Aphthous-Like Stomatitis in a Patient Receiving Panitumumab

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ABSTRACT

Background: Panitumumab is an anti-epithelial growth factor receptor monoclonal antibody, approved for the treatment of metastatic colorectal cancer. Panitumumab has been more commonly associated with skin toxicity; oral adverse events have been scarcely reported in the literature. Herein, we present a case report of panitumumab-associated aphthous-like stomatitis.
Methods: A 58 years old female visited the Oral Oncology Unit complaining of severe oral pain. The patient had been diagnosed with colon cancer metastatic to the liver and was receiving panitumumab (every 14 days) concurrently with irinotecan and 5-fluorouracil.
Results: Clinical examination revealed multiple aphthous-like ulcers on the ventral surface and lateral borders of the tongue, lower lip and mucolabial fold, buccal mucosa and soft palate. Dexamethasone oral solution 0.5 mg/5 ml was topically administered t.i.d. along with tramadol 50 mg per os t.i.d. for pain management. One week later, the pain was relieved and the ulcers were almost completely healed. Tramadol administration was discontinued and dexamethasone was tapered during the following 8 days. There was no need for discontinuation of panitumumab. In close follow-up for the next four months, no painful oral symptomatology was reported.
Conclusions: Anti-epithelial growth factor receptor agents are associated with oral adverse events that may cause severe pain, even necessitating discontinuation of the antineoplastic treatment. The implementation of preventive measures, early diagnosis, proper treatment and close monitoring of patients receiving anti-epithelial growth factor receptor agents are mandatory in order to preserve patients' quality of life and their compliance to therapeutic regimen.

Keywords: aphthous-like ulcers; colorectal cancer; panitumumab; stomatitis.

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INTRODUCTION

Current targeted therapies for the management of various cancers are extremely advanced, improving the clinical outcomes [1,2]. However, a new spectrum of oral adverse events (OAEs) is rising, compromising the mucosal integrity; OAEs are different from the conventional chemotherapy-related complications, presenting a unique toxicity profile [3,4]. Among these, development of aphthous-like lesions resembling recurrent aphthous stomatitis (RAS), rather than conventional oral mucositis, has been described [5-7]. In patients receiving mammalian target of rapamycin inhibitors (mTORI), aphthous-like lesions in the oral cavity are known as mTORI - associated stomatitis (mIAS) [4,5,7]. Aphthous-like lesions have also been associated with agents against epithelial growth factor receptor (EGFR) [8,9], so that (aphthous-like) EGFR inhibitor-associated stomatitis could be a descriptive term for this complication [4].

Panitumumab is an EGFR recombinant inhibitor, a fully humanized monoclonal antibody approved for the treatment of metastatic colorectal cancer (mCRC) [10]. Colorectal cancer is the third cause of cancer-related death without gender predilection in the United States and the first in men younger than 50 years. Also, despite the widespread screening, more patients are diagnosed at an advanced stage compared to 30 years ago [11].

EGFR activates downstream signaling pathways, like PI3K/AKT/mTOR and RAS/RAF/MAPK, promoting cell proliferation, migration and survival, and angiogenesis [12]. In patients with chemo-resistant mCRC receiving the best supportive care (fluoropyrimidine, irinotecan, and oxaliplatin), the additional administration of panitumumab has significantly improved progression free survival [13]. Furthermore, in rat sarcoma virus wild type mCRC tumours, panitumumab plus an irinotecan or oxaliplatin-based regimen can be administered as first- or second-line therapy [14,15].

Panitumumab has been more commonly associated with skin toxicity as an adverse event (AE) [16]; OAEs reported in the literature are scarcely well documented and clinically characterized [17,18]. Even though the terms mucositis and/or stomatitis have been used in patients under panitumumab administration, panitumumab-related OAEs include phenotypically distinct lesions from oral mucosal injury caused by conventional high-dose chemotherapy, usually reported as mucositis [2]. The emergence of OAEs related to these medications can have deleterious effects on basic life functions, may affect oral and overall health, leading to significant morbidity and treatment discontinuation, and may have an impact on survival and quality of life.

Herein, we present, following the case report (CARE) Guidelines [19], a case of aphthous-like stomatitis associated with the administration of panitumumab.

CASE DESCRIPTION AND RESULTS

This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Ethics Committee of National and Kapodistrian University of Athens - NKUA (08.08.2024/No 658). Informed consent was obtained from the participant. The participant provided written informed consent for publication of the images included in the manuscript.

A 58 years old female visited the Oral Oncology Unit, Department of Oral Medicine & Pathology and Hospital Dentistry, NKUA, Greece, on October 30, 2019, complaining of severe oral pain. The patient had been diagnosed with colon cancer metastatic to the liver and had been receiving panitumumab (Vectibix® - Amgen Europe B.V.; Breda, Holland), intravenous injection 6 mg/kg over 60 minutes, every 14 days, as a first line therapy, with concurrent intravenous administration of irinotecan and 5-fluorouracil (5-FU) for the last 7 months. She was also on minocycline, 100 mg/day (Minocin® - Teofarma S.r.l.; Pavia, Italy) prophylactically. Otherwise, her medical history was impeccable. Her latest blood counts were within normal limits, including: 4.2 M/μL red blood cells (normal values: 3.9 to 5.6 M/μL), 41.4% hematocrit (normal values: 37 to 48%), 14.1 g/dL haemoglobin (normal values: 12 to 16 g/dL), 5.19 K/μL white blood cell (normal values: 4.0 to 11.0 K/μL) and 48.9% neutrophil (normal values: 40 to 75%).

Clinical intraoral examination revealed multiple small, superficial aphthous-like ulcers surrounded by a red halo on the buccal mucosa and soft palate bilaterally, as well as on the mucosa of the lower lip and mucolabial fold, ventral surface and lateral borders of the tongue and floor of the mouth (Figure 1). The patient reported that the ulcers had appeared 8 days after the last administration of panitumumab, which was the 14th cycle, without any changes in the treatment schema hitherto. There was no report of any aphthous-like ulcerations before panitumumab administration.

Based on the clinical presentation and the time-point of the appearance of the lesions (related to the panitumumab administration), a diagnosis of panitumumab related aphthous-like ulcers, grade 2 (according to the National Cancer Institute Common

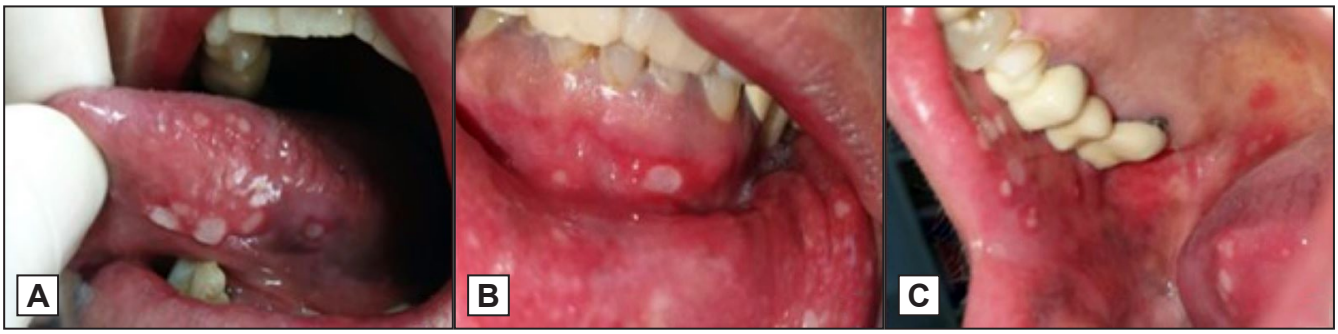

Figure 1. Multiple aphthous-like ulcers: A = on the ventral surface and lateral borders of the tongue; B = on lower lip and lower mucolabial fold; C = on buccal mucosa and soft palate.

Terminology Criteria for Adverse Events version 5.0 [20] considering that the patient could tolerate semi-liquid diet) was made.

Dexamethasone oral solution 0.5 mg/5 ml (Dexsol® - Rosemont Pharmaceuticals Ltd.; Lavrion, Greece) was administered for mouthrinses (10 ml, t.i.d. for 5 min each time) for one week, along with tramadol 50 mg per os t.i.d. (Tramal® - Vianex SA; Athens, Greece) for pain management, after consulting with the medical oncologist of the patient.

One week later, the pain was relieved and most of the ulcers were fully healed (Figure 2). Tramadol (Tramal®) administration was discontinued, and dexamethasone (Dexsol®) was tapered in the following 8 days.

There was no need for discontinuation of panitumumab (Vectibix®) administration. The patient was maintained under close follow-up for 4 months and no recurrence of the oral ulcers or any other painful symptomatology was reported.

DISCUSSION

Several studies reporting the toxicity of panitumumab in the oral cavity use the broad terms stomatitis or mucositis in order to describe the lesions, which are not specific for panitumumab OAEs [2-5].

To the best of our knowledge, there are only two studies [8,9] published in the literature that report clearly and adequately the aphthous-like oral lesions related to the administration of panitumumab (Table 1). Gomes-Silva et al. [8] described seven cases of aphthous-like stomatitis related to panitumumab and Thermos et al. [9] reported two cases of aphthous-like stomatitis related to EGFR inhibitors (one case associated to panitumumab and one case associated to osimertinib).

In the present case, the aphthous-like ulcers were localized exclusively on the non-keratinized oral mucosa. In previous studies, both non-keratinized and keratinized mucosal surfaces were involved in some cases, although the presence of ulcerations in the latter location was attributed either to concurrent herpes infection [8] or to trauma [8,9]. In our case, the ulcers were almost fully healed after one week of topical application of dexamethasone, which was rapidly tapered; no recurrences were noted in the next 4 months of follow-up. Similarly in the literature, the lesions were resolved in most of the patients (5 out of 8, 62.5%) in a mean time of one week, after topical application or systemic administration of corticosteroids [8,9].

Regarding the time of presentation, although the aphthous-like ulcers in the 6 out of 8 cases (75%), mentioned above, appeared after the first or

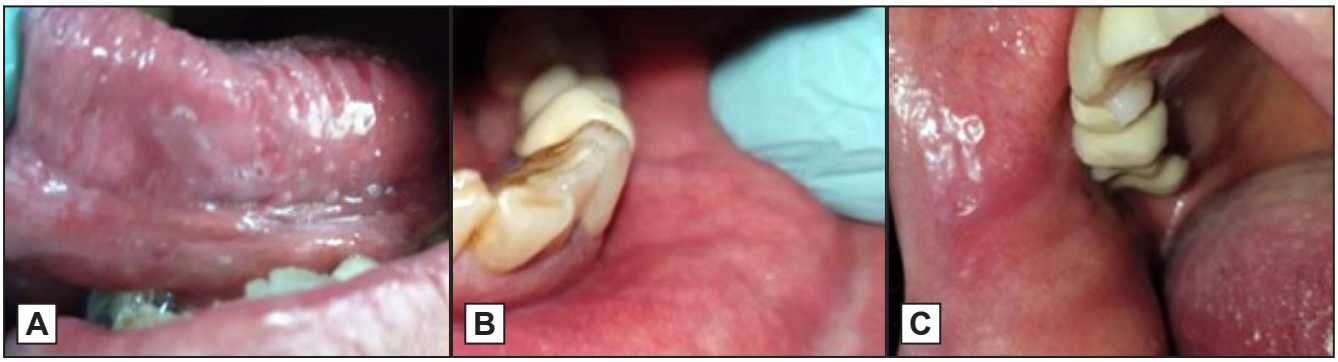

Figure 2. Healing of the ulcers after one week of topical application of dexamethasone: A = on the ventral surface and lateral borders of the tongue; B = on lower lip and lower mucolabial fold; C = on buccal mucosa and soft palate.

Table 1. Summary of reported cases of aphthous-like stomatitis related to panitumumab

Study	Time of onset (days)/ number of cycle	Symptoms	History of recurrent aphthous stomatitis	Keratinized/ non-keratinized mucosa	Steroid use	Clinical outcome/time	Recurrence	Panitumumab dose reduction or discontinuation (due to oral complications)
Gomes et al. [8]	8/1st - 2nd	Pain, feeding discomfort	None	-/+	Acetonide triamcinolone (topical)	Resolved/ complete resolution in a mean time of 1 week (1 to 3 weeks) after the initial oral management	Yes	Dose reduction in 2 patients. Drug discontinuation in 1 patient
	7/1st - 2nd			+[a]/+	No		Yes	
	11/1st - 2nd			-/+	No		No	
	10/4th			+[b]/+	Clobetasol propionate (topical)		No	
	10/1st - 2nd			-/+	Clobetasol propionate (topical), prednisone (per os)		Yes	
	7/1st - 2nd			+[a,c]/+	Clobetasol propionate (topical)		Yes	
	11/ rechallenge of therapy			+[d,c]/+	No		No	
Thermos et al. [9]	10/1st	Multiple oral aphthae	None	+[a]/+	Prednisolone (topical)	Resolved/ 1 week	Yes	Drug discontinuation
Our case	8/14th	Pain	None	-/+	Dexamethasone (topical)	Resolved/ 1 week	No	No

Lesions on keratinized mucosa: [a]tip of the tongue; [b]gingiva; [c]alveolar mucosa at mandibular torus; [d]dorsum of the tongue; [e]herpes infection.

the second cycle of panitumumab administration, there was one case that the lesions appeared after the 4th cycle of panitumumab and another case that the outbreak occurred after the re-initiation of panitumumab administration. In our case, the ulcers appeared relatively late, after the 14th cycle of panitumumab administration, despite the fact that there were not any changes in the therapeutic schema. Dote et al. [18] also reported the onset of "oral mucositis" grade 2, in a patient under panitumumab administration after the 11th cycle. The possibility of late appearance of aphthous-like stomatitis denotes the need of assessment of the oral cavity of patients under panitumumab throughout the duration of the therapy.

RAS, viral (herpetic) stomatitis, ulcers due to trauma and neutropenic ulcers should be included in the differential diagnosis of the aphthous-like stomatitis associated to panitumumab administration. Interestingly, none of the patients, neither in our case nor in the previously mentioned cases [8,9], reported any incidents of RAS before the administration of panitumumab. Further, in our case, the clinical appearance did not resemble herpes virus infection and no traumatizing factor involvement could be identified, while her neutrophil count was normal. Medical history, time of onset, site and clinical characteristics of the ulcers should be taken into consideration for proper diagnosis.

In the aforementioned previous literature reports [8,9], recurrence of the ulcers led to dose reduction in two patients and to discontinuation of the panitumumab administration in another two patients. In the present case, no recurrences were noted and there was no need for panitumumab discontinuation or dose reduction. This is important since dose reduction or discontinuation of the antineoplastic medication can lead to recrudescence of cancer, increased morbidity and worsening of patients' quality of life.

Severe oral pain was the chief complaint of our patient on her first visit to the Oral Oncology clinic due to multiple ulcers; Gomes-Silva et al. [8] also reported that patients felt moderate to severe pain. However, apart from the pain related to aphthous-like ulcers, Eryilmaz et al. [21] described two cases of patients with panitumumab-associated tongue pain, without any other complication in the oral cavity, which recurred after consecutive administrations of panitumumab. As there were no lesions or other symptoms in the oral cavity, the pathogenesis of pain remained unclear and the authors hypothesized that serum zinc and vitamin B12 deficiency could contribute to tongue pain.

EGFR plays a critical role in the homeostasis of epidermal and epithelial cells, so that agents targeting EGFR may produce a spectrum of mucocutaneous toxicities. The pathogenesis of panitumumab toxicity in the oral mucosa is not yet fully elucidated. Dote et al. [18] hypothesized a correlation between the distribution of the anti-EGFR antibodies and their affinity to EGFR to the incidence of oral mucositis. According to this hypothesis, the reported oral toxicity after the administration of panitumumab could be attributed to the distribution of anti-EGFR antibodies mainly in the blood and blood flow-rich tissues, like the oral mucosa; further, the higher affinity to EGFR of panitumumab compared to cetuximab could explain the significantly higher incidence of grade 2 to 3 oral mucositis after the administration of the former.

The concurrent administration of panitumumab with conventional chemotherapy may increase the risk and severity of mucosal involvement, as there might be a combined presentation of both superficial aphthous-like (due to panitumumab) and deeper, classic oral mucositis (due to chemotherapy) ulcers [5]. Additionally, anti-EGFR combined with 5-FU administration could lead to oral mucosa toxicity due to blockage of EGF; salivary EGF has been found to be important for the healing of the mucositis' oral ulcers induced by radiotherapy and chemotherapy [22,23]. Noticeably, in our case, 5-FU was administered concurrently with panitumumab.

Although irinotecan was also co-administered, the key role of the anti-EGFR therapy involvement in the development of aphthous-like stomatitis can be indicated from the fact that the cases of Gomes-Silva et al. [8] were previously treated with irinotecan alone, before the administration of panitumumab, without the presence of any oral lesions. Moreover, in patients with advanced non-small-cell lung cancer, the anti-EGFR tyrosine kinases inhibitors treatment has been associated with the presence of aphthous-like ulcers [24]. These findings support the notion that EGFR blockage effects appear to be crucial for the manifestation of this OAE. Furthermore, the inhibition of the PI3K-AKT-mTOR downstream pathway by the EGFR blockage [8,12] could provide an explanation for the clinical resemblance between the observed mTORI-associated (aphthous-like) stomatitis and the panitumumab-related aphthous-like ulcers.

The deterioration in the functionality and quality of life of patients developing OAE to antineoplastic agents, such as EGFR inhibitors, denotes the need for careful clinical examination of the oral cavity of all patients for complications and the need for proper treatment when such complications appear; it is encouraging that panitumumab related aphthous-like stomatitis seems to respond well to topical application or systematic administration of corticosteroids [5]. Moreover, studies on drugs efficacy and safety could provide more detailed information on the oral complications manifested during or after drug administration.

CONCLUSIONS

Aphthous-like ulcers in the oral cavity related to panitumumab administration may cause severe pain and incapability of feeding, leading to dose reduction or even discontinuation of the treatment. Examination of the oral cavity, early diagnosis, proper treatment and close monitoring of patients receiving anti-epithelial growth factor receptor agents are mandatory in order to preserve patients' quality of life and their compliance with the therapeutic regimen.

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The authors report no conflicts of interest related to this study.

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