

Researchers develop prostate cancer testing, treatment guidelines

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Julio M. Pow-Sang, M.D., chair of Moffitt Cancer Center's Department of Genitourinary Oncology, and colleagues have published two prostate cancer articles in the September issue of *JNCCN – The Journal of the National Comprehensive Cancer Network*. The articles review and clarify recent updates made to the National Comprehensive Cancer Network's (NCCN) guidelines for the screening and treatment of prostate cancer.

According to the NCCN, nearly 242,000 cases of prostate cancer will be diagnosed in 2012, accounting for 29 percent of new cancers among men. It is estimated that more than 28,000 men will die from the disease this year.

According to the journal, prostate cancer is "over diagnosed and over treated" and is subject to a controversy "fueled by large screening studies." This month, Prostate Cancer Awareness Month, the NCCN has offered support for [active surveillance](#), a strategy by which men with low-risk tumors, often classified as clinically insignificant, are monitored over time.

"Depending on the disease characteristics and the patient's life expectancy and personal preference, active surveillance may be a viable alternative to immediate and radical treatment," Pow-Sang said. "For others with high-risk, localized tumors or locally advanced disease, there are recent treatment advances that should be considered."

New agents and therapy combinations

According to the NCCN, [external beam radiation](#) and androgen deprivation therapy have been the traditional treatments for patients with high-risk tumors. However, the NCCN reports that brachytherapy, either permanent seed implant or temporary placement (high [dose radiation](#)), combined with external beam radiation and androgen deprivation therapy is increasingly being used for these patients.

The first article, [Prostate Cancer, version 3.2012](#), noted that two new agents – abiraterone acetate and immunotherapy sipuleucel-T – are welcome therapeutic additions for patients with late-stage disease and [poor prognosis](#).

Abiraterone acetate, which inhibits a key enzyme related to prostate cancer, can be given to patients after their chemotherapy. Studies have shown that it can also be used in chemotherapy-naïve patients.

Sipuleucel-T, a second line therapy, is a live cancer vaccine approved in 2010 for treating asymptomatic or minimally symptomatic patients with metastatic prostate cancer. The NCCN has recommended the new drug for use after chemotherapy failure or as treatment along with chemotherapy.

"The new NCCN guidelines highlight important updates to the management of prostate cancer," concluded Pow-Sang and his co-authors. "These protocols are updated annually and more often when new, high-quality clinical data become available. The guidelines are based on evidence from clinical trials combined with expert consensus."

Active surveillance and PSA density, percent free, and biopsy cores

In a second article, [Enrollment Criteria Controversies for Active Surveillance and Triggers for Conversion to Treatment in Prostate Cancer](#), Pow-Sang and co-author David D. Buethe, M.D., a urologic oncology fellow at Moffitt, examine the controversy and criteria for implementing active surveillance for patients with asymptomatic prostate cancer and identify the triggers that would convert active surveillance patients to active treatment status.

The authors note that for those patients with prostate cancers at low-risk for progression, the active surveillance strategy was proposed a decade ago but is recently receiving more attention as a viable management option.

"However, critical uncertainties still surround active surveillance," Pow-Sang said. "The criteria that qualify a patient as low or very low risk are not clear, nor is the definition of disease progression."

In this article, Pow-Sang and Buethe reviewed recent literature regarding those uncertainties, examining criteria for assisting in selecting men for active surveillance, including PSA density, percent free versus percent total PSA, biopsy positive core results and "volume of involvement" data.

"A PSA density of greater than 0.08 ng/mL/g has been identified as a significant predictor of future disease progression in those with low-risk prostate cancer," reported Pow-Sang. "However, some clinicians use a level of 0.15 ng/mL/g as a threshold."

Percent-free PSA has been found to be a significant predictor of organ-confined disease, said Pow-Sang and Buethe, noting that some reports have shown a significant indirect correlation between percent-free PSA and prostate cancer volume; but as yet this parameter is "not widely accepted as a predictor of cancer extent."

They also looked at studies on positive cores from biopsies and the extent to which core results could be used to develop criteria for treatment. Reports have shown the predictive value of positive biopsy cores, but the frequency for performing prostate biopsies remains controversial for outcomes of active surveillance patients, Pow-Sang said.

"Biopsies are not without consequences," he said. "Rectal bleeding and serious infectious complications from frequent biopsies need to be considered."

Additionally, no standard protocol exists, and controversy remains, for the frequency of PSA testing and the digital rectal exam for patients who are under active surveillance.

"Current guidelines vary," Pow-Sang said. "There are recommendations that the PSA and digital rectal exam should be performed every three to six months, or the PSA every three months and the digital rectal exam every six months. The frequency of biopsies is also variable, from once a year to up to every three years."

New potential tools

Pow-Sang and Buethe also report that a new tool, the PCA3 urinary marker, may be useful. PCA3 is a urine test used to quantify copies of the known prostate cancer gene 3. A PCA3 score of 35 or greater is considered possibly malignant. The test is prostate cancer specific and unaffected by prostatitis or benign prostatic hyperplasia, both of which have confounded the results of PSA testing.

The future of active surveillance

"Most studies report that 30 percent of active surveillance-classified men will be reclassified in the short term to clinically significant cancer that may require treatment," noted Pow-Sang. "Once more, PSA velocity (how quickly the PSA score rises) or PSA doubling time (how often the score doubles) has no clear role in active surveillance."

When counseling men with early prostate cancer, all treatment options, risks and complications should be discussed, Pow-Sang confirmed.

"Active surveillance is a reasonable management strategy for low-risk and very low risk [prostate cancer](#), but allows for continual reassessment and identification of progressive tumors."

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