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Customized Medications to Solve Podiatric Problems

Topical Therapy: High Tissue Levels and Fewer Side Effects

Oral NSAIDs (Non-Steroidal Anti-Inflammatory Drugs) can produce undesirable side effects, such as gastrointestinal irritation. Topical NSAID administration offers the advantage of local, enhanced delivery to painful sites with a reduced incidence of gastrointestinal upset or bleeding when compared to the same drugs taken orally. When properly compounded using an appropriate base, tissue concentrations of ketoprofen were found to be 100-fold greater below the application site (knee) compared to systemic concentrations.

Ankle sprains may lead to severe complications If not treated immediately and correctly. A study compared the efficacy and safety of topically applied ketoprofen versus orally administered ketoprofen in 20 patients with grade I ankle sprain and 34 patients with grade II sprain. Patients received either topically applied ketoprofen 10% spray-gel or orally administered ketoprofen tablets (3x50 mg/day) for one week. Reduction of spontaneous pain and pain on active movement in the topical spray group was significantly greater than in the oral treatment group, irrespective of sprain severity. Regarding mobility impairment and ankle swelling, topically-applied ketoprofen turned out to be significantly superior to orally administered ketoprofen. Additionally, the topical preparation was well tolerated, whereas ketoprofen tablets caused gastrointestinal side effects in some patients.1

To assess the concentration of ketoprofen after topical application in various tissues, compared to plasma levels in 60 patients undergoing surgery for Achilles or patellar tendinopathy; and to analyze whether tissues act as a reservoir of ketoprofen, Rolf et al. evaluated tissue concentrations in relation to plasma concentration. In random order, patients applied 30 mg of ketoprofen once daily for 5 consecutive days, or took a single 50 mg oral dose before surgery. Tissue samples of skin, subcutaneous fat, tendon sheath, tendon, and plasma were collected intraoperatively at 0, 6 and 14 hours after removal of the fifth ketoprofen application, and at 2, 6, and 14 hours after oral intake. High concentrations of ketoprofen were observed in fat, tendon sheath, and tendon after topical applications, whereas plasma levels of ketoprofen were low. The study concluded that ketoprofen attains high concentrations in subcutaneous tissues after multiple topical applications, and that subcutaneous tissues appear to act as a reservoir of ketoprofen.2 In a subsequent study, the researchers reported that topical applications of ketoprofen allow the attainment of high intra-articular tissue concentrations.3

Topical NSAIDs have a safety profile which is superior to oral formulations. Topical NSAID administration offers the advantage of local, enhanced delivery to painful sites with higher tissue levels beneath the site of application and a reduced incidence of systemic (such as gastrointestinal) adverse effects.4

1 Minerva Cardioangiol. 2008 Oct;56(5 Suppl):47-53.
2 J Rheumatol. 1997 Aug;24(8):1595-8.
3 Rheumatology (Oxford). 1999 Jun;38 (6):564-7
4 Advanced Studies in Medicine, Johns Hopkins University, Volume 3 (7A), July 2003

Sample Prescription

Compounded Medication

Ketoprofen 20% in Lipoderm
Sig: Apply 0.5 gm (pea-sized amount) to affected area four times daily.
Disp: 60 gm

Therapy for Onychomycosis (Fungal Nail)

A large prospective study has shown that onychomycosis (fungal nail) is among the most significant predictors of foot ulcer in patients with diabetes. As the severity of onychomycosis may be associated with the length of time the individual has had the infection, early intervention is advisable owing to the progressive nature of the fungal infection. If left untreated, thickened toenails can cause pressure and irritation, and thus act as a trigger for more severe complications.

In the treatment of onychomycosis, compliance, drug interactions and the potential for adverse events associated with antifungal therapy are important considerations. Diabetic patients frequently take concomitant medications, and therefore, topical therapy may be preferred. Most antifungal medications are not used topically and are not commercially available as topical preparations due to concerns about lack of penetration. However, we can solve this problem by dissolving the preferred antifungal agent (e.g. terbinafine HCl) in pharmaceutical grade DMSO (a penetrant enhancer). Because topical therapy results in lower systemic blood levels of medications, topical therapy reduces the potential for serious adverse events associated with oral antifungal therapy, and topically administered meds are less prone to drug-drug interactions than systemic medications.

Various synergistic combinations can be compounded to treat athlete's foot and onychomycosis. Research points to the benefit of using ibuprofen, alone or in combination with azoles, in the treatment of candidosis, particularly when applied topically, taking advantage of ibuprofen's antifungal and anti-inflammatory properties. Ibuprofen (10 mg/ml) in combination with fluconazole resulted in synergic activity for 8 of 12 Candida strains studied, including 4 of 5 fluconazole-resistant strains. The MICs of fluconazole for the fluconazole-resistant strains decreased 2 to 128-fold when ibuprofen was added.

At the Nail Disease Centre, Cannes, France, 13 patients with onychomycosis, aged 25-78 years, most with involvement of the matrix region, were treated with a solution of 1% fluconazole and 20% urea. In four patients there was complete resolution of the condition; four patients who had involvement of one nail only demonstrated a 90% improvement. Of the four patients who had presented with involvement of both big toenails, two showed 50% improvement bilaterally and in the remaining two patients there was a 90% improvement in one nail and a 50% improvement in the other.

Am J Clin Dermatol. 2009;10(4):211-20.
J Dermatolog Treat. 2005 Feb;16(1):52-5
J Cutan Med Surg. 2004 Jan-Feb;8(1):25-30.
J Cutan Med Surg. 2004 Jan-Feb;8(1):25-30.
Prescrire Int. 2009 Feb;18(99):26-30.

Sample Prescription

Compounded Medication

Fluconazole 1% and Urea 20% in ethanol and water
Sig: Apply to nail once daily at bedtime.
Disp: 60 ml

Urea Plasters for Non-Surgical Nail Removal

Urea plasters have been shown to be effective for non-surgical removal of traumatized, dystrophic, or diseased nails. Although surgical excision is the most popular method for removing nails, the use of urea plasters may be superior. Surgery has inherent disadvantages - necessity for anesthesia, risk of infection, and significant postoperative pain. In contrast, the use of urea plasters can be much less costly, several nails can be treated in one session, and the procedure is essentially painless. Because there is no risk of infection or hemorrhage, the procedure is ideal for treating diabetics and others with vascular insufficiency and peripheral neuropathy. Urea is non-toxic and non-allergenic, and may also possess antibacterial, antifungal, and antipruritic properties.

At a meeting of the American Academy of Dermatologists, two Stanford University dermatologists reported the use of urea compounds to remove toenails and fingernails from many patients whose problems included onychomycosis, psoriasis, bacterial infection, traumatic injuries, and structural nail dystrophies. Urea's action in these cases probably results from its ability to denature protein and its hydrating and keratolytic properties, allowing easy removal of the diseased portion of the nail. Cloth adhesive tape was used to cover the normal skin surrounding the affected nail plate after pretreatment with tincture of benzoin. Next, the urea compound was applied to the affected nail surface and covered with an occlusive dressing. Most diseased nails could be removed in 5 to 10 days. The only adverse effects were mild irritation, slight pinpoint bleeding, and tape contact dermatitis.

Sample Prescription

Compounded Medication

Urea 40%
Sig: Apply to affected nail once daily at bedtime and cover with an occlusive dressing.
Disp: 30 gm