Complementary Therapies in Medicine 37 (2018) 64–68

Contents lists available at ScienceDirect

Complementary Therapies in Medicine

journal homepage: www.elsevier.com/locate/ctim

Functional outcome from sacroiliac joint prolotherapy in patients with sacroiliac joint instability

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ARTICLE INFO

Keywords:
Dextrose
Joint instability
Low back pain
Sacroiliac joint

ABSTRACT

Objectives: Examine the effectiveness of sacroiliac (SI) joint prolotherapy for SI joint instability, and characterize the patients most likely to benefit from this treatment.
Design: Retrospective cohort study.
Setting: Department of Veterans Affairs outpatient physical medicine clinic.
Interventions: Patients referred for low back pain and diagnosed with SI joint instability received a series of three SI joint prolotherapy injections (15% dextrose in lidocaine) at approximately a one-month interval. The outcome of those completing treatment was retrospectively examined, and characteristics were compared between those with at least a minimum clinically important improvement and those without improvement.
Main outcome measures: Patients completed the Oswestry Disability Index (ODI) before treatment was initiated, immediately preceding each prolotherapy injection, and at 3–4 month follow-up.
Results: Of 103 treated patients returning for post-treatment follow-up at a median of 117 days, 24 (23%) showed a minimum clinically important improvement despite a median of 2 years with low back pain and a mean (± SD) pre-intervention ODI of 54 ± 15 points. Much of the improvement was evident after the initial prolotherapy injection, and a 15-point improvement in ODI prior to the second prolotherapy injection had a sensitivity of 92% and specificity of 80% for determining which patients would improve.
Conclusions: A satisfactory proportion of patients with symptomatic SI joint instability as an etiology of low back pain can have clinically meaningful functional gains with prolotherapy treatment. The patients who are not likely to improve with prolotherapy are generally evident by lack of improvement following the initial prolotherapy injection.

1. Introduction

Chronic low back pain has considerable economic, social and individual health consequences. While various underlying etiologies are known to exist, the sacroiliac (SI) joint is now recognized as a primary source of low back pain in up to 15% of the population.[1] The pathophysiology of pain related to the SI joint is often thought to be due to mechanical dysfunction, although this has not gone without question.[2] Nonetheless, recent treatment trials directed at increasing SI joint stability with prolotherapy have suggested this might be an effective treatment for this condition.[3,4]

Prolotherapy has been used for approximately 100 years, but its modern applications can be traced to Hackett[5] in the 1950s who coined the term from the word “proles”, which means “growth” or “offspring” in Latin under the premise that it induces increased growth of connective tissue from a local inflammatory response setting off the wound healing cascade. It has subsequently been recognized that the tissue response from prolotherapy may also be evoked through stimulating the release of various tissue growth factors,[6,7] Recent animal studies have demonstrated increased cross-sectional area of connective tissue,[8–11] and increased load to rupture and increased tissue strength[9—11] after 10–20% dextrose injections. Furthermore, biopsies of the posterior sacroiliac ligaments of human subjects before and 3 months after prolotherapy with a solution of 1.25% phenol, 12.5% glucose and 12.5% glycerine in lidocaine showed increased collagen and size of the collagen fibers.[12]

A recent review of the use of prolotherapy in chronic low back pain[13] concluded that there is conflicting evidence regarding its efficacy but noted that the conclusions were confounded by clinical heterogeneity. We are aware of only two clinical trials focusing on the

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https://doi.org/10.1016/j.ctim.2018.01.014
Received 8 November 2017; Received in revised form 24 January 2018; Accepted 24 January 2018
Available online 08 February 2018
0965-2299/ Published by Elsevier Ltd.

effectiveness of prolotherapy specifically for SI joint pain. Cusi and coworkers[3] reported on prolotherapy treatment (18% dextrose, 3 injections at 6 week intervals) of 25 patients who were clinically diagnosed with SI joint pain that had been unresponsive to an exercise program. Each continued to receive physical therapy during treatment. Favorable clinical outcomes, based upon functional questionnaires, were reported. In another clinical trial, Kim and colleagues[4] randomized 48 patients with SI joint pain, confirmed by diagnostic block, to prolotherapy (25% dextrose, 2–3 injections at 2 week intervals) or corticosteroid injections (1–2 injections at 2 week intervals). The prolotherapy group demonstrated significantly better outcomes than the steroid group in terms of incidence of ≥50% reduction in pain rating at 6 and 15 months post-treatment.

Thus, the limited research supporting prolotherapy for SI joint instability provides rational for further exploration of this treatment approach. The present work examines the outcome from a large cohort of patients in order to provide additional insight into the potential effectiveness of the treatment and to characterize the patients who are most likely to benefit from the treatment.

2. Methods

The present work is a retrospective cohort study of patients treated with SI joint prolotherapy for SI joint instability by the first author between December 2010 and April 2017. Patients were United States Veterans who had been referred to an outpatient physical medicine clinic for low back symptoms. Data were collected retrospectively by chart review on all patients receiving SI joint prolotherapy during this time period. The research was approved by the VA Northern California Health Care System Institutional Review Board with waiver of consent.

The possibility of SI joint instability was considered in patients with pain symptoms involving the low back and buttock and emanating from an area immediately inferomedial to the posterior superior iliac spine,[14] with or without referred pain into the hip, groin and leg. The supporting examination used a modification of the diagnostic algorithm of Laslett and colleagues[15] with focus on local tenderness over the involved SI joint and lack of SI joint motion with the standing SI mobility (Gillet) test.[16,17] In one small study, pain originating from immediately inferomedial to the posterior superior iliac spine was found to have 100% sensitivity and specificity in identifying patients with SI joint dysfunction.[14] The standing SI mobility test has been shown to have 93% specificity for identifying SI joint hypomobility[18] and has a small false positive rate of 13–16% in populations without low back pain[16,17,19] SI joint arthritis was ruled out with radiological examination when it was a consideration.

When the diagnosis of SI joint instability was uncertain, patients underwent a fluoroscopically-guided diagnostic injection with lidocaine and triamcinolone acetonide, or the initial prolotherapy injection was considered to serve a dual treatment and diagnostic purpose. In general, only those with at least transient reduction in symptoms after an injection continued the prolotherapy injection series. Prolotherapy injections were largely performed with fluoroscopic guidance in the early stages of the analysis period, but as fluoroscopy access became increasingly challenging, most of the prolotherapy injections were performed in the clinic without guidance from any imaging technique. The treating physician had previously verified his successful needle placement with his imaging-free injection technique.

The fluoroscopically-guided injections were performed with the patient in the prone position and pelvis on a pillow. The lower portion of the anterior and posterior SI joint lines were aligned with a contralateral oblique fluoroscopy angle.[20] From the skin location within this plane and overlying the lower third of the joint line, a 22G 90 mm spinal needle was directed to the lower third of the joint using aseptic technique after locally anesthetizing the area. Position in the SI joint was verified by medial and lateral deflection of the needle hub and observation of a characteristic bend of the needle while the tip remained stationary (Fig. 1). For the imaging-free technique, the needle was inserted approximately 3 cm caudal and one-third of the distance towards the midline from the posterior superior iliac spine. The needle was inserted obliquely and the tip was then walked medially or laterally if necessary until it could be felt passing through dense ligamentous tissue and slipping into the joint.

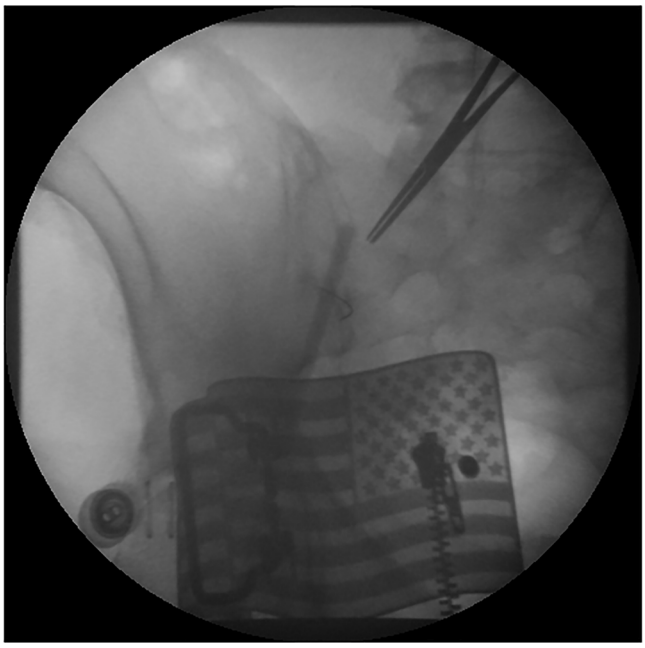

Fig. 1. Fluoroscopic view showing alignment of the anterior and posterior joint lines of the lower portion of the left SI joint and characteristic bend of the needle positioned in the joint during lateral deflection with an aluminum rod. The patient's belt buckle and pants and a hemostat, which had been used as a pointer, were inadvertently not removed from the field.

Prolotherapy treatment involved a series of three injections at approximately one month intervals. Post-treatment follow-up was requested at 3–4 months following the third prolotherapy injection. Prolotherapy injections used a mixture of 7 ml of 1% lidocaine and 3 ml of 50% dextrose (15% dextrose solution), with the solution being injected directly into the involved SI joint. Patients were requested to stop non-steroidal anti-inflammatory drugs for a day before and for a few days after each injection.

The Oswestry Disability Index (ODI)[21] was used as the outcome measure, and was completed by patients at each clinic visit and prior to diagnostic and prolotherapy injections. For data analysis, the "pre-intervention" ODI was defined as the average of the ODI at the initial clinic visit and prior to the initial prolotherapy injection, if these were separate visits, or the average of the ODI at the initial clinic visit and prior to a diagnostic injection if performed. Based on prior work of others,[22–25] a minimum clinically important improvement for the ODI of 15 points was selected. Patients with a reduction in ODI of 15 points or more were considered to have improved, and those with no change or an increase in the ODI were considered to have not improved.

Characteristics of the group that improved and the group that did not improve were compared. Continuous data were analyzed with the unpaired *t*-test when the data passed the D'Agostino-Pearson normality test and the Mann Whitney test when the data were determined to be skewed. Categorical data were analyzed with the Fisher's exact test. ODI data across time were examined with one-way repeated-measures ANOVA and Tukey posttests when following a normal distribution and the Friedman test when skewed. A paired *t*-test was used to compare ODI scores for those who completed the ODI twice before receiving a diagnostic or prolotherapy injection. Statistical significance was set at $P < .05$.