GENSCO LABORATORIES®

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Got Pain?™

by Robert Wilbur, PharmD, CPh

...Millions Suffer from Acute or Chronic Pain

every year and it is the leading reason for those seeking medical care. Mild to moderate musculoskeletal injuries – Sprains, strains, contusions, repetitive use, and minor trauma – are the most common acute causes of pain. Therapeutic options are typically limited to over-the-counter medications, such as non-steroidal anti-inflammatory medications, also known as NSAID), counter irritants and prescription strength drugs such as higher dose NSAIDs and, to a lesser extent, muscle relaxants and opioids.

Non-steroidal anti-inflammatory drugs (NSAID) medications are the most widely used treatment for pain and inflammation in the US. It is estimated that every day, more than 30 million Americans use NSAIDs for pain from headaches, arthritis, and other conditions. These drugs work by interrupting the inflammatory cascade and prostaglandin synthesis resulting in decreased pain and tissue inflammation. However, as effective as these drugs are, they are associated with many drug interactions and adverse effects. In 2005, the FDA put a Black Box warning on all NSAIDs discussing cardiovascular and gastro-intestinal risks.

A meta-analysis, published in May 2013 in The Lancet, included more than 600 clinical trials that evaluated about 353,000 patients. Researchers wanted to provide more reliable estimates of the effect that NSAIDs have on vascular and coronary events such as heart attacks, strokes, and death as well as on gastrointestinal complications including perforations, obstructions, or bleeding.

All of the NSAIDs studied, including naproxen, roughly doubled the risk of being hospitalized because of congestive heart failure. All NSAIDs were linked with a 2- to 4-fold increased risk of gastrointestinal complications, primarily bleeding. The lowest risk was associated with using COX2 Inhibitors. The high incidence of GI bleeding resulted in the addition of gastro-protective medications, such as omeprazole, to many NSAID treatment regimens. This common strategy increases both the cost of treatment and the potential for further drug interactions and adverse effects associated with the added medication.

The overall results mean that, compared with placebo, about 3 excess major vascular events, including 1 death, could be expected annually per 1000 patients taking high-dose diclofenac or a COX2 Inhibitor. But for every 1000 patients at high risk of major vascular events, taking a COX2 Inhibitor or high-dose diclofenac would result in an additional 7 or 8 of those events occurring, about 2 that would be fatal.

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Gensco Laboratories Releases a Research Report on the Safety and Efficacy of SpeedGel Rx®

A Randomized, Double-Blind, Clinical Study to Evaluate the Safety and Efficacy of SpeedGel Rx® in the Symptomatic Treatment of Osteoarthritis in the Interphalangeal Joints

Background

This study evaluated the efficacy of SpeedGel Rx® for the treatment of Osteoarthritis of the Interphalangeal joints. In a two-week, randomized, double-blind, placebo-controlled, parallel-group trial, SpeedGel Rx® was administered at a dose of four times daily on the treatment hand. Pain was assessed using a 10-point visual analog scale. The reliability of the scale has been demonstrated in multiple studies.

Findings:

1. By day two pain was lower in the treatment group than the control group.
2. By day five pain was over 10% lower in the treatment group.
3. Overall a 60% reduction in pain was found between the treatment group from baseline.
4. No subject in the treatment group reported a side effect.
5. A majority of subjects in the treatment group were taking some type of blood thinner.

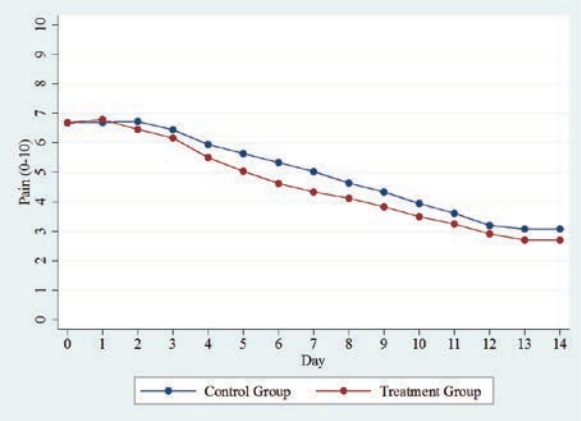

Figure 1. Time Plot of Pain Reduction by Treatment Method

Accelerated Resolution of Laser-Induced Bruising with SpeedGel Rx®

A Rater-Blinded Randomized Controlled Trial

Gensco Laboratories, a leading manufacturer of transdermal medications, demonstrates in a randomized controlled trial that SpeedGel Rx® possesses superior results compared to a placebo in the treatment of bruises with no adverse systemic effects.

Trauma sufficient to cause bruising can occur from a wide variety of situations including accidents, falls, and surgeries. To the extent that bruises can occur on the face or exposed areas, and take days or weeks to resolve, they can be a problematic form of temporary disfigurement. Oral analgesics are commonly prescribed to treat bruising, but these agents often produce adverse systemic effects, which can be severe. Additionally, agents with the coagulative properties required to mitigate bruising may potentially induce undesirable systemic coagulative effects.

SpeedGel Rx® is a prescription homeopathic topically applied transdermal analgesic gel that provides an effective treatment for treating bruises. Non-steroidal topical agents, such as SpeedGel Rx®, offer the potential to provide the same relief provided by oral analgesics but with minimal adverse systemic effects. Gensco Labs designed a randomized, double-blind, placebo-controlled trial to compare the efficacy of SpeedGel Rx® to a placebo in the prevention and resolution of laser induced bruising.

The study's primary aims were: (1) to determine the effectiveness of SpeedGel Rx® in the reduction of pain in laser induced bruising over time, (2) to determine the effectiveness of SpeedGel Rx® in the change of appearance of the bruise over time, and (3) to determine the effectiveness of SpeedGel Rx® in the reduction of pigmented lesions that are monitored via a VISIA™ complexion analysis tool over time.

Results demonstrate that SpeedGel Rx® reduced pain more quickly than placebo. On day two subjects were 6% more likely to experience pain using the placebo gel than SpeedGel Rx®. This increased to 15% at day four. SpeedGel Rx® also improved the appearance of the bruise more quickly than placebo. Subjects indicated a 10% quicker resolution in the color and appearance of the bruise using SpeedGel Rx®.

This research indicates that SpeedGel Rx® is more effective than placebo in reducing the pain and negative appearance associated with bruising. The measurement of specific components of bruising, such as severity and burden of pain are often difficult to combine in a consistent way into the broader aspects of overall quality of life. Given that the goal of medical therapy for bruising focuses on improving aspects of a patient's life, the patient-reported outcomes reported here are important and accepted endpoints in clinical research trials. As such, health care professionals now have SpeedGel Rx® as a viable alternative to oral analgesics in the treatment of bruises.

"Prospective Project to Determine the Efficacy of Prescription SpeedGel Rx® in Decreasing Post-Operative Surgical Site Pain and Narcotic use"

James R. Andrews M.D., Filippo Chillemi M.D., Mary Jane Robinson

The prospective project utilizing SpeedGel Rx®, a prescription homeopathic topical analgesic gel, in decreasing post-operative surgical site and overall narcotic use is nearing completion. We are nearing our goal of obtaining 20 patients, who had shoulder or knee procedures (10 each), with an adequate amount of data to utilize for comparison and analysis. Currently we have completed 9 shoulder and 4 knee patients, and are actively in the process of following another 3 shoulder and 4 knee patients.

Subjectively, all patients have had positive remarks concerning SpeedGel Rx® with all stating that it was beneficial in both decreasing post-operative pain and narcotic use.

Objectively, positive results have also been noted. The majority of patients, (9/13) had not used SpeedGel Rx® on POD4, however by 1 week post-op, 92% compliance was achieved (12/13). Pain scores were obtained on post-op day 4, post-op weeks 1-4, and post-op week 6. The average pain scores were 3.60, 2.58, 1.89, 0.88, 1.13, and 0.83, respectively. Utilizing a Mosby Pain Scale, on post-op day 4, patients experienced Moderate pain, on post-op weeks 1-2, they experienced Mild pain, and on post-op week 3, the average pain score fell between None to Mild. This data shows a positive trend towards no pain by post-op week 3, with the most common score given being 0 on that week. The small increase in pain score on post-op week 4 (1.13) can be explained by the decreased variation in scores with two patients being unavailable at the time the evaluation phone call was performed and one patient having actually stopped using the product by that time.

Also, positive trends were visualized in narcotic use. Overall, only 2 out of 13 patients required a refill of the original 40 pill narcotic prescription, and 1 individual actually didn't even require narcotics during the 6 week post-operative period. There was also a decreasing trend in the weekly use of narcotics. From the day of surgery to post-op week 1, an average of 15 pills were used, from week 1 to week 2, 5 additional pills were used on average, and from week 2 to week 3, on average only 1 additional pill was used. This showed that peak narcotic use took place in the initial 7 days post-op, and reached a plateau around week 2 to week 3, with individuals still having half of their original prescription intact.

This project will continue over the next several months, as the final data will be gathered.

Upon completion, a final comparison of the data will be performed and analyzed.

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Millions Suffer...

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A meta-analysis published in the British Medical Journal in January 2011 noted NSAIDs have been linked to about 30% of drug-related hospital admissions, and it estimated that 12,000-16,000 Americans die annually as a result of gastrointestinal bleeding caused by NSAIDs.

Other than NSAIDs, counter irritants are the mainstay of over the counter (OTC) treatment of muscle injury and pain. Counter irritants, including preparations containing camphor, mint oil, capsaicin, or menthol, cause irritation or mild inflammation of the skin at the site of application producing a temporary paradoxical pain-relieving effect that masks pain in muscles, joints and other tissues distal to the site of application. These compounds do not treat the underlying muscle injury and inflammation. Potential adverse effects include local skin reactions, such as redness, rash, burning and stinging. Serious injuries such as first- to third-degree chemical burns associated with products containing menthol, methyl salicylate and capsaicin have been reported frequently enough for the FDA to issue a drug safety communication to consumers and healthcare professionals.

What is needed is a safer and effective alternative for initial treatment of mild to moderate musculoskeletal injuries. A recently introduced product may be a candidate for the job.

Gensco Laboratories, a specialty pharmaceutical company specializing in novel topical medications, has added SpeedGel Rx to the list of prescription alternatives for both patients and retail pharmacies. This prescription product is a combination of several natural ingredients in a patented transdermal base. Gensco states that this medication will reduce inflammation, bruising, and associated pain. Company supplied study data supports this assertion but more importantly, patients have consistently reported positive outcomes. The company reports that larger trials are underway evaluating SpeedGel Rx efficacy in more chronic conditions, such as osteoarthritis. Since this product is topical, it can be applied directly to the site of injury for local effects and because it does not contain NSAIDs, aspirin, or APAP there is a much lessened incidence of adverse drug effects. These features along with the positive patient experiences, makes SpeedGel Rx a suitable consideration as a first step in the treatment of musculoskeletal pain especially in those patient populations at risk for ADRs from NSAIDs as well the comorbidities associated with anti-coagulation drugs and GI distress.

Originally published in the August 11, 2014 issue of *Chain Drug Review*.

ePrescribe Information

Product Name	Form/Strength	Size	Dosage Form	NDC
SpeedGel Rx®	0.25mL (per pump)	10mL (40 Doses)	Transdermal Gel	NDC 35781-0210-1
SpeedGel Rx®	0.25mL (per pump)	30mL (120 Doses)	Transdermal Gel	NDC 35781-0210-2
LiDORx®	7.5mg/0.25mL (per pump)	10mL (40 Doses)	Transdermal Gel	NDC 35781-0300-1
LiDORx®	7.5mg/0.25mL (per pump)	30mL (120 Doses)	Transdermal Gel	NDC 35781-0300-3

SPEEDGELRx® TOPICAL ANTI-INFLAMMATORY/ANALGESIC

Indications: Pain, Inflammation, and Bruising

Active Ingredients: Aconitum Napellus 3X, **Arnica Montana 1X, Belladonna 3X,** Bellis Perennis 1X, Calendula Officinalis 1X, Chamomilla 1X, **Colchicinum Autumnale 3X,** Echinacea Angustifolia 1X, Echinacea Purpurea 1X, Hamamelis Virginiana 1X, **Hypericum Perforatum 1X,** Millefolium 1X, Symphytum Officinale 3X, Zingiber Officinale 1X

Inactive Ingredients: Docusate Sodium, Ethyl Alcohol, Isopropyl Myristate, Lecithin, Purified Water, Urea

SpeedGelRx.com

LiDORx® FAST PAIN RELIEF

Indications: Pain

Active Ingredients: Lidocaine Hydrochloride 3%

Inactive Ingredients: Deionized Water, Caromer, Isopropyl Alcohol, Petrolatum, Polysorbate-20, Triethanolamine

LiDORx.com

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