PCCA XemaTop™

Hand-Foot Syndrome Induced by Chemotherapy

SUMMARY: An adult male diagnosed with colon cancer developed Hand-Foot Syndrome (HFS), a common dermatologic adverse reaction to certain systemic chemotherapy drugs (e.g. fluorouracil). The patient was suffering from numbness, pain and a tingling sensation in his hands and was dispensed a XemaTop[™] topical cream including naltrexone 1%, beta glucan 0.5% and hyaluronic acid (PCCA Formula 12566). According to the HFS-14 questionnaire, the compounded medication provided great relief of the patient's HFS induced by chemotherapy.

Introduction:

Hand-Foot Syndrome (HFS) or Palmar-Plantar Erythrodysesthesia (PPE) is a common dermatologic adverse reaction to certain systemic chemotherapy drugs. It is clinically presented by cutaneous erythema, edema, desquamation and a tingling/burning sensation, especially over palmoplantar surfaces. The hands are usually more severely involved than the feet and may be the only body part affected [1,2]. Although the pathogenesis is not known, it is believed that the skin reaction occurs when a small amount of the drug leaks out of the capillaries (small blood vessels), damaging the surrounding tissues. It tends to happen in the hands and the feet because of the increased friction and heat that these body parts are exposed to through daily activities [3]. HFS is the most common chemotherapy-induced side effect after alopecia and mucositis [1].

Treatment of HFS requires a reduction or complete stop of the chemotherapy treatment [3], which is not recommended in most cases. However, it is possible to manage the HFS symptoms by applying topical medications associated with emollients. Although not life threatening, identification and early intervention are essential to prevent HFS from becoming progressive and debilitating [1].



Figure 1. Photograph of the patient's hands before treatment with PCCA Formula 12566.

Case Report:

A 67-year-old male was diagnosed with colon cancer and was taking the antineoplastic agent fluorouracil (5-FU), which is frequently associated with HFS. In particular, 5-FU continuous infusion schedules are more likely to cause HFS than bolus dosing [2,4]. The patient was suffering from numbness, pain and a tingling sensation in his hands (peripheral neuropathy). In addition, his hands were very dry and the skin was peeling, as displayed in Figure 1. These symptoms are consistent with HFS induced by chemotherapy and caused a great deal of distress to the patient. After consulting with a compounding pharmacist, the patient was dispensed a XemaTop topical cream including naltrexone 1%, beta glucan 0.5% and hyaluronic acid, as displayed in Table 1. XemaTop is a proprietary compounding base specifically developed for patients with dermatological conditions such as xerosis (dry skin), eczema and psoriasis. It uses the power and synergy of natural boswellic acid, avenanthramides from oats, phosphatidylglycerol and elegant film formers to deliver and improve the action of common active pharmaceutical ingredients (APIs) used in formulations for these patients. Naltrexone HCl 1% has been demonstrated to inhibit the expression of the cytokine IL-6 in vitro and it is thus likely to attenuate the inflammatory response [5]. Beta glucan 0.5% and hyaluronic acid were added to the formula for their immunomodulatory and anti-inflammatory activities [6,7].

Rx	For 75 gm
Naltrexone HCI USP Anhydrous	1%
Beta Glucan (1,3) NQ	0.5%
Hyaluronic Acid (Hydrolyzed)	0.5%
Base, PCCA XemaTop™	q.s. 100 gm

Table 1. PCCA Formula 12566: Naltrexone HCl 1%, Beta Glucan 0.5% and Hyaluronic Acid Topical Cream (XemaTop[™]).

Hand-Foot Syndrome Induced by Chemotherapy

Methodology:

The Hand–Foot Syndrome questionnaire, HFS-14, is a specific scale developed to assess the quality of life in patients suffering from HFS induced by chemotherapy. It consists of 14 questions categorized into three domains: hands disability, feet disability and social impact. Each question is scored on a three-point Likert scale: 6 (yes, always), 3 (yes, from time to time) and 0 (no, never) [8,9].

The HFS-14 includes two introductory questions to specify the area affected (hands, feet or both) and to measure the level of pain, and a visual analogue scale for pain (scored 0-10) at the end of the questionnaire. The introductory area item is scored 1 (if only the hands or feet were affected) or 3 (if both were affected) whereas the pain item is scored on a three-point scale: 1 (not painful), 2 (moderately painful) and 3 (very painful). The higher the total HFS score (ranging from 2 to 100), the higher the impairment of the patient's quality of life because of HFS [8,9].

The HFS-14 was the research instrument used in this case study since it is a simple and easy-to-use, self-administered questionnaire that has demonstrated internal consistency and clinical validity [8]. The visual analogue scale was substituted by a numeric rating scale to allow for a verbal completion of the questionnaire.

Results and Discussion:

The patient applied the topical compounded medication twice daily, as directed, for a period of 2 weeks. In addition, the patient applied the emollient creams Aquaphor® Healing Ointment, at night with gloves, and Aveeno® Daily Moisturizing Lotion during the day.

Before initiating the compounding treatment, the patient completed the HFS-14 and obtained a total score of 33/100. The highest impairment was reported for the hands disability domain; there was no social impact of the HFS on the patient's quality of life. After treatment, the patient reported only a moderately painful HFS and a much lower total score of 7/100 was obtained. A decrease in the HFS-14 total score indicates an improvement of the patient's quality of life impaired by the HFS condition. The HFS-14 is a useful research tool to assess the clinical efficacy of symptomatic treatments of this syndrome. It is therefore concluded that the XemaTopTM topical cream (PCCA Formula 12566) provided great relief of the patient's HFS induced by chemotherapy.

References:

- 1. Braghiroli, C.S., Leiri, R., Ocanha, J.P. *et al.* (2017) 'Do you know this syndrome? Hand-foot syndrome', *Anais Brasileiros de Dermatologia*, 92(1), p.131-133.
- 2. Nagore, E., Insa, A. and Sanmartín, O. (2000) 'Antineoplastic therapy-induced palmar plantar erythrodysesthesia ('hand-foot') syndrome: Incidence, recognition and management', *American Journal of Clinical Dermatology*, 1(4), p. 225-34.
- 3. Texas Oncology (2018) Hand-Foot Syndrome. Available at: https://www.texasoncology.com/cancer-treatment/side-effects-of-cancer-treatment/less-common-side-effects/skin-reactions/hand-foot-syndrome (Accessed: May 25, 2018).
- 4. Cancer Network (2003) 'Experts debate bolus vs continuous infusion 5-FU', eNewsletter, 12 (2). Available at: http://www.cancernetwork.com/articles/experts-debate-bolus-vs-continuous-infusion-5-fu (Accessed: May 24, 2018).
- 5. PCCA (2017) Technical Report: Evaluation of Naltrexone HCl 1% Topical Cream (#11934) applied to Psoriasis Tissue In Vitro [Online]. Available at: http://www.pccarx.com/science.
- 6. Jesenak, M., Urbancek, S., Majtan, J. *et al.* (2016) 'β-Glucan-based cream (containing pleuran isolated from pleurotus ostreatus) in supportive treatment of mild-to-moderate atopic dermatitis', *Journal of Dermatological Treatment*, 27(4), p.351-354.
- 7. Schlesinger, T. and Powell, R. (2012) 'Efficacy and Safety of a Low-Molecular Weight Hyaluronic Acid Topical Gel in the Treatment of Facial Seborrheic Dermatitis', *The Journal of Clinical and Aesthetic Dermatology*, 5(10), p.20-23.
- 8. Sibaud, V., Dalenc, F. and Chevreau, C. et al. (2011) 'HFS-14, a Specific Quality of Life Scale Developed for Patients Suffering from Hand–Foot Syndrome', *The Oncologist*, 16, p. 1469-1478.
- 9. Mikoshiba, N., Yamamoto-Mitani, N., Sato, K. *et al.* (2015) 'Validation of the Japanese version of HFS-14, a disease-specific quality of life scale for patients suffering from hand-foot syndrome', *Supportive Care in Cancer*, 23(9), p. 2739-2745.

Click the QR to see more PCCA studies and reports.



Last updated: 05.26.18

