



ELSEVIER

The Spine Journal 5 (2005) 310–328

THE
SPINE
JOURNAL

Review Article

Intraligamentous injection of sclerosing solutions (prolotherapy) for spinal pain: a critical review of the literature

Simon Dagenais, DC, PhD^{a,b,*}, Scott Haldeman, DC, MD, PhD^{c,d,e}, James R. Wooley, DC^b

^aDepartment of Environmental Health, Science, and Policy, University of California, Irvine, CA 92697, USA

^bCAM Research Institute, 2102 Business Center Drive, Irvine, CA 92612, USA

^cDepartment of Neurology, University of California, Irvine, CA 92697, USA

^dDepartment of Epidemiology, School of Public Health, University of California, Los Angeles, CA 90095, USA

^eResearch Division, Southern California University of Health Sciences, 16200 E. Amber Valley Dr., Whittier, CA 90604, USA

Received 3 March 2004; accepted 28 September 2004

Abstract

BACKGROUND CONTEXT: The injection of various solutions aimed at producing a sclerosing effect has been used to treat soft tissues injuries (eg, inguinal hernia) for more than 100 years. In the 1930s, this treatment approach was applied to injured joints in an attempt to stimulate connective tissue repair. Although several studies have been published about this method of treatment for various orthopedic and spinal indications (termed prolotherapy), its use remains controversial.

PURPOSE: To conduct a critical review of the literature on prolotherapy for spinal pain.

STUDY DESIGN/SETTING: Critical review of the literature.

METHODS: Computerized medical literature databases (Medline, CINAHL, Mantis, Cochrane Central Register of Controlled Trials) were searched to uncover all published information about the use of sclerosing injections in humans with spinal pain disorders. Search results were reviewed for relevance, and information was abstracted from full-text articles.

RESULTS: Our search uncovered almost 200 reference materials in various media related to prolotherapy, including 31 clinical studies related to spinal pain. There were 26 observational cohorts and 5 randomized clinical trials (RCTs). Indications in these studies were low back pain (22), neck pain (3), cervical headaches (3) and dorsal or thoracic pain (3). A total of 20 sclerosing solutions were used in these studies; the most common was a mixture of dextrose 12.5%, glycerin 12.5%, phenol 1.25% and lidocaine 0.25%. Wide variations were found in treatment protocols, such as dose, number of treatments and use of adjunct therapies. Most cohort studies were only of moderate quality and varied greatly in the substances injected and the use of co-interventions. Most clinical studies reported positive results such as decreased pain or disability, although differences between treatment and control groups did not always reach statistical significance. Commonly reported adverse reactions to this treatment include temporary postinjection pain and stiffness. A handful of more serious adverse events were reported in the 1950s and 1960s with stronger or unknown solutions.

CONCLUSION: Prolotherapy describes a variety of treatment approaches rather than a specific protocol. Results from clinical studies published to date indicate that it may be effective at reducing spinal pain. Great variation was found in the injection and treatment protocols used in these studies that preclude definite conclusions. Future research should focus on those solutions and protocols that are most commonly used in clinical practice and have been used in trials reporting effectiveness to help determine which patients, if any, are most likely to benefit from this treatment. © 2005 Elsevier Inc. All rights reserved.

Keywords:

Prolotherapy; Sclerotherapy; Injections; Back pain; Neck pain; Headache

FDA device/drug status: regulatory status is discussed in this manuscript.

Nothing of value received from a commercial entity related to this manuscript.

* Corresponding author. 2102 Business Center Drive, Suite 130, Irvine, CA 92612, USA. Tel.: (949) 253-4178; fax: (949) 266-8951.

E-mail address: Simon@CamResearch.com (S. Dagenais)

Introduction

The treatment options for patients with spinal pain and for physicians attempting to help them are extremely numerous and diverse. Unfortunately, no single approach has developed a sufficient body of research that demonstrates clinical benefit to stand out as the treatment of choice. Patients with spinal pain are commonly unsatisfied with treatments they have received by mainstream physicians, especially after having tried multiple approaches without success. Under these circumstances patients with back and neck pain are increasingly turning to practitioners who offer so-called complementary and alternative medicine (CAM) for symptomatic relief. A recent survey of US adults with back or neck pain reported that 54% had used complementary therapies to treat their condition in the previous 12 months; chiropractic, massage and relaxation techniques were the most commonly used forms of CAM [1]. Although recognition of many CAM therapies by mainstream practitioners (ie, spinal manipulation) is growing, other CAM therapies remain largely unknown despite extensive and prolonged use. One such treatment (actually offered by medical doctors but considered a CAM therapy) is a procedure commonly referred to as prolotherapy but also known by several other names (Table 1).

Prolotherapy is defined as “the rehabilitation of an incompetent structure (as a ligament or tendon) by the induced proliferation of new cells” [22]. This procedure has been used to treat spinal complaints for more than 60 years [23].

Table 1
Terms used in the literature to describe prolotherapy

Reference	Term
Reeves et al. [2]	Dextrose prolotherapy
Barbor [3]	Dextrose sclerosant
Klein et al. [4]	Dextrose-glycerin-phenol injection
Reeves [5]	Growth factor injection
Reeves [5]	Growth factor stimulation injection
Hackett [6]	Induced ligamentous sclerosis
Shuman [7]	Joint sclerotherapy
Bumpus and Nichols [8]	Ligament and muscle sclerosing agents
Friedlis [9]	Ligament reconstructive treatment by injection
St. Anthony's [10]	Ligamentous injections with sclerosing agents
Faber [11]	Nonsurgical tendon, ligament and joint reconstruction
Klein et al. [12]	Proliferant injection
Zale [13]	Proliferative therapy
Hauser and Hauser [14]	Prolo
Hackett [15]	Prolotherapy
Yelland et al. [16]	Prolotherapy injections
Faber and Walker [17]	Reconstructive therapy
Linetsky et al. [18]	Regenerative injection therapy
Tanner [19]	Sclerosant injections
Barbor [20]	Sclerosant therapy
Green [21]	Sclerotherapy

Despite the controversy that has surrounded this treatment [19,24–28], its use appears to be growing when judged by the number of recently published scientific articles [2,16,29], medical textbooks [18,30,31], mass media books [14,32–34] and other popular press articles [35,36]. The American Association of Orthopaedic Medicine (AAOM) directory contains more than 200 listings of physicians currently offering prolotherapy [37]; membership is voluntary so the true figure is likely much higher.

Because patients will often turn to conventional medical providers for advice about CAM therapies, it is important for physicians who specialize in spinal disorders to be knowledgeable about these treatment approaches to offer their patients some guidance. The primary purpose of this paper was, therefore, to conduct a critical review of the literature about the injections of sclerosing agents (prolotherapy) for spinal disorders to inform physicians who specialize in spinal disorders about the current state of knowledge in this area. The secondary purpose of this paper was to review all human clinical studies that involved prolotherapy for spinal pain so that clinicians may be able to compare the evidence for this treatment approach with that of more commonly used methods of care.

Methods

Search strategy

Computerized medical literature databases (Medline, CINAHL, Mantis, Cochrane Central Register of Controlled Trials) were searched with the following strings for all years available on each database: prolotherapy, proliferant therapy, proliferant injection, joint sclerotherapy, sclerosing solution AND back pain, ligament sclerosing injections. Search results were broadened using the “Related Articles” feature on PubMed [38]. Reference sections of relevant articles were also hand searched to uncover additional references not discovered by our computerized search. Clinical studies reported in textbooks, abstracts and conference proceedings were also included. The search was also run on Expanded Academic ASAP database to uncover additional materials in nonacademic journals [39].

To satisfy our primary goal, we conducted a broad review of this topic, including terminology (Table 1), solutions injected (Tables 2 and 3), mechanism of action (Table 4) and adverse events (Tables 5 and 6). For our secondary goal, the inclusion criteria for clinical studies were 1) prolotherapy for spinal pain disorders, 2) original research, 3) human subjects and 4) outcomes reported. Exclusion criteria were 1) non-English language, 2) solution not identified and 3) fewer than 5 patients. If available, the following information was extracted from relevant clinical studies: 1) condition treated, 2) number of patients, 3) study type (cohort or randomized clinical trial, RCT), 4) solution injected, 5) dose, 6) number of treatments, 7) treatment interval, 8) concurrent

Download English Version:

<https://daneshyari.com/en/article/9360378>

Download Persian Version:

<https://daneshyari.com/article/9360378>

[Daneshyari.com](https://daneshyari.com)