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Case Report

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A Surprising Adverse Event Related to Elranatamab in a Relapsed/Refractory Multiple Myeloma Patient: Sialadenitis

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ABSTRACT

Elranatamab, a bispecific T-cell engager (BiTE), has demonstrated significant efficacy in patients with relapsed or refractory multiple myeloma (MM) who have received multiple prior treatments. A 65-year-old female patient diagnosed with MM received elranatamab as fifth-line therapy. Three days after receiving a 76-mg dose in the first cycle, the patient developed swelling of the submental and submandibular areas of the neck, but experienced no fever, redness, difficulty swallowing, hoarseness, shortness of breath, or pain. Laboratory tests revealed elevated serum amylase and C-reactive protein levels, but procalcitonin was not elevated. A subsequent ultrasound examination revealed that the bilateral submandibular glands were heterogeneous and edematous in the cervical region. The diagnosis was immune-mediated, elranatamab-related sialadenitis. The patient was treated with 40 mg of methylprednisolone over three days. Symptoms improved after the first dose, and the swelling disappeared by the third day. To the best of our knowledge, immune-mediated sialadenitis associated with elranatamab has not been well characterized in the current literature. Short-term treatment with a steroid seems to be an effective therapeutic approach without considerable side effects.

Keywords: Multiple myeloma, bispecific antibody, elranatamab, sialadenitis

Introduction

Multiple myeloma (MM) is an incurable hematological malignancy despite recent advances in treatment modalities. Since MM patients are at high-risk of relapse, treatment should be initiated immediately to reduce morbidity and mortality associated with the disease. MM is considered "triple-class refractory" if the disease has progressed during or after treatment with a proteasome inhibitor, an immunomodulatory agent, and a monoclonal antibody, which confers a poor prognosis [1].

Elranatamab is a bispecific T-cell engager (BiTE) that targets B-cell maturation antigen on plasma cells and cluster of differentiation 3 (CD3) on T-cells. It has demonstrated significant efficacy, achieving an overall response rate (ORR) of 61% in relapsed or refractory MM (RRMM) patients who have received multiple prior treatments in the Phase 2 MagnetisMM-3 study [2]. It is administered subcutaneously with increasing doses during the first week, followed by weekly, bi-weekly, and monthly dosing. Patients require close monitoring for at least 48 hours after each dose escalation, owing to the potential immune- mediated cytotoxicity [2].

Acute sialadenitis is a relatively common disorder, usually arising from infection or salivary duct obstruction [3]. While acute sialadenitis has rarely been described after treatment with immune checkpoint inhibitors, to the best of our knowledge, immune-mediated sialadenitis associated with elranatamab is not well characterized in the existing literature. In this report, we present the development of non-infectious acute sialadenitis following the first full dose of elranatamab in a patient with RRMM, and its management.

Case Report

A 65-year-old female patient was referred to our center with severe anemia and back pain in September 2023. Non-contrast lumbar magnetic resonance imaging revealed no pathology other than varying degrees of intervertebral disc bulging.

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Tests performed to assess the patient's anemia revealed immunoglobulin G Kappa MM. The percentage of kappa-positive monoclonal plasma cells in the bone marrow was 70%. Bone marrow fluorescence *in situ* hybridization analysis showed 55% positivity for 13q, Ig heavy chain rearrangement at 14q31.33, and trisomy 1q. Its stage was compatible with International Staging System III. After receiving two cycles of bortezomib-cyclophosphamide-dexamethasone and four cycles of bortezomib, lenalidomide, and dexamethasone (VRD), the patient achieved a very good partial response. Then she underwent autologous stem cell transplantation. Isoniazid (INH) prophylaxis was started before transplantation. On day 100 post-autologous transplantation, serum and urine immunofixation were negative, confirming a complete response. Maintenance therapy with lenalidomide was deferred in accordance with the patient's preference until completion of INH prophylaxis. At six months post-transplantation, serum protein electrophoresis demonstrated a monoclonal spike, and positron emission tomography/computed tomography imaging showed a new lytic lesion in the posterior aspect of the left iliac bone with significantly increased fluorodeoxyglucose metabolism (maximum standardized uptake value: 7.7). VRD chemotherapy was restarted for reinduction. However, biochemical progression was observed after the fourth cycle, and we promptly switched to a chemotherapy regimen consisting of daratumumab, pomalidomide, and dexamethasone. Once again, disease progression occurred during treatment with daratumumab, pomalidomide, and dexamethasone. Following a comprehensive evaluation of available therapeutic options, treatment with elranatamab was initiated. The patient received elranatamab during the 1st cycle at doses of 12 mg sc on day 1, 32 mg sc on day 4, and 76 mg sc on day 8, without signs of cytokine release syndrome. Three days after receiving a 76 mg dose, the patient developed submental and submandibular swelling of the neck (Figure 1). The swelling in the neck was not accompanied by fever, redness, difficulty swallowing, hoarseness, shortness of breath, or pain. Laboratory tests revealed an unexpectedly high serum amylase level and an elevated C-reactive protein level, but not an elevated procalcitonin level. A subsequent ultrasound examination of the neck demonstrated that the bilateral submandibular glands appeared heterogeneous and edematous in the cervical region. Furthermore, the subcutaneous tissue thickness appeared increased in this area. The elevated serum amylase level in the patient was attributed to ongoing sialadenitis in the absence of clinical signs or symptoms of acute pancreatitis. The investigations yielded negative results for the respiratory tract viruses and autoimmune markers. Consequently, a diagnosis of elranatamab-related immune-mediated sialadenitis was made. The patient was treated with 40 mg of methylprednisolone for 3 days; the dose was reduced to 20 mg after 3 days, and the treatment was discontinued on day 5. Symptoms improved after the first dose, and the swelling disappeared by the third day. Sialadenitis developed after the initial administration of the 76 mg dose; it was treated with steroids, and weekly administration of elranatamab was initiated and continued, with no recurrence of sialadenitis. Serum amylase levels at follow-up and on days of elranatamab administration are shown in Figure 2. Written informed consent was obtained from the patient for publication of this case report and use of their photographs.

Discussion

Relapsed/refractory MM poses significant therapeutic challenges. In 2023, The European Medicines Agency approved elranatamab for patients with RRMM who were triple-class refractory. The phase 2 MagnetisMM-3 study demonstrated an ORR of 61%, including complete remission in approximately 31.7% of patients treated with elranatamab. The triple-class-refractory patients had previously been exposed to an immunomodulatory drug, a proteasome inhibitor, and an anti-CD38 antibody. Also, the median time to response was relatively low with 1.2 months (range: 0.9-7.4 months) [2]. As previously mentioned, our patient also experienced relapses following autologous transplantation and developed resistance to all three classes of chemotherapeutic agents.

Figure 1. Photographs demonstrating submandibular swelling in the patient's neck

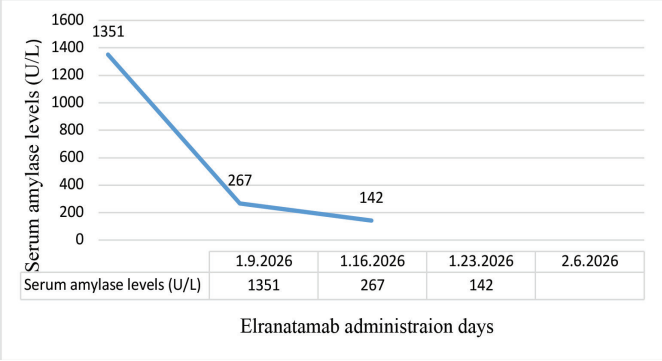

Figure 2. Serum amylase levels (U/L) and administration days of elranatamab 76 mg. The normal range of serum amylase is 28-100 U/L

Treatment with elranatamab was initiated as a fifth-line option in our patient.

Non-infectious immune-mediated sialadenitis remains a poorly documented adverse event, with only a few anecdotal cases reported in association with immune checkpoint inhibitor therapy [3-5]. Oral immune-related adverse effects (irAEs) such as dysgeusia, mucosal toxicity, and xerostomia can be severe and may require modifications of cancer therapy. Conducting a comprehensive evaluation and effectively preventing and treating these side effects can help ensure the continuation of cancer treatment. A working group focused on the oral care of cancer patients developed a Clinical Practice Statement that summarizes the management of oral irAEs [6]. Although this overview does not provide definitive recommendations for the management of immune-related sialadenitis, current treatment approaches appear to be largely guided by the clinical course and institutional experience in managing other immune-related adverse events [7]. We believe that increased reporting of such cases will enhance awareness and, over time, facilitate their incorporation into standardized toxicity management guidelines.

Conclusion

To the best of our knowledge, this is the first case report describing immune-mediated sialadenitis associated with BiTEs. In this case, short-term steroid treatment seems to be an effective therapeutic approach without significant side effects. Consequently, this case contributes to the limited body of evidence on BiTE-associated sialadenitis and emphasizes the need for increased awareness of its management.

Ethics

Informed Consent: Written informed consent was obtained from the patient for publication of this case report and use of their photographs.

Footnotes

Financial Disclosure: The authors have not disclosed any funding.

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