Estrogen Patches Slashed PSA in Prostate Cancer

By Patrice Wendling

Orlando — Estrogen patches produce a similar fall in testosterone and prostate-specific antigen levels when compared with luteinizing hormone-releasing hormone analogues in locally advanced and metastatic prostate cancer, according to interim results from the phase II, multicenter PATCH trial.

Intention-to-treat data from the first 100 patients show that castration was achieved at 4 weeks in 67% of 30 men who started treatment with three patches that were changed twice weekly. This increased to 91% of 33 men who started with four patches changed twice weekly. In comparison, 64% of 33 men who were treated with LHRH analogues achieved castration by that time point.

At 12 weeks, castration rates were 72%, 87%, and 93%, respectively, coauthors Dr. Ruth Langley and Dr. Paul Abel reported in a poster at a symposium on genitourinary cancers. Castration was defined as a testosterone level of 50 ng/dL or less.

PSA responses were observed in all three groups after 6 months. Levels fell from a baseline median of 51 ng/mL in both patch groups to 1.3 ng/mL with four patches changed twice weekly and 3.2 ng/mL with three patches changed twice weekly. They went from a median of 35 ng/mL at baseline to 0.9 ng/mL at 6 months in the control group.

“Providing [that data] continue to look promising, we are aiming to extend this to a phase III study,” Dr. Langley of Imperial College London, disclosed at Clinical Trials Unit said in an interview.

The hypothesis behind the PATCH (Prostate Adenocarcinoma: Transcutaneous Hormones) trial is that the application of estrogen to the skin will avoid first-pass hepatic metabolism (that is, the hepatic metabolism of a drug when it is absorbed from the gut and delivered to the liver via the portal vein), and therefore will not be associated with the same cardiovascular toxicity previously shown by oral estrogens.

Prolonged use of LHRH analogues has also raised concerns about long-term toxicity, particularly osteoporosis and metabolic syndrome. Estrogen has been shown in previous studies to protect against bone mineral density loss in women, and pilot data from a study in 20 men with prostate cancer show that transdermal estrogen improved bone density at 1 year (J. Urol. 2004;172:2030-7).

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The PATCH trial is sponsored by the Imperial College London and funded by Cancer Research U.K. Dr. Abel, of Imperial College London, disclosed con-...