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Case Report

# Vertebral compression fractures in patients under treatment with denosumab: a contraindication for percutaneous vertebroplasty?

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**Abstract**

**BACKGROUND CONTEXT:** Denosumab (XGeva) is a receptor activator of nuclear factor-κB ligand (RANKL)–antibody that was approved by the Food and Drug Administration (FDA) in 2010 for the prevention of skeletal fractures in patients with bone metastases from solid tumors. Although there is a widespread use of such drug in patients under risk of pathological fractures, the compatibility of denosumab therapy with percutaneous vertebroplasty (an interventional procedure commonly used for pain control in such population) has not yet been established.

**PURPOSE:** To present the serial imaging findings and technical report of an attempted percutaneous vertebroplasty in a patient with refractory pain and a lytic pathological vertebral fracture related to small cell lung cancer spinal metastasis and who was actively under medical treatment with denosumab.

**STUDY DESIGN:** Retrospective review and case report.

**METHODS:** The authors present the imaging findings and technical report of an attempted percutaneous vertebroplasty in the only patient found to be actively under treatment with denosumab after a retrospective review of the databank of patients with pathological fractures referred to the Department of Radiology of the Ohio State University for percutaneous vertebroplasty (a total sample of 20 patients) since the FDA approval of denosumab (November 2010) until June 2013 (a 30-month period).

**RESULTS:** Although the computed tomography scan of the thoracic spine, performed 6 weeks after the initiation of the treatment with denosumab, presented a remarkable remodeling of the previously lytic vertebral lesion (which became markedly sclerotic in appearance), the clinical response in terms of pain improvement was not satisfactory. At the time of the percutaneous vertebroplasty (which was indicated for pain control), after advancing the 11-gauge needle through the pedicle with extreme difficulty, the needle repeatedly deviated laterally and, despite several attempts, it was not possible to penetrate the vertebral body and perform the cement injection.

**CONCLUSIONS:** This is the first report of the technical peculiarities of percutaneous vertebroplasty in patients under medical treatment with denosumab. According to our experience, because of its RANKL-mediated effects on osteoclasts activity, denosumab has been shown to induce a fast and marked sclerotic response on vertebral bodies that may not be accompanied by a satisfactory improvement in pain control (especially in patients with mechanical type of pain) and which may actually prevent the successful performance of percutaneous vertebroplasty. Therefore, it is of paramount importance that future studies evaluating patients with vertebral fractures under treatment with denosumab include long-term pain outcome measures. Additionally, further investigation is warranted to determine the optimal order of treatment and the best timeframe for combining percutaneous vertebroplasty and denosumab therapy in patients presenting with acute vertebral compression fractures and refractory axial pain. 

*Keywords:* Percutaneous vertebroplasty; Pathological fractures; Denosumab; RANK ligand antibody; Spinal metastasis; Osteoporosis

FDA device/drug status: Approved (Denosumab [XGeva]).

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## Case report

The authors performed a retrospective review of the databank of patients with pathological fractures referred to the Department of Radiology of the Ohio State University for percutaneous vertebroplasty (a total sample of 20 patients) since the Food and Drug Administration (FDA) approval of denosumab (XGeva; Amgen, Inc., Thousand Oaks, CA, USA) for the prevention of fractures in patients with bone metastases from solid tumors (November 2010) until June 2013 (a 30-month period). Only one patient who was actively under treatment with such drug was found.

This 41-year-old female patient, who had been diagnosed with Stage IV metastatic non–small cell lung cancer—an adenocarcinoma with positive epidermal growth factor receptor mutation—3 months earlier, presented with acute onset of midthoracic pain. The computed tomography (CT) scan of the thoracic spine demonstrated a pathological compression fracture of T5 and superior end plate of T6 because of lytic vertebral body lesions (Fig. 1). The magnetic resonance imaging of the thoracic spine confirmed the presence of acute pathological fractures with marked surrounding bone marrow edema (Fig. 2). At this point, the oncology team decided to initiate erlotinib (Tarceva; Genetech, San Francisco, CA, USA) as first-line therapy for patients with nonsmall cell lung cancer presenting positive epidermal growth factor receptor mutation, as well as denosumab (XGeva) because of the presence of widespread metastatic bone lesions. Six weeks after the initiation of the chemotherapy regimen with such drug, as the patient persisted with refractory midthoracic pain despite the use of narcotics, she was offered the option of percutaneous vertebroplasty.

During the procedure, after advancing the 11-gauge needle through the pedicle with extreme difficulty, the needle repeatedly deviated laterally and, despite several attempts, it was not possible to penetrate the vertebral body and perform the injection of cement (Fig. 3). A postprocedure CT scan demonstrated complete remodeling of the medullary bone of the vertebral bodies in comparison with a CT scan performed 6 weeks earlier, with a marked sclerotic appearance of the previously lytic bony lesions.

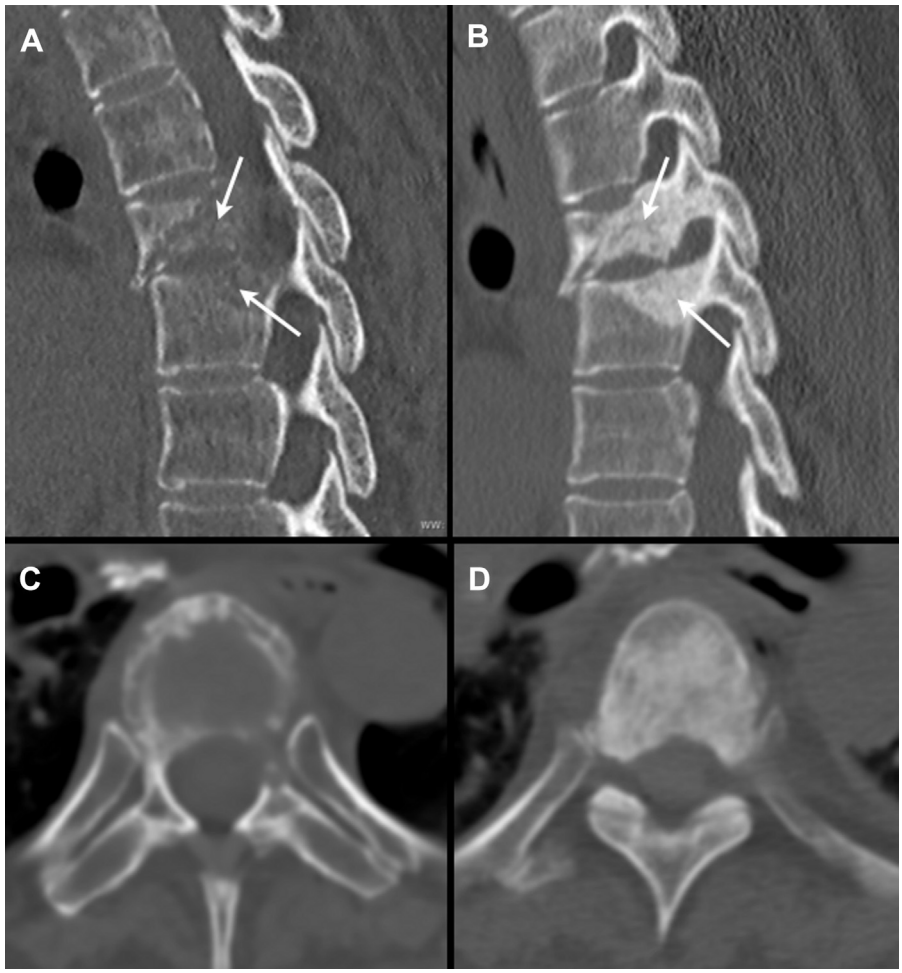


Fig. 1. (A) Sagittal and (C) axial computed tomography (CT) scans of the thoracic spine performed 6 weeks before the attempted vertebroplasty and right before the initiation of medical therapy with denosumab, demonstrating the presence of pathological compression fractures because of lytic lesions at T5 and superior end plate of T6 (white arrows). (B) Sagittal and (D) axial CT scans of the thoracic spine performed after the attempted vertebroplasty demonstrating complete remodeling of the vertebral bodies, with the presence of markedly sclerotic lesions at the same site (white arrows).