Eight-Year Results From the US Osteosarcoma Surveillance Study

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Osteosarcoma Surveillance Study

Figure 1. Participating and Targeted US Registries and Residence of Cases Identified in the US Adult Osteosarcoma Surveillance Study

Methods
This is an ongoing prospective, population-based, case-control surveillance study of adults (≥40 years) diagnosed with osteosarcoma in the US during a 15-year period. The study began in 2003 to provide an update on results, including descriptive characteristics of patients aged 40 years and older with osteosarcoma in the US.

OBJECTIVE
To provide an update on results, including descriptive characteristics of patients aged 40 years and older with osteosarcoma in the US.

RESULTS
Results have been updated since the abstract was submitted and include data as of June 30, 2013. The latest available data at the time of the final preparation of this chapter were used. There were no reported exposures to teriparatide before osteosarcoma diagnoses.

DISCUSSION AND CONCLUSIONS
These have been no reports of teriparatide treatment before an osteosarcoma diagnosis.

At this time, we have adequate power to detect a risk (91%), or one of additional 10,886 tested cases (i.e., a 40% increase in risk), with 90% confidence level, with 5% significance level.

We considered with what we would expect, the most common known risk sites, in order, were bone sites, other than bone sites, and unknown.

Of the osteosarcomas reported by the cancer registries, 98 (14%) occurred in a site other than bone.

The estimated incidence rate of osteosarcoma is 3.2 cases per million per year.

The Osteosarcoma Surveillance Study, an ongoing 15-year drug safety surveillance study, was conducted by RTI Health Solutions, Research Triangle Park, NC, USA, on behalf of the US Food and Drug Administration. The study was designed to identify cases of osteosarcoma occurring in adults aged 40 years and older in the US from 2003 to 2010.

Among patients interviewed, mean age was 60 years, 47% were female, and 86% were white. Osteosarcoma, not otherwise specified (NOS) (72%) and chondroblastic osteosarcoma (13%) were the most common morphologic types; leg bones (31%) and vertebral bones (15%) were the most common bone sites.

There were no reported exposures to teriparatide before osteosarcoma diagnoses.

As of September 30, 2012, 1,729 patients diagnosed between 2003 and 2010 had been identified. Of these patients, 1,729 (100%) were participating cases and 85% of those cases had been interviewed. Characteristics were available for 1,705 patients (98%).

The treatment indication was expanded to include treatment of men and women with glucocorticoid- and gonadal-hypogonadal osteoporosis who are at high risk for fracture. In 2009, the treatment indication was further expanded to include treatment of men and women with glucocorticoid-induced osteoporosis who are at high risk for fracture.

A total of 8,040 patients aged 40 years and older with osteosarcoma were identified from the 16 participating cancer registries and 643 had been identified through cancer registries in the US. After consent, case information, including demographics, prior treatment with medications, and exposure to possible risk factors, was associated with telephone interviews. Medical record review was performed for a random sample each year to validate self-reported information.

The 16 participating registries were selected to represent the demographic diversity of the US adult population. The registries included the following: Surveillance, Epidemiology, and End Results (SEER) 9 registries, 1 registry each from the Behavioral Risk Factor Surveillance System (BRFSS) 2 registries, and 1 registry each from the National Cancer Information Clearinghouse 2 registries.

As of January 1, 2003, 132 (19%) cases were identified in a site other than bone, as of June 30, 2013, 194 (26%) cases were identified in a site other than bone.

As of June 30, 2013, 26 US registries were actively participating in the study or were targeted for participation (Figure 1).

As of January 1, 2003, 132 (19%) cases were identified in a site other than bone, as of June 30, 2013, 194 (26%) cases were identified in a site other than bone.

Site not specified = 2

Bone sites = 613 (86%) Sites other than bone = 98 (14%)

Age, sex, vital status

Cases diagnosed with osteosarcoma in Paget's disease

13 (2%)

Other personal history of other cancers

98 (12%)

Incidence cases of adult osteosarcoma diagnosed on or after January 1, 2003, to other risk factors for osteosarcoma.

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