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PRESCRIPTION COMPOUNDING FOR

PAIN MANAGEMENT

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FIBROMYALGIA

The following clinical paper concludes that low-dose naltrexone may be an effective, highly tolerable, and inexpensive treatment for fibromyalgia - “Fibromyalgia symptoms are reduced by low-dose naltrexone: a pilot study” (Pain Med. 2009 May-Jun;10(4):663-72).

OBJECTIVE: Fibromyalgia is a chronic pain disorder that is characterized by diffuse musculoskeletal pain and sensitivity to mechanical stimulation. In this pilot clinical trial, we tested the effectiveness of low-dose naltrexone in treating the symptoms of fibromyalgia.

DESIGN: Participants completed a single-blind, crossover trial with the following time line: baseline (2 weeks), placebo (2 weeks), drug (8 weeks), and washout (2 weeks). PATIENTS: Ten women meeting criteria for fibromyalgia and not taking an opioid medication.

OUTCOME MEASURES: Participants completed reports of symptom severity everyday, using a handheld computer. In addition, participants visited the lab every 2 weeks for tests of mechanical, heat, and cold pain sensitivity.

RESULTS: Low-dose naltrexone reduced fibromyalgia symptoms in the entire cohort, with a greater than 30% reduction of symptoms over placebo. In addition, laboratory visits showed that mechanical and heat pain thresholds were improved by the drug. Side effects (including insomnia and vivid dreams) were rare, and described as minor and transient. Baseline erythrocyte sedimentation rate predicted over 80% of the variance in drug response. Individuals with higher sedimentation rates (indicating general inflammatory processes) had the greatest reduction of symptoms in response to low-dose naltrexone.

CONCLUSIONS: We conclude that low-dose naltrexone may be an effective, highly tolerable, and inexpensive treatment for fibromyalgia. PMID: 19453963

With our state of the art compounding laboratory and pharmaceutical experience, we have the ability to compound naltrexone into capsules in a variety of strengths.

An example of how you might prescribe follows:

**COMPOUNDED MEDICATION**

**Low Dose Naltrexone 4.5mg**

Capsules

#30

Take 1 capsule HS
**CONNECTIVE TISSUE DISORDERS**

Phonophoresis represents a method to apply topical medications through the skin to treat soft tissue injuries and inflammatory conditions. The following study concluded that phonophoretic effect occurred with dexamethasone - “Phonophoresis and the absorption of dexamethasone in the presence of an occlusive dressing” (J Athl Train. 2007 Jul-Sep;42(3):349-54).

**CONTEXT:** Phonophoresis is purported to represent a method to apply topical medications through the skin to treat soft tissue injuries and inflammatory conditions. Few data are available to demonstrate the clinical effectiveness of the treatment.

**OBJECTIVE:** To determine the effect of ultrasound on the transcutaneous absorption of dexamethasone when occluded with a dressing.

**DESIGN:** Crossover design.

**SETTING:** University general clinical research center.

**PATIENTS OR OTHER PARTICIPANTS:** Ten healthy subjects (age = 29.2 +/- 8.8 years; height = 170.0 +/- 3.9 cm; mass = 67.5 +/- 18.4 kg).

**INTERVENTION(S):** Two grams of 0.33% dexamethasone cream were applied to a 10-cm (2) area on the anterior forearm. The drug was applied to the skin and occluded with a dressing for 30 minutes before the ultrasound and sham ultrasound treatments. The treatments were applied over the drug and occlusive dressing. Ultrasound treatments were delivered at an intensity of 1.0 W/cm (2) (50% pulsed) at an output frequency of 3 MHz for 5 minutes and compared with sham ultrasound treatments that were delivered at an intensity of 0.0 W/cm (2) (50% pulsed) at an output frequency of 3 MHz for 5 minutes. All subjects received both the ultrasound and sham treatments, and the order in which subjects received the treatments was counterbalanced.

**MAIN OUTCOME MEASURE(S):** Serum samples were drawn before treatment and immediately posttreatment and at 2, 4, 6, 8, and 10 hours posttreatment. Using high-performance liquid chromatography, we analyzed serum to determine dexamethasone concentrations.

**RESULTS:** A 2-way repeated-measures analysis of variance (condition x time) revealed a significant main effect for ultrasound treatment (P = .047). The rate of appearance and the total concentration of dexamethasone in the serum were greater in subjects after phonophoresis than after sham ultrasound. The sham group had only trace amounts of dexamethasone in the serum, indicating that drug absorption was negligible without the ultrasound energy. The effect size of the phonophoresis condition fell within a 95% confidence interval after the baseline measurement.

**CONCLUSIONS:** We found that a phonophoretic effect occurred with dexamethasone when its application saturated the skin. PMID: 18059989.

**We have the ability to compound dexamethasone as an ultrasound gel for use in phonophoresis.**
MUSCLE SORENESS

The following study found that transdermal ketoprofen was effective in treating delayed-onset muscle soreness, with a minimal incidence of systemic absorption and/or adverse events - “Efficacy of transdermal ketoprofen for delayed onset muscle soreness” (Clin J Sport Med. 2003 Jul;13(4):200-8).

OBJECTIVE: To determine the efficacy of transdermal ketoprofen in reducing delayed-onset muscle soreness (DOMS), limiting systemic absorption, and improving postexercise function following repetitive muscle contraction.

DESIGN: Double-blind, placebo-controlled clinical trial.

SETTING: OrthoMed, University of California at San Diego, La Jolla, CA, U.S.A.

PARTICIPANTS: Thirty-two healthy males 18 to 35 years old.

INTERVENTIONS: Subjects performed a leg extension and flexion exercise program designed to create DOMS in quadriceps muscles. Subjects were randomly assigned to receive any combination of transdermal ketoprofen or placebo cream, applied TID, to their right and left quadriceps.

MAIN OUTCOME MEASURES: Subjective measure of DOMS in quadriceps muscles, serum ketoprofen levels, strength index scores (a measure of postexercise function), and adverse reactions were assessed at baseline, 24 hours, and 48 hours.

RESULTS: Within-subjects analysis (n = 16) showed a significant reduction in DOMS scores in legs receiving transdermal ketoprofen compared with legs receiving placebo cream (P = 0.002 at 48 hours and 0.000 at 24 and 48 hours combined). Between-subjects analysis (n = 16) showed a marginally significant reduction in DOMS scores at 48 hours (P = 0.05 in right legs and 0.053 in left legs). Systemic absorption was minimal, with serum ketoprofen levels in the ng/mL range. No differences in strength index scores were observed. No adverse reactions were reported.

CONCLUSIONS: Transdermal ketoprofen appears to be effective in reducing self-reported DOMS after repetitive muscle contraction, particularly after 48 hours. Systemic absorption of the drug was minimal. Treatment did not appear to have any effect on postexercise function, and there were no reported adverse reactions. PMID: 12855921

This study found that ketoprofen treatment after muscle damaging exercise reduces muscle soreness and improves force recovery - “Effect of ketoprofen on muscle function and sEMG activity after eccentric exercise” (Med Sci Sports Exerc. 2001 May;33(5):702-10).

PURPOSE: This study examined whether ketoprofen, a nonsteroidal anti-inflammatory drug, attenuated muscle soreness (SOR), improved maximal isometric force (MIF) recovery, and/or altered myoelectric activity after high-force eccentric exercise.

METHODS: 48 subjects were randomly assigned to one of four groups: CON: no exercise/no drug (N = 12); PLA: exercise + placebo (N = 12); TRT-100: exercise + 100 mg oral ketoprofen (N = 12); and TRT-25: exercise + 25 mg oral ketoprofen (N = 12). PLA, TRT-100, and TRT-25 were administered in a double-blind fashion. Baseline measurements of SOR, MIF, and surface electromyographic (EMG) amplitude were taken, and PLA, TRT-100, and TRT-25 performed 50 maximal eccentric contractions of the elbow flexors; 36 h later, subjects reporting moderate soreness were given ketoprofen or placebo and SOR measures were taken hourly for 8 h. EMG amplitude was assessed during MIF before dosing and again 8 h later and during submaximal contractions of 5%, 10%, and 20% of MIF before dosing and hourly for 8 h.

RESULTS: Eccentric exercise increased myoelectric activity during submaximal force measurements in PLA, TRT-100, and TRT-25 in all conditions. Ketoprofen had no effect on reducing this increase in EMG activity. Ketoprofen attenuated perceived SOR (P < 0.05) and enhanced MIF recovery (P < 0.05) compared with placebo. TRT-100 and TRT-25 demonstrated 10% and 19% reductions in SOR, respectively, and 16% and 9% increases in MIF, respectively, whereas PLA demonstrated a 1% increase in SOR and 9% decrease in MIF over 8 h.

CONCLUSION: Ketoprofen treatment after muscle damaging exercise reduces muscle soreness and improves force recovery. PMID: 11323536

An example of how you might prescribe follows:

Ketoprofen 10%
Transdermal Gel
90gm
Apply sparingly TID

We have the ability to compound ketoprofen as a transdermal gel in varying strengths to meet the unique needs of each of your patients.
Fibromyalgia

[ ] Low Dose Naltrexone 4.5mg
Capsules
Quantity #30
Directions: Take 1 capsule HS

Connective Tissue Disorders

[ ] Dexamethasone 0.4%
Phonophoresis Gel
Quantity 30ml
Directions: Use as directed office

Muscle Soreness

[ ] Ketoprofen 10%
Transdermal Gel
Quantity 90gm
Directions: Apply sparingly TID

All topical compounds are per 1 ml or 1 gm unless otherwise noted.

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