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Use of bone health agents (BHAs) in patients with metastatic castration-resistant prostate cancer (mCRPC) treated with radium-223 after abiraterone: An interim review of REASSURE

Background

When the radium-223 Phase III clinical trial (ALSYMPCA) was conducted, abiraterone was an investigational agent that was only available through clinical trials. REASSURE is a prospective, observational clinical study of radium-223 in patients with mCRPC with a 7-year follow-up (NCT02141438). Patients could have had antihormonal agents, such as abiraterone, prior to receiving radium-223. The objective of this interim review was to evaluate the fractures and symptomatic skeletal events (SSEs) based on prior abiraterone use and the use of BHAs, denosumab and bisphosphonates.

Methods

Descriptive statistics were generated for baseline characteristics, fractures, SSEs, and overall survival (OS) by BHA use in patients who had completed abiraterone treatment prior to receiving radium-223 (prior abiraterone) or who had no prior abiraterone (abiraterone-naïve). SSEs consisted of events reported as "musculoskeletal"adverse events (fracture, spinal cord compression, radiotherapy to bone, surgery, and SSE documented as a type of progression).

Results

As of November 2017, 1439 patients were enrolled, with a median follow-up time of 9.1 months. 720 (50%) patients had received BHAs prior to, concomitantly with, or after radium-223. 431 (30%) patients received prior abiraterone; 675 (47%) patients were considered abiraterone-naïve. For the prior-abiraterone group, median time of exposure to abiraterone was 11 months. The median time from diagnosis of CRPC to initiation of radium-223 was 9 months in abiraterone-naïve patients and 23 months in prior-abiraterone patients. In the prior-abiraterone group, SSEs occurred in 18% and 25% of patients with and without BHAs, respectively. In the abiraterone-naïve group, 19% of patients with BHAs and 20% of those without BHAs had SSEs. Fractures were reported in 10/431 patients (2%) in the prior-abiraterone group. In the abiraterone-naïve group, fractures were reported in 5/302 (2%) and 11/373 (3%) patients with and without BHAs, respectively. OS from the initiation of radium-223 initiation was 15.5 months in the abiraterone-naïve group and 11.3 months in the prior-abiraterone group.

Conclusion

Similar rates of fractures were observed in abiraterone-naïve patients and those who received abiraterone prior to radium-223. Patients with prior abiraterone treatment had a shorter OS, and these patients received radium-223 at a later time during their disease course, as reflected by a longer time from CRPC to radium-223 initiation.

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