such a small number chose this type of management, Dr. Barocas said that factors such as the anxiety produced by a new diagnosis of cancer and the uncertainty of active surveillance as a strategy for management probably were involved.

Men who were older were more likely to choose surveillance. Men aged 63-70 years were 5 times more likely to choose surveillance than were men younger than 63, and men older than 70 years were 26times more likely to choose surveillance than were men younger than 63.

Dr. Eric A. Klein, a professor of surgery at the Cleveland Clinic, noted that such reluctance to choose surveillance also is related to the inability to cure those men who progress after they have chosen observation.

"It's very clear that we are overtreating some men, but the problem right now [is that] we do not have the right tools to identify just who is going to run into trouble if they are not treated immediately. Until we have those tools at hand, there's going to be hesitation on the part of most patients and also clinicians about recommending a surveillance strategy," he said.

That being said, active surveillance still is an option to offer to patients. "I have several dozen patients on active surveillance.

We are comfortable with the idea, but there's always some uncertainty at the back of my mind about it," Dr. Klein said.

Dr. Barocas agreed: "You have to explain the situation to the patient and be a partner in that decision-making process with him. The older the patient, the more prudent the watchful waiting approach becomes, Dr. Barocas said at the meeting, which was cosponsored by the Society of Urologic Oncology and the American Society for Therapeutic Radiology and Oncology.



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References: 1. CHANTIX [package insert]. New York, NY: Pfizer Inc; May 2006. **2.** Center for Drug Evaluation and Research. Approval package for application number NDA 21-928: statistical review(s). Food and Drug Administration Web site. Available at: http://www.fda.gov/cder/foi/nda/2006/021928_s000_Chantx_StatR.pdf. Accessed August 25, 2006. **3.** Gonzales D, Rennard SI, Nides M, et al, for the Varenicline Phase 3 Study Group. Varenicline, an α 4 β 2 nicotinic acetylcholine receptor partial agonist, vs sustained-release bupropion and placebo for smoking cessation: a randomized controlled trial. *JAMA*. 2006;296:47-55. **4.** Jorenby DE, Hays JT, Rigotti NA, et al, for the Varenicline Phase 3 Study Group. Efficacy of varenicline, an α 4 β 2 nicotinic acetylcholine receptor partial agonist, vs placebo or sustained-release bupropion for smoking cessation: a randomized controlled trial. *JAMA*. 2006;296:56-63.

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