Use of Topical Salicylate (10%) Delivered Via Liposomes to Treat Chronic Pain

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Citation

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Abstract

Three patients with diverse conditions causing chronic pain obtained good relief with use of a liposome delivery system containing trolamine salicylate (10%), as described in the following Case Reports.

INTRODUCTION

A liposome delivery system containing trolamine salicylate (10%) (ALCiS® Daily Relief - pain relief cream₁) has been developed for temporary relief of muscular and joint aches and pains associated with overexertion, strains, sprains and muscle tension, as well as relief from simple backache and arthritis pain. The over-the-counter topical formulation may be applied 3 – 4 times daily and provides for deep penetration of the active ingredient. The following case studies describe successful use of the formulation in treatment of patients with various chronic pain syndromes.

CASE REPORTS A. CHRONIC KNEE PAIN

A 59 year old Caucasian man presented at the Pain Clinic with a 12-month history of chronic left medial knee pain, although he reported no recent trauma or antecedent event that might be the cause of the pain. The patient had a partial tear of the anterior cruciate ligament (ACL) 10 years previously which was treated with open repair followed by an uneventful recovery that included physical therapy and rehabilitation. He resumed normal activity, including playing tennis, without pain until one year prior to his referral to the Pain Clinic.

The patient was first seen by an orthopedist who gave a diagnosis of "probable scar neuroma". An MRI showed normal results with the ACL intact and no significant degenerative joint disorder (DJD). The patient was then referred to a neurologist who was in agreement with the diagnosis of "probable neuroma", and sent him to the Pain Clinic for possible nerve block and phenol injection if

necessary. Prior medical history at the time of his visit to the Pain Clinic included elevated cholesterol. Prior surgical history included left knee surgery to repair the ACL, tonsillectomy and adenoidectomy, and vasectomy. The patient had no known medical allergies, and was currently taking Lipitor 20mg/day, and ASA 81mg/day. He was a nonsmoker and consumed 1- 2 ounces per week of alcohol. While he was normally an avid tennis player, he was unable to play for the previous 6 months due to the knee pain he experienced.

Examination at the Pain Clinic showed normal results except for positive Tinel's sign over the scar tissue on the medial aspect of the left knee overlying the femoral condyle. There was no swelling, redness or edema of the knee. We suggested topical therapy as the first approach to treatment, and gave the patient trolamine salicylate (10%) cream (ALCiS® Daily Relief - pain relief cream) to be applied to the area twice daily. At a return visit one week later, the patient reported he was able to play tennis twice and had no pain. At 6 months follow-up the patient is still using ALCiS episodically (3-5x/week, usually once per day) and experiences pain relief within 30 minutes. At this time, he is not seeking any other treatment.

B. CHRONIC LOW BACK PAIN

A 46year old Caucasian woman who was head of nursing at a local community hospital came into the Pain Clinic with a 1 year history of low back pain with right lumbar radiculopathy. She was diagnosed with discrete right L5-S1 herniated nucleus pulposus. She was an otherwise healthy individual who had a bilateral tubal ligation, but no other pertinent medical or surgical history and no known allergies

to medication. The patient has had no neurological symptoms. She was initially sent for physical therapy, massage, and acupuncture. Treatment with oral NSAIDs and a one week course of oral steroids provided no noticeable change in pain. In April 2007, we performed ®L5-S1 ESI, which resulted in complete relief of radicular pain within 3 days.

She re-injured herself in early September 2007 and experienced recurrence of low back pain. She chose to delay repeat ESI, and did not want to use oral medications due to her concern of having adverse events. We suggested topical therapy as an alternative approach to treatment, and gave the patient trolamine salicylate (10%) cream (ALCiS Daily Relief - pain relief cream) to be applied to the painful area of her low back. She reported obtaining 90% relief of the back pain without any adverse effects, and, importantly, was able to sleep at night.

In addition, the leg symptoms she previously reported have lessened with time and she is able to do Pilates. She has chosen to watch and wait and is seeking no other treatment at this time.

C. FIBROMYALGIA, OSTEOARTHRITIS AND CERVICAL DYSTONIA

A 56 year old Caucasian woman came to the Pain Clinic reporting a history of cervical dystonia, fibromyalgia, and osteoarthritis for more than 5 years. Additional medical history included IBS and hypertension which resolved following discontinuation of NSAIDs. The patient has 2 C-sections (1972 and 1975) and a cholecystectomy in 1985.

She reported allergies to pollen and to penicillin. She had been receiving cervical botulinum toxin injections (Botox) every 4-6 months for her neck symptoms which provided good relief. Other medications for pain management included methadone at a stable dose of 5mg three times daily for 4 years, tramadol HCL at a stable dose of 50mg once or twice daily as needed for 4 years, and pregablin (Lyrica) 150mg nightly for 18 months. She had been also been using both OTC and prescription NSAIDs (Ibuprofen 200-1600mg/day; Celecoxib 200mg/day) on an ongoing basis for years.

In May 2006, we suggested topical therapy as an additional treatment for pain, and gave the patient trolamine salicylate (10%) cream (ALCiS Daily Relief - pain relief cream) to be applied to painful areas of the hip, shoulder, and knee 2-3 times daily. The patient reported a decrease of 80-90% in pain in these joints, and uses no NSAID's. She continues to report neck symptoms and trunk/axial fibromyalgia trigger points.

CONCLUSION

The case reports detailed here indicate that topical therapy with trolamine salicylate (10%) cream (ALCiS Daily Relief pain relief cream) provides a substantial benefit to patients suffering with various chronic pain syndromes. The topical treatment has been well-tolerated and offers an alternative or add-on to systemic therapy.

References

1. ALCiS® Daily Relief - pain relief cream Product Label: Active Ingredient: Trolamine Salicylate 10%; Purpose: Topical Analgesic

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