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Sincerely,

Jim Andreesen, R.Ph., Angie Svoboda, Pharm.D. FIACP, and Ray Scott, R.Ph

How Compounding and Transdermal Medications May Help with the Opioid Crisis

Traditionally, opioid analgesics were reserved for a few select conditions, such as terminal illness and surgery, but more recently opioids have been readily prescribed for multiple conditions. Bucher, Day and Carvalho of Xavier University and Professional Compounding



Centers of America discussed the current state of opioid use and alternative transdermal analgesic therapies for pain management. Transdermal compounded medications are patient-specific and customizable to include different types of drugs, in various dosage strengths, that can be delivered simultaneously in one application. Due to the different origins and types of pain, treatments may be most beneficial when multiple classes of drugs with various mechanisms of action are included. In addition, combination drug therapy may include nontraditional pain management options, and has the ability to maximize therapeutic effects of medications through additive or synergistic properties, often allowing the dosage of individual drugs to be decreased. Many of the challenges faced when using oral opioid therapy may be overcome by using transdermal drug delivery since this route of administration reduces adverse effects, increases patient compliance, and limits exposure to potentially abusive drugs. Although prescribing practices surrounding opioids remains a controversial topic, the use of compounded pain medications may help healthcare providers to effectively treat their patients while avoiding the use of opioids.

Regression of GERD Symptoms with a Custom Dietary Supplement, Compared to Omeprazole

The prevalence of gastroesophageal reflux disease (GERD) is increasing. GERD is a chronic disease and presenting symptoms may include heartburn, regurgitation, dysphagia, coughing, hoarseness or chest pain. An estimated 44% of US adults experience GERD symptoms monthly, costing our healthcare system over \$20 billion per year.

A single-blind randomized study included patients aged 18 to 88 years and compared the benefits of 20 mg omeprazole (a "proton pump inhibitor") to a dietary supplement containing melatonin 6 mg, methionine 100 mg, L-tryptophan 200 mg, hydroxocobalamin 50 micrograms, pyridoxine 25 mg, betaine 100 mg and folic acid 10 mg. Melatonin has known inhibitory activities on gastric acid secretion and nitric oxide biosynthesis. Nitric oxide has an important role in the transient lower esophageal sphincter relaxation (TLESR), which is a major mechanism of reflux in patients with GERD. 176 patients underwent treatment using the supplement and 175 received treatment of 20 mg omeprazole, once daily after dinner for 40 days. Symptoms were recorded in a diary and changes in severity were noted. All patients of the supplement group (100%) reported a complete regression of symptoms after 40 days of treatment. On the other hand, only 115 subjects (65.7%) of the omeprazole group reported regression of symptoms in the same period. Also, some of the patients in the supplement group experienced 24-hour relief from GERD symptoms in as little as 7 days, and 90.3% of the supplement group had significant improvements in sleep quality by the end of the study.

Conclusion: The customized supplement formulation promoted regression of GERD symptoms with no significant side effects.

<u>J Pineal Res. 2006 Oct;41(3):195-200.</u> <u>https://www.naturalhealthresearch.org/34410-2/</u>

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Relief for Burning Mouth Syndrome

Burning mouth syndrome (BMS) is characterized by the presence of burning, paresthesia or pain of the oral mucosa in the absence of pathologic lesions. The pain may be accompanied by oral dryness, hypersensitivity to some foods and taste disorders. Potential systemic causes include diabetes mellitus, B group vitamin deficiency (vitamins B1, B2, B6 and B12), folic acid and iron deficiency, hormonal imbalance, gastrointestinal diseases, psychiatric and neurological disorders and druginduced side effects. The hypothesis concerning the role of hormonal changes in the development of BMS seems to be confirmed by a high incidence of this condition in perimenopausal women.

To investigate possible relationships among oral mucosal epithelial MUC1 expression, salivary female hormones and stress markers, and clinical characteristics in patients with burning mouth syndrome, 30 post-menopausal female patients with BMS (60.0 ± 5.0 years) received clinical and psychological evaluations, and their levels of oral mucosal epithelial MUC1, cortisol, DHEA, 17β -estradiol, and progesterone were analyzed.

Oral MUC1 expression protects oral epithelial cells. Salivary progesterone level had significant positive correlations with oral mucosal epithelial MUC1 expression level and with salivary cortisol and DHEA levels, i.e., the women with higher progesterone levels had higher oral MUC1 expression levels. Higher salivary levels of 17β -estradiol were correlated with longer symptom duration, greater severity of oral problems, and more significant results from psychological evaluations. Women with higher cortisol levels had a significantly less severe sensation of oral burning.

A retrospective chart review included 57 patients diagnosed with BMS and managed with topical clonazepam solution between 2008 and 2015. An 0.5-mg/mL solution was prescribed until 2012, when this was changed to an 0.1 mg/mL solution. Patients were instructed to swish with 5 mL for 5 minutes and spit two to four times daily. The efficacies of the two concentrations were compared using patient-reported outcome measures at the first follow-up, including the reported percentage of improvement in burning symptoms and the change in burning severity from baseline ranked on an 11-point numeric rating scale (NRS).

At a median follow-up of 7 weeks, the median overall percentage improvement was 32.5% in the 0.1-mg/mL cohort and 75% in the 0.5-mg/mL cohort. The median reduction in NRS score was 0.5 points in the 0.1-mg/mL cohort and 6 points in the 0.5-mg/mL cohort. The use of either outcome measure revealed that the response to treatment with the 0.5-mg/mL solution was superior to that of the 0.1 mg/mL solution. These findings suggest that a 0.5-mg/mL topical clonazepam solution is effective in the management of BMS.

Notes: 1) When prescribing this compounded medication, it's important to emphasize to the patient and in the prescription directions that clonazepam mouth rinse is Swish and SPIT, and should not be swallowed. This will decrease the risk of sedation and addiction potential associated with oral benzodiazepines. 2) A mucoadhesive base is ideal for an oral rinse when treating burning mouth syndrome.

<u>Menopause Review 2014; 13(3): 198-202.</u> <u>Arch Oral Biol. 2017 Jun;78:58-64.</u> J Oral Facial Pain Headache. 2017 Summer;31(3):257-263.

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