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The Mortar & Pestle:

MD Custom Rx's monthly e-newsletter

January 2017

Greetings!

Thank you for entrusting in the compounding services at MD Custom Rx to help meet the unique medication needs of your patients. We are excited to share our monthly newsletter with you and look forward to continuing to be your medication problem solvers. Please don't ever hesitate to let us know how we can be of further assistance to you and your practice.

Sincerely,
Dan, Monica and John

Absorption and Efficacy of Combination of Hormones in a Vaginal Cream

Is a combination hormone-containing cream absorbed when applied vaginally for local and systemic symptom relief? A pilot study examined the extent of absorption of a single cream containing micronized estriol USP, micronized estradiol USP, micronized progesterone USP, micronized DHEA, and micronized testosterone propionate USP. A combination cream was administered to postmenopausal women in two differing doses over two independent time periods.

In the first arm of the study, patients were instructed to apply 0.25ml of cream to the mucous membranes of the labia and vagina each morning using their index finger, supplying a daily dose of estriol 0.5mg, estradiol 0.125mg, progesterone 25mg, DHEA 1.25mg, and testosterone 0.25mg. In the second arm of the study, patients applied 0.5ml of a cream containing estriol 0.5mg, estradiol 0.5mg, progesterone 50mg, DHEA 50mg, and testosterone 0.5mg. Following therapy for 28 days (arm 1), some women continued therapy for 14 additional days (arm 2) with higher doses. During arm 2, saliva was collected 6 hours after the cream was applied vs. 24 hours after application in arm 1, with documented absorption of all hormones in arm 2.
Throughout the study, these parameters were measured: hormones in saliva and blood,

symptom relief, patient tolerability, and health-related quality of life (HRQoL).

"Patients found the once daily, single cream, mucous membrane/vaginal method convenient and easy to use... Vaginal delivery of hormones provided relief of systemic symptoms along with relief of vaginal and urinary symptoms; 87% of patients in this study had genital urinary symptoms before therapy and all patients had relief of genital urinary symptoms with therapy at day 28." In the second arm of the trial, one woman had complaints consistent with androgen excess and "the 50mg dose of DHEA was felt to be excessive".

This study is the first documenting systemic absorption of multiple hormones by both saliva and blood as well as improvement of HRQoL. This therapy was generally well-tolerated with only 2 patients experiencing minor irritation. Additional studies in larger numbers of patients will provide better knowledge for clinicians wanting to provide similar therapy at the lowest effective dose.

Gynecol Obstet Invest. 2008 Apr 29;66(2):111-118.

Compounded Glycyrrhizin for Psoriasis Vulgaris and Generalized Vitiligo

Psoriasis vulgaris is a chronic skin condition affecting patients' quality of life. Long-term use of conventional therapy increases risks of unwanted side effects. A review of 11 randomized controlled trials which compared oral compounded glycyrrhizin (OCG) plus conventional therapy to conventional therapy alone for psoriasis vulgaris evaluated the efficacy and safety of compounded glycyrrhizin. Oral compounded glycyrrhizin in conjunction with conventional therapy enhances clinical response, and compounded glycyrrhizin as add-on therapy does not appear to pose any additional risk in the treatment of psoriasis vulgaris.

Several modalities have been used to treat generalized vitiligo in the active stage. Oral trimethylpsoralen plus sunlight showed variable results in several independent studies. Psoralens must be used with caution because of their phototoxic properties; other known side effects of this class of drugs include nausea, pruritus and increased contrast between the lesion and normally pigmented skin. L-Phenylalanine plus UVA has been reported to yield good results in patients with slowly spreading vitiligo, but results have not been confirmed. The administration of systemic steroids in children has alleviated vitiligo in some cases, especially the rapidly progressing type, but the risk of suppression of the adrenal cortex should not be underestimated. While steroids can adequately control the condition, treatment interruption is difficult and vitiligo lesions can recur easily after interruption. Several studies suggest using methotrexate to control active vitiligo, but the side effects of this drug are significant (myelosuppression and hepatotoxicity) and it is not well tolerated by all patients. Topical steroids or topical tacrolimus are sometimes used, with variable results, to treat limited areas in patients with extensive vitiligo. Therefore, researchers have suggested there is a need for some type of combination therapy or an individualized approach to treatment because there is still no safe and effective commercially available therapy to treat patients who are in the active stage and who have not satisfactorily responded to conventional therapy.

OCG (oral compounded glycyrrhizin) has been used for years to treat several dermatologic disorders including mild to moderate alopecia areata, because it effectively inhibits CD4+ and CD8+ cells and their cytokine generation. A 68-year-old male who had erythrodermic psoriasis with bullous pemphigoid was successfully treated

using a combination of methotrexate and OCG.

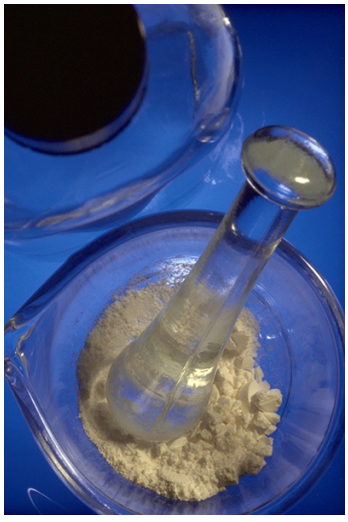
The pathogenesis of vitiligo is not clear, but studies have demonstrated that altered cellular immunity is present in vitiligo, in addition to and perhaps in combination with a humoral immune response, and inflammation is present in the dermis. OCG can inhibit inflammatory actions and regulate T cell activation. OCG acts like corticosteroids with almost no side effects. The results of a study indicate that OCG plus narrow-band UVB or 308-nm excimer laser therapy can represent a valuable option for treating vitiligo in the active stage. The treatment may result in improved cosmetic appearance and psychosocial functioning of vitiligo patients. OCG can help stabilize the disease and narrow-band UVB treatment can promote quick pigment recovery.

When OCG combined with narrow-band UVB was administered, the percentage of patients achieving overall repigmentation was 87.5%, which is promising for active-stage vitiligo patients. Most of the patients who did not respond to previous treatments showed excellent repigmentation after therapy with OCG and narrow-band UVB. The face and neck showed the best results, whereas the trunk and proximal extremities exhibited moderate repigmentation. In contrast, the acral sites (fingers, feet), and areas of bony prominences and with lower hair density (wrists, ankles and joints), showed little repigmentation. Vtiligo has a negative impact on patients' quality of life, and repigmentation of white patches, especially those on the face and other exposed areas, significantly reduced the effect of the disease on daily life. In the group treated with OCG alone, there was a 77.1% overall repigmentation rate. Therefore, those patients who are allergic to, or refuse to receive UVB treatment, can opt for OCG only.

There were some limitations to this study, such as the small sample size and relatively short investigative period. Therefore, a multicenter, randomized controlled trial is still needed to substantiate these findings. Properly designed follow-up studies should investigate the permanency of OCG plus narrow-band UVB therapy-induced repigmentation in acute-stage vitiligo.

Curr Med Res Opin. 2016 Nov 10:1-9.
Braz J Med Biol Res. 2016; 49(8): e5354.

Tranilast: A Review of its Therapeutic Applications



Tranilast (N-[3',4'-dimethoxycinnamoyl]-anthranilic acid) is an analog of a tryptophan metabolite. Initially, tranilast was identified as an anti-allergic agent, and used in the treatment of inflammatory diseases, such as bronchial asthma, atypical dermatitis, allergic conjunctivitis, keloids and hypertrophic scars. Subsequently, the results showed that it could be also effective in the management of a wide range of disease states, such as fibrosis, proliferative disorders, cancer, cardiovascular problems, autoimmune disorders, ocular diseases, diabetes and renal diseases. Tranilast has anti-angiogenesis and anti-inflammatory effects. In vitro and in vivo experiments have led to the hypothesis that local administration of tranilast may be clinically useful in treating psoriasis. Tranilast is an inhibitor of collagen synthesis which is beneficial for wound treatment.

Tranilast's major mode of action appears to be the suppression of the expression

and/or action of the TGF-ß pathway. Several trials have shown that tranilast has few adverse effects and it is generally well tolerated by patients.

Pharmacol Res. 2015 Jan;91:15-28.
Dermatol Ther (Heidelb). 2014 Dec;4(2):259-69.

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