Prostate Cancer Therapy Breaks Deemed Risky

BY JANE SALODOF MACNEIL
Senior Editor

LOS ANGELES — For men with low-risk prostate cancer, skipping more than two sessions of radiotherapy beyond their scheduled weekends off can have long-term consequences, investigators found when they reviewed nearly 1,800 patients treated from 1989 to 2004 at a single cancer center.

Biochemical control at 5 and 10 years was significantly worse for men who skipped more than 2 days even though they ultimately completed their treatments, Dr. David J. D'Ambrosio reported at the annual meeting of the American Society for Therapeutic Radiation and Oncology.

The impact of treatment interruptions was significant for the population as a whole, but the disparity was driven by a highly significant difference within the low-risk group. Interruptions had little to no impact in men with medium- or high-risk disease.

At 5 years the freedom-from-biochemical-failure (FFBF) rate was 90% in patients who skipped the equivalent of more than 2 days for low-risk prostate cancer versus 95% in those who took shorter breaks or no breaks. At 10 years, the FFBF rates were 57% and 82%, respectively.

"Our hypothesis for why this was seen in the low-risk group is that the low-risk patients are the ones most likely to have cancer just confined to the prostate. So … they are the ones who have the most to gain and lose from the local treatment," Dr. D'Ambrosio, a radiation oncology resident at Fox Chase Cancer Center in Philadelphia, said during an interview.

Findings of previous studies have conflicted on the question of whether small interruptions in prostate cancer treatment can be harmful, Dr. D'Ambrosio said.

The new study identified 1,796 men who received 3-D conformal radiation therapy (76%) or intensity-modulated radiation therapy (24%) between April 1989 and November 2004 at Fox Chase. None had androgen deprivation therapy.

The median dose was 76 Gy, median patient age was 69 years, and median follow-up was 62 months. On the basis of a Gleason score, pretreatment prostate-specific antigen (PSA) levels, and tumor stage, the patients were stratified into three groups: high risk (209 patients, 12%), medium risk (798 patients, 44%), and low risk (789 patients, 44%). The investigators created a nontreatment days ratio (NTDR). They calculated each patient's NTDR by dividing the total elapsed days during treatment into the number of nontreatment days during a course of treatment.

The investigators determined that patients with a ratio of 33% or higher were less likely to maintain long-term biochemical control. "This is the first time [the impact of skipped treatment days] has been shown, and it needs to be repeated before it is taken as dogma," Dr. D'Ambrosio said. ■

Cialis Gets Approved for Once-Daily Use

BY BROOKE MCMANUS
"The Pink Sheet"

The erectile dysfunction drug Cialis (tadalafil) has been approved by the Food and Drug Administration for once-daily use in 2.5-mg and 5-mg doses, the drug's manufacturer announced.

"This low-dose daily treatment option of Cialis may be most appropriate for men with ED who anticipate more frequent sexual activity," according to a statement issued by Eli Lilly & Co. "For other men, Cialis taken as needed—the previously approved dosing regimen—may be most appropriate."

Cialis was approved in 2003 in 5-mg, 10-mg, and 20-mg doses as the first and only phosphodiesterase type 5 inhibitor to provide sustained efficacy for up to 36 hours.

The approval of Cialis once daily is based on results from three phase III randomized, double-blind, placebo-controlled studies, which demonstrated that men with erectile dysfunction who took tadalafil 2.5 mg or 5 mg once daily without regard to their timing of sexual activity experienced improved erectile function, compared with placebo, the statement said.

The most commonly reported adverse events were headache, indigestion, back pain, muscle aches, nasal congestion, flushing, and pain in a limb. These side effects were transient.

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