



Osteonecrosis of the Jaw Associated with Bevacizumab: A Case Series using the FDA Adverse Event Reporting System (FAERS) Database

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Introduction:

- Osteonecrosis of the jaw (ONJ) is a rare but serious adverse drug reaction (ADR) historically associated with denosumab and bisphosphonate therapy.
- Common symptoms of ONJ include jaw discomfort, mouth sores, loose teeth, and poor healing following dental procedures
- ONJ is diagnosed when exposed, necrotic bone is present in maxilla or mandible for at least 8 weeks (Figure 1)
- Rare case reports have described an association between ONJ and bevacizumab, a VEGF-inhibitor commonly used for advanced malignancies including colorectal cancer and hepatocellular carcinoma.
- ONJ can present as a delayed diagnosis due to lack of familiarity with the condition

Objective:

- This study reviewed cases of bevacizumab associated ONJ reported to the FDA Adverse Event Reporting System (FAERS) database

Methods:

- The FAERS database was searched for all reported cases of ONJ from 2010 to 2021.
- A dataset was created for bevacizumab associated ONJ and demographics were summarized.
- Only adults (age 18 and older) and reports from Healthcare Professions were included for analysis.
- Duplicate cases were removed.
- Cases lacking patient age or gender were excluded from review.
- A subgroup analysis was performed for subjects receiving bevacizumab without prior or concomitant denosumab or bisphosphonate therapy.

Results:

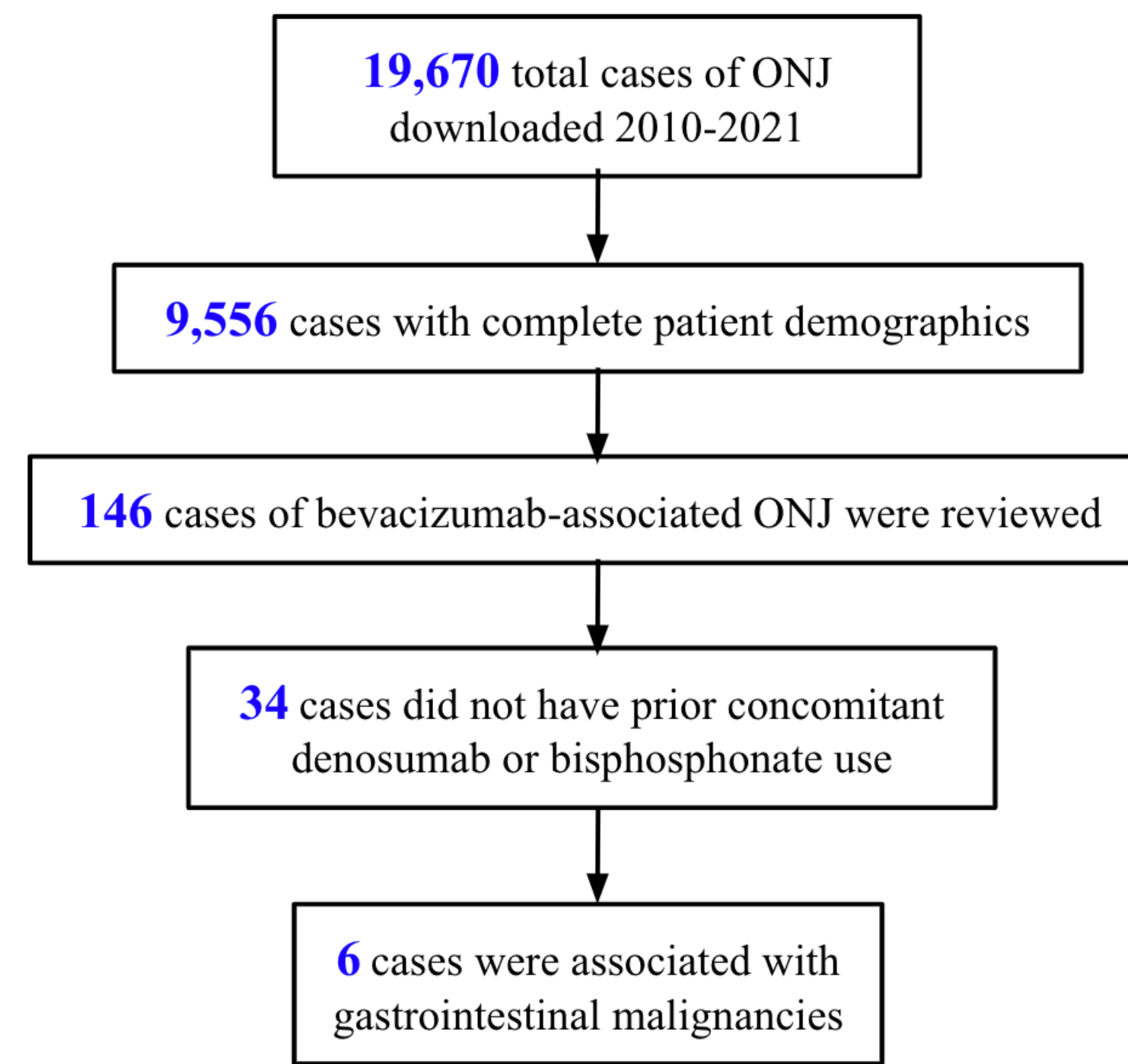


Figure 1: X-ray showing diffuse sclerosis and cortical thickening (arrows) with complete loss of corticomедullary differentiation.

Indication for Use	Number of cases
Colorectal cancer	5
Breast	5
Prostate	5
Unspecified	5
Renal Cell	4
Lung	3
Other	3
Esophageal cancer	1
Brain	1
	1
Plasma Cell Myeloma	1
Total	34

Summary:

- **GI malignancy** was the most common primary malignancy for which bevacizumab was being used when they experienced ONJ
- Gastroenterologists should consider ONJ as a potential adverse effect in patients with malignancies that are being treated with bevacizumab

References:

Morag Y, Morag-Hezroni M, Jamadar D, et. al. Bisphosphonate-related Osteonecrosis of the Jaw: A Pictorial Review. RadioGraphics 2009 29:7, 1971-1984