Introduction

Prolotherapy, a treatment for some types of chronic musculoskeletal pain, involves the injection of a solution into damaged ligaments or tendons. The solution causes local irritation and inflammation, which are believed to stimulate tissue growth and repair. The solutions that are used in prolotherapy are often called “proliferants.” These solutions may include sclerosing agents, glucose, glycerine, zinc sulfate, psyllium seed oil, particles of pumice, Sarapin® (an herbal extract) and phenol, sometimes in combination with each other or mixed with a local anesthetic. Protocols used in administering prolotherapy also vary. Typically, a series of injections are given over several weeks, but vitamin and mineral supplementation, exercise, spinal manipulation or physical therapy may also be included as part of the treatment.

The term “prolotherapy” (prolo=proliferation) was coined by George Hackett in the 1950s, though variations of the procedure (sometimes called joint sclerotherapy, regenerative injection or ligament reconstructive therapy) had been investigated long before this time. The procedure is also promoted for other chronic pain conditions, including migraine, temporomandibular joint disorders, carpal tunnel syndrome and fibromyalgia.

Although prolotherapy has a long history, there are few controlled studies of its effectiveness. Many health insurance agencies consider the procedure to be “unproven,” “experimental” or “investigational.”

Research Questions

A provincial ministry of health asked the Canadian Coordinating Office for Health Technology Assessment (CCOHTA) for information on the effectiveness of prolotherapy. Before this, a similar question had been directed to the Alberta Heritage Research Foundation for Medical Research’s (AHFMR) health technology assessment (HTA) unit. The Alberta HTA unit prepared an information letter on prolotherapy in 1998. This was updated in 2002, in response to a second request. It seemed that a summary of assessment information on this procedure might also be of interest to others.

Assessment Process

Building on the work done by the Alberta HTA unit, an updated literature search was conducted in February 2004, using PubMed, The Cochrane Library (Issue 1, 2004) and the UK Centre for Reviews and Dissemination databases (DARE, HTA and NHS EED). The Cochrane Collaboration Back Group was contacted for information on their systematic review of prolotherapy for chronic low back pain. Other references were obtained through an Internet search using Google.com.
Summary of Findings

The forthcoming Cochrane Collaboration Back Group systematic review, *Prolotherapy injections for chronic low back pain*, will provide the best available evidence on this therapy. This review is to be published in The Cochrane Library, Issue 2, April 2004.8

The lead author of this review, Dr. Michael Yelland, was also the primary investigator for a randomized controlled trial comparing prolotherapy and saline injections, with or without exercise therapy, in 110 participants with chronic low back pain.1 A computer-generated random number system was used to allocate participants to receive a series of prolotherapy injections (a mixture of glucose, lignocaine and water) or “control” injections (saline); and to an exercise program or normal daily activity. Most participants (80%) were followed for two years. The authors found that participants experienced “marked and sustained improvements in their pain and disability, even with saline injections and normal activity….” The authors note that: “In essence, there were no attributable effects of the glucose-lignocaine and exercise components of the prolotherapy protocol. Nevertheless, participants exhibited marked and sustained improvements in their pain and disability, even with saline injections and normal activity. The basis for this response is intriguing….”1

Yelland et al. speculate that the number of injections given to participants may have played a role. In an earlier trial by Dechow et al., only three injections were administered and no benefit was found.9 Another explanation may be the influence of increased contact with caregivers throughout the trial; or the effect may have been due to the injection itself, rather than to the use of a solution.

The AHFMR’s HTA unit prepared an information letter (rapid assessment) on prolotherapy in 1998. This was updated with a literature search in 2002. These papers can be obtained, upon request, from the unit (e-mail ahfmrinfo@ahfmr.ab.ca). They summarize the evidence from the few controlled trials of prolotherapy, available as of early 2002.10 An AHFMR assessment of a related treatment for chronic pain, “trigger point therapy,” is available on their web site http://www.ahfmr.ab.ca. AHFMR’s assessment report on trigger point therapy will be released in mid-2004.9,11-14

The British Columbia Office of Health Technology Assessment (BCOHTA) was collaborating with the Workers’ Compensation Board of British Columbia to do an assessment of prolotherapy, but work on this project stopped when the BCOHTA office closed.

Conclusion

The new Cochrane systematic review will provide us with the best available evidence to date on prolotherapy.8 There is little point in CCOHTA undertaking a further assessment of this therapy at this time, though evidence from further controlled clinical trials of prolotherapy is clearly needed.
References


