PCCA MucoLox™

Chemoradiation Therapy-Induced Oral Mucositis

SUMMARY: Chemoradiation therapy-induced oral mucositis is a debilitating condition that compromises patients' nutrition, sleep and overall quality of life. Oromucosal formulations including multiple topical agents are commonly prescribed to these patients. PCCA Formula 11382, an anesthetic popsicle including a mucoadhesive compounding base (MucoLox), was recommended to a tongue cancer patient for palliative care. Following 12 days of treatment, the self-reported pain of the patient was reduced by 98.3%, as demonstrated by the SF-MPQ validated questionnaire.

Introduction:

The American Cancer Society estimates that about 50,000 people in the United States will get oral cavity or oropharyngeal cancer in 2017 and about 1/5 will die of these cancers. The most common sites of oral cancer are the mouth, gums and tongue, with an average age of diagnosis of 62 years old[1]. The cancer of the tongue, in particular, is a type of oral cancer that develops in the front two-thirds of the tongue[2] (Figure 1), often in the squamous cells – the flat, skin like cells that cover the lining of the tongue. Treatment of the cancer of the tongue commonly requires a multidisciplinary approach including surgery for removal of the tumor cells, followed by chemotherapy in combination with radiation therapy to the cancerous tissues of the tongue[2].

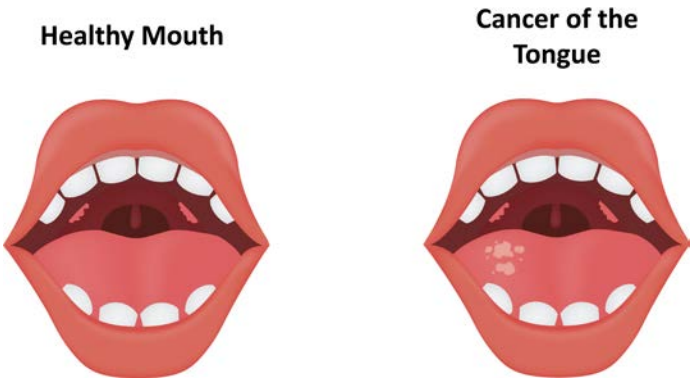

Figure 1. *Illustration of a healthy mouth versus tongue cancer.*

A common adverse effect of chemoradiation is oral mucositis, damage to the oral mucosal tissue that results in ulceration and infection. This is a debilitating condition that often leads to pain, difficulties eating and overall reduced quality of life. The majority of oral cancer patients receiving chemotherapy experience at least some degree of oral mucositis. Treatment options include topical agents to alleviate pain, soothing mouth moisturizers and antifungals, which may be combined in one single oromucosal formulation such as the "magic mouthwash"[3].

The purpose of this case study is to discuss the palliative care of chemoradiation therapy-induced oral mucositis with a topical, mucoadhesive compounded medication.

Case Report:

A 63-year-old Caucasian female was diagnosed with stage IV tongue cancer. A 12-hour surgical procedure was undertaken to remove 40% of her tongue, which was replaced with a skin graft from the arm and the stomach. Four molar teeth were also removed to facilitate radiation therapy to the tongue and the throat. Following surgery, the patient went through daily sessions of radiotherapy for 6 weeks, and three sessions of chemotherapy. As a consequence of the damage to the oral cavity, the patient lost 4 additional teeth and developed chemoradiation therapy-induced oral mucositis. The patient complained of difficulties eating and sleeping due to the pain in the affected areas, in particular the lower and upper gums, which persisted after the conclusion of the chemoradiation therapy. The patient did not take any acute or chronic medications for pain relief but only coenzyme Q10 (capsules 100 mg) twice a day.

The patient was recommended an anesthetic popsicle to be applied topically twice a day, 15 minutes prior to lunch and dinner. Table 1 details the ingredients of the compounded medication (PCCA Formula 11382), which includes Lidocaine, Beta Glucan, Dexpanthenol, Vitamin E Acetate and Glutamine in MucoLox, a proprietary polymer gel that acts as a delivery system to improve mucoadhesion and prolong retention of medications at application sites within the oral mucosa[4].

Rx	*For 20 mL*
Lidocaine Hydrochloride USP Monohydrate	0.2132 g
Beta Glucan (1,3) NQ	0.1 g
Dexpanthenol USP	0.2 g
Vitamin E Acetate (DL) USP Liquid (1IU/mg)	0.4 g
Glutamine (L) USP	0.4 g
Acesulfame Potassium FCC	0.1 g
Steviol Glycosides 95%	0.1 g
Flavor, Orange Cream	0.2 mL
Base, PCCA MucoLox™	q.s. 20 mL

Table 1. *PCCA Formula 11382: Lidocaine HCl 1%, Beta Glucan 0.5%, Dexpanthenol 1%, Vitamin E Acetate 2% and Glutamine 2% Popsicle (MucoLox™).*

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Methodology:

The patient's self-reported pain relief, as a result of the anesthetic popsicle, was assessed by 2 adapted research instruments: the short-form McGill Pain Questionnaire (SF-MPQ) and the Numeric Rating Scale (NRS).

The SF-MPQ is a short questionnaire that has been validated for the measurement of pain. It consists of 15 descriptors (11 sensory and 4 affective) which are scored on an intensity scale from 0 (none) to 3 (severe). Three pain subscales may be derived from this assessment by adding the individual scores obtained for selected descriptors, as follows: sensory pain (descriptors 1-11), affective pain (descriptors 12-15) and overall pain (descriptors 1-15)[5]. The Present Pain Intensity (PPI) is an additional evaluative category of the overall pain that consists in five verbal descriptors associated to a numerical value, from 0 (no pain) to 5 (excruciating pain). The PPI may be used alone or combined with the scores obtained from the sensory and affective pain. The original SF-MPQ also includes a Visual Analogue Scale (VAS), which was substituted in this case study by an adapted NRS. Permission was obtained to use the SF-MPQ for the purposes of research: *copyright R. Melzack 1984, 1987*.

The NRS is a generic, unidimensional assessment that consists of a segmented, 11-point intensity scale (from 0 to 10); it is commonly used to assess pain. The raw change and percent change are calculated taking into account the baseline and endpoint scores selected by the patient[6].

Results and Discussion:

The patient scored the NRS, PPI and 10 descriptors in the SF-MPQ, before and 12 days after treatment with the anesthetic popsicle. Before treatment, the patient scored 6 in the NRS (moderate to high pain) and 2.5 in the PPI (discomforting to distressing pain). The highest scored descriptors of pain were: throbbing, shooting, sharp, sickening and fearful (3=severe); followed by gnawing, aching, tender, tiring/exhausting and cruel/punishing (2.5=moderate to severe). After treatment, the patient scored 1 in the NRS, 0.5 in the PPI (mild to no pain) and 0 in all initially scored SF-MPQ descriptors of pain (none), as detailed in Table 2. Considering the overall pain and PPI assessments combined, the patient's self-reported pain decreased by 98.3%, which corresponds to a remarkable improvement of the patient's condition.

	Before Treatment	*After Treatment*
NRS	6	1
PPI	2.5	0.5
Sensory Pain	16.5	0
Affective Pain	11	0
Overall Pain	27.5	0
Overall Pain + PPI	30	0.5

Table 2. *Patient's self-reported pain scores, before and 12 days after treatment with the anesthetic popsicle.*

Conclusions:

The patient's self-reported pain, as a result of chemoradiation therapy-induced oral mucositis, has decreased remarkably following 12 days of treatment with PCCA Formula 11382, an anesthetic popsicle containing MucoLox. This compounding base is characterized by high mucoadhesive strength and retention at local sites, which is likely to have contributed to the efficacy of the compounded medication. Chemoradiation therapy-induced oral mucositis is a debilitating condition that compromises patient's nutrition, sleep and overall quality of life. Compounded medications may play a crucial role in the palliative care of these patients by allowing multiple topical agents to be combined in a mucoadhesive base.

References:

1. American Cancer Society (2017) *What Are the Key Statistics About Oral Cavity and Oropharyngeal Cancers?* Available at: http://www.cancer.org/cancer/oral-cavity-and-oropharyngeal-cancer/about/key-statistics.html (Accessed: January 18th).

2. Cancer Treatment Centers of America (2017) *Tongue Cancer.* Available at: http://www.cancercenter.com/oral-cancer/types/tab/tongue-cancer/ (Accessed: January 18th).

3. The Oral Cancer Foundation (2017) *Mucositis*. Available at: http://oralcancerfoundation.org/complications/mucositis/ (Accessed: January 18th).

4. Song, G., Banov, D., Bassani, A.S. and Valdez, B.C. (2016) 'Evaluation of the Safety, Cell Migration and Mucoadhesive Properties of a Mucoadhesive Polymer Blend in Human Oral Mucosa', *AAPS PharmSciTech*, DOI: 10.1208/s12249-016-0630-z.

5. Melzack, R. (1987) 'The short-form McGill Pain Questionnaire', *Pain*, 30, p. 191-197.

6. Farrar, J.T., Young Jr., J.P., LaMoreaux, L. et al. (2001) 'Clinical importance of changes in chronic pain intensity measured on an 11-point numerical pain rating scale', *Pain*, 94 (2), p. 149-158.

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