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Should We Make Active Surveillance More Active for Localized Prostate Cancer?

Announcer:
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Dr. Agarwal:
Hi, my name is Dr. Neeraj Agarwal. I'm a Professor of Medicine, and Director of Genitourinary Oncology Program at the Huntsman Cancer Institute, University of Utah in Salt Lake City, Utah. Today, I'll be discussing active surveillance for our patients with localized prostate cancer, and discuss if we should make active surveillance more active.

So let's discuss active surveillance first. Many of our colleagues in the urology community are very familiar with active surveillance. But beyond that community, many of our colleagues may equate active surveillance to observation. In fact, active surveillance is an active intervention with the objective to avoid definitive surgery and radiation therapy in many patients with localized prostate cancer.

So before I talk about active surveillance and what it entails, let's see according to the NCCN guidelines, who are the candidates for active surveillance. So, these are the patients with very low risk prostate cancer and a life expectancy of 10 years or more. It is also applicable to most patients with low-risk prostate cancer and a life expectancy of more than 10 years. So 10 years or more. And it can also be considered for patients with favorable intermediate-risk prostate cancer, who have a life expectancy of 10 years or more.

And as we can see here, active surveillance entails active intervention, where disease is actively monitored with periodic PSA levels, digital rectal examination, prostate biopsies, MRIs of the prostate, and in many cases, molecular tumor analysis. I will not go through the frequency of these testing, which is already displayed here. But again, I would like to make a point that active intervention - or active surveillance is an active intervention and intensity of this active surveillance may be tailored based on patient's life expectancy and risk of disease aggressiveness, if you will.

So, in this context, a clinical trial has been conducted. It is a small trial of 227 patients who had low or intermediate-risk disease. And these patients who were already chosen to undergo active surveillance were randomized to enzalutamide 160 mg daily versus placebo. The primary endpoint was pathologic or therapeutic prostate cancer progression. Patient-reported outcomes was one of the important secondary endpoints. The results are summarized here. Most importantly, the treatment with enzalutamide significantly reduced the risk of prostate cancer progression by 46% versus active surveillance, and hazard ratio was 0.5 for favoring enzalutamide. The incidence of pathologic or therapeutic prostate cancer progression was lower with enzalutamide at 7.9% versus active surveillance alone, which was 23% at 1 year. At 2-year mark, incidents were similar between the treatment arms.

If we look at the secondary endpoints, in my view, the most important secondary endpoint is the effect on quality of life. We can see here a treatment with enzalutamide was not associated with clinically significant worsening of patient-reported outcomes except sexual and physical function, which resolved by month 24, after treatment cessation or treatment discontinuation of enzalutamide. And many other secondary endpoints favored enzalutamide. The trial investigators concluded that enzalutamide monotherapy was well tolerated and achieved a significant treatment response in patients with low-risk or intermediate-risk localized prostate cancer. In my view, we

need a larger trial with a significantly large component of quality of life before we can consider enzalutamide monotherapy as a treatment option.

I hope you liked the video. Thank you.

Announcer:
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