

Pain Journal Update

Prolotherapy finally getting its due respect?

As a recent editorial on prolotherapy published in *The Spine Journal* summarized "This fringe treatment is no longer at the periphery and seems to be at the frontier of a justifiable, rational treatment with a significant potential to avoid destructive procedures."¹ The mere fact that this editorial appeared in *The Spine Journal*; which is the official journal of the conservatively minded International Spinal Injection Society, attests to the changing atmosphere surrounding prolotherapy, also known as scler-

otherapy or regenerative injection therapy (RIT). An ever growing number of studies, including a handful of high quality double blinded randomized controlled trials, have supported the efficacy of this relatively safe, minimally invasive, regenerative therapy for treating knee pain and dysfunction, spine pain of various etiologies, and thumb and finger osteoarthritic pain, to name a few. Considering the problems that often arise when these pain problems are treated surgically, or even pharmacologically

(NSAIDs, especially in the elderly comorbid population, are responsible for a disturbingly high number of GI bleeds and deaths every year.) it behooves us to consider a therapy that has existed at least since the days of Hippocrates and boasts a very low adverse effects profile.

1. Mooney V. Prolotherapy at the fringe of medical care, or is it the frontier? *The Spine Journal* 2003; 3: 253-254.

Prolotherapy with Dextrose Improves Knee Pain and Function.

A recent study by Reeves and Hassanein¹ prospectively evaluated sixteen patients with knee pain and anterior cruciate ligament (ACL) laxity treated with dextrose prolotherapy. All included patients had greater than six months of knee pain and greater than 2mm of ACL laxity. They were treated with intra-articular injections of 10% dextrose solutions at 0, 2, 4, 6 and 10 months. At 12 months they were treated with a 25% solution. Following this injection the patients then had the option of choosing 10% or 25% dextrose solutions at 2 to 4 month intervals through 36 months. At 36 months, 10 of the 16 knees showed no ACL laxity, with nine of these knees having no laxity at 1 year. Knee flexion was significantly improved at one and three year follow-up, with the average increase being 10.5 degrees. Pain with walking and stair use were also significantly improved at both one and three year follow-up. The majority of patients

chose the 10% dextrose injections over the 25%. A precedent study by the same authors looked at dextrose prolotherapy for knee osteoarthritis with or without ACL laxity.² In a randomized, double-blind, placebo controlled trial they assessed response to either 10% prolotherapy or placebo injections in a total of 38 knees. Patients with six months or more of pain plus radiographic evidence of at least grade 2 joint narrowing or osteophytic changes were included. Patients received three bimonthly injections of either 10% dextrose plus .075% lidocaine in bacteriostatic water or the same solutions sans dextrose. The dextrose-treated patients were then given 3 further bi-monthly injections (ie. at 6, 8 and 10 months) in an open label fashion. At twelve month follow-up the dextrose treated knees enjoyed a 40% improvement in pain scores (VAS), 63% improve-

ment in swelling, knee buckling frequency diminished by 855, and knee flexion range improved by 14 degrees. Furthermore, radiologists blinded to the timing of the x-rays, evaluated 13 films of knees taken before treatment and following active treatment. While most variables remained stable there was a significant increase in lateral patello-femoral cartilage thickness (P=.019) and a decrease in femur width including osteophytes (P=.02). Of the thirteen dextrose treated knees with ACL laxity, eight were no longer lax at one year.

1. Reeves D, Hassanein K. Long Term Effects of Dextrose Prolotherapy for Anterior Cruciate Ligament Laxity. *Alternative Therapies* 2003; 9 (3): 58-62.

2. Reeves D, Hassanein K. Randomized Prospective Double-Blind Placebo-Controlled Study of Dextrose Prolotherapy for Knee Osteoarthritis with or without ACL Laxity. *Alternative Therapies* 2000; 6(2): 68-80.

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Dedicated to research, education and advocacy for persons with chronic spinal injuries.

Lumbo-pelvic ligament injections with either glucose or normal saline improve nonspecific chronic low back pain.

A recent randomized controlled, triple blinded trial assessed the efficacy of prolotherapy verses control injections into tender lumbosacral ligaments in patients with chronic lumbar pain.¹ One hundred and ten patients with an average 14 year duration of axial low back pain were randomized to receive injections of either 20% glucose plus 0.2% lidocaine or a control solution consisting only of normal saline into tender ligaments. A total of 6 injections at 2 week intervals were performed initially. These injections were repeated again at 4 and 6 month evaluation if a partial but incomplete response had been obtained. The average number of injections performed was 7.1. Follow-up at 12 months (106 patients) found that 46% of patients in

the prolotherapy group had achieved a greater than 50% reduction in pain (on the 100mm VAS) compared to 36% in the control group. In terms of disability as assessed by the 23 item Roland Morris assessment, 42% of the prolotherapy patients versus 36% in the saline group had achieved greater than 50% improvement. Overall, at 12 months, 76% and 68% of patients respectively rated their pain and disability as improved compared to when they entered the study. These improvements were maintained at 2 year follow-up (88 patients). The difference in response between the glucose and saline groups was not statistically significant. It is interesting to note however that at 4 months follow-up 47% of the glucose-lidocaine patients but only 28% of the saline group had achieved greater than 50% disability reduction.

Furthermore, there is a trend, albeit not statistically significant, toward better outcomes in the glucose/lidocaine group at one and two years.

Equally intriguing is this study's finding that lumbar stabilization exercises played no role in outcomes. Patients were simultaneously randomized to either an exercise group or a normal activity group. At twelve and twenty four months follow-up, the exercise group showed no trend toward better outcomes either in terms of pain or disability.

1. Yelland M, Glasziou P, Bogduk N, et al. Prolotherapy Injections, Saline Injections, and Exercises for Chronic Low-Back Pain: A Randomized Trial. *Spine* 2003; 29(1): 9-16.