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Abstract Submission FORM

MEDICATION-RELATED OSTEONECROSIS OF THE JAW: CASE REPORTS BY PHARMACOVIGILANCE MONITORING IN SANTA CROCE CARLE CUNEO HOSPITAL

SECTION: 1A

AUTHORS: *Allione M.¹, Viglione M.¹, Vandone A.M.², Numico G.M.², Fruttero C.¹

AFFILIATION:

1. Hospital Pharmacy - AO Santa Croce Carle, Cuneo, 2. Oncology Unit - AO Santa Croce Carle, Cuneo, Italy

Background.

Medication-related osteonecrosis of the jaw (MRONJ) is a serious adverse drug reaction (ADR) that can occur during treatment with bisphosphonates and denosumab. These drugs are mainly used to reduce the risk of skeletal complications in patients with bone loss resulting from long-term cancer treatment or osteoporosis. As required by the protocol, orthopantomography, dental visit and preventive care are performed before starting treatment with bisphosphonates and denosumab.

Patients and methods.

In Santa Croce Carle Hospital of Cuneo, ten cases of MRONJ were collected from 2014 to 2024 by pharmacovigilance monitoring in collaboration with the Oncology Unit. Eight patients were treated with denosumab and two with zoledronic acid. Another case of MRONJ was reported for a non-cancer patient with severe osteoporosis in treatment with denosumab. In all cases MRONJ was confirmed by clinical criteria (surgical consultation) and radiological criteria (pan radiography or CT scan).

Results.

Nine patients were female. Eight of them had breast cancer: two of them were being treated with abemaciclib, one with trastuzumab deruxtecan, one with letrozole, one with eribuline, one with bevacizumab and one with everolimus and exemestane. For patients treated with denosumab MRONJ occurred after an average of 11 months and surgical treatment and/or antibiotics were used for treatment. One of these patients before the onset of MRONJ presented a submandibular purulent fistula so she was treated with antibiotics. After five months, mandibular bone exposure was observed and denosumab was interrupted.

The eighth patient was in treatment with trastuzumab and paclitaxel for breast cancer and MRONJ occurred after 8 months of treatment with zoledronic acid.

One case involved a female patient with severe osteoporosis, treated with denosumab 60 mg every six months. After about 3 years frequent dental abscesses appeared and teeth extractions was performed. Furthermore, the patient was also hospitalized for necrotic exposure of the bone and severe infection treated with antibiotics.

One case involved a male patient with kidney cancer treated with sunitinib: after 6 months of therapy with denosumab MRONJ occurred with exposure of necrotic bone associated with infection. To reduce the risk of complications, a course of antibiotics was necessary.

The last case involved a male patient with prostate cancer treated with taxanes. After about a year of treatment with zoledronic acid, MRONJ occurred with pain and bone exposure.

Conclusions.

In each case reported it was necessary to stop the suspected drug. Moreover, two patients were hospitalized and underwent surgery for the ADR. Six reports have already been entered into the national pharmacovigilance network and, also according to the Important Medical Event (IME) list, these ADRs were classified as serious.

REFERENCES:

1. Nicolatou-Galitis O, Schiødt M, Mendes RA, Ripamonti C, Hope S, Drudge-Coates L, Niepel D, Van den Wyngaert T. Medication-related osteonecrosis of the jaw: definition and best practice for prevention, diagnosis, and treatment. *Oral Surg Oral Med Oral Pathol Oral Radiol.* 2019 Feb;127(2):117-135. doi: 10.1016/j.oooo.2018.09.008. Epub 2018 Oct 9. PMID: 30393090