



Literature Reviews: Prolotherapy for Sports Injuries

Gary B. Clark, MD, MPA

PROLOTHERAPY OF SPORTS INJURIES

Case Study: Roy was the stellar center and captain for the local University ice hockey team. During the third period of a particularly important intercollegiate game, Roy was forcibly body checked by an opposing player and sent crashing into the boards. The result was immediate, excruciating pain of Roy's left knee bringing him to the ice—he was unable to comfortably play out the remainder of the period. His team managed to hold their winning lead through the rest of that final period, but they were hard pressed without Roy's skating skills and leadership.

In three weeks, Roy's hockey team was to play in the season's final league championship game and his teammates desperately needed Roy to captain them to a hard-fought season victory.

INTRODUCTION

Sports injuries are a central concern of any musculoskeletal medical specialist. Whether the athlete's accidental injury occurs directly on the playing field or indirectly on an icy grocery store parking lot, the resultant laceration, sprain, fracture, or concussion can affect that player's and team's destiny.

Prolotherapy, including variations of the theme such as Neural Therapy and Platelet-Rich Plasma (PRP) Therapy, can be of significant importance in returning an injured player to the sports arena, field, court, course, or rink. The following literature review focuses on the few journal articles that currently address Prolotherapy of sports injuries.

Our main intention is to familiarize both physician and patient with the basic concepts and language of Prolotherapy, as well as whatever literature exists that provides evidence for its clinical efficacy. We would like to stimulate reading and increase the general level of understanding of Prolotherapy of sports injuries—as

well as stimulate interest in improving private clinical and academic research evidence of the efficacy of the treatment. Please use Google and the website of the National Library of Medicine (www.pubmed.gov) to access the following and other articles.

GROIN AND PUBIC INJURIES

Efficacy of dextrose Prolotherapy in elite male kicking-sport athletes with chronic groin pain. Topol GA, et al. *Arch Phys Med Rehabil.* 2005 Apr;86(4):697-702.

Treatment of longstanding groin pain in athletes: a systematic review. Jansen JA, et al. *Scan J Med Sci Sports.* 2008 Jun;18(3):263-74.

Treatment of osteitis pubis and osteomyelitis of the pubic symphysis in athletes: a systematic review. Choi H, et al. *Br J Sports Med.* 0:bjism.2008.050989v2.

ABSTRACT SUMMARIES

Topol, et. al. (2005), reported a consecutive case study of dextrose Prolotherapy for treatment of elite kicking-sport athletes acquiring chronic groin pain from osteitis pubis or adductor tendinopathy. They studied 24 rugby/soccer players with chronic groin pain. The subjects were treated with Prolotherapy, using monthly injections of 12.5% dextrose/0.5% lidocaine into the tender groin areas. Injections were continued until complete resolution or non-improvement for two consecutive treatments. A mean of 2.8 treatment sessions was required. The mean reduction in pain was 6.3 to 1.0 (VAS pain scale) and 5.3 to 0.8 (NPPS pain scale). At the end of the study, 20 of the 24 patients had no pain and 22 out of 24 were unrestricted to degree of sports activity. (Study design: Consecutive case series: Level 4 evidence)

Jansen, et. al. (2008), reported a systematic review of articles describing longstanding groin pain in athletes, treated

with rest/restricted activity, passive or active physical therapy, corticosteroid injection, dextrose Prolotherapy, or surgery. Although mentioning Prolotherapy as an optional treatment, the report focused on surgical results and provided little insight into the effect of the more conservative treatments. (Study design: Systematic review: Level 4 evidence)

Choi, et. al. (2008), reported a systematic review of 25 journal articles that consisted of case reports or case series; there were no random controlled trials. One hundred and ninety-four athletes were cited as being diagnosed with osteitis pubis and treated with some combination of conservative treatment, e.g., rest, nonsteroidal anti-inflammatories, physical therapy (six case reports); local anesthetic injection; corticosteroid injection (four case reports); dextrose Prolotherapy (one case series); antibiotic therapy (ten case reports/series of osteomyelitis of the pubic symphysis); or surgery (six case reports/series). Without any clinical studies available providing direct comparison of treatment modalities, the authors graded the quality of evidence at Level 4—they could not determine the comparative effectiveness of the various treatments based on the studies currently existing. They deemed that further, more scientifically rigorous study is necessary. (Study design: Systematic review: Level 4 evidence)

ACHILLES TENDINOSIS

Prolotherapy injections and eccentric loading exercises for painful Achilles tendinosis: a randomized trial. Yelland MJ, et al. *Br J Sports Med*. Published Online: 22 June 2009. doi:10.1136/bjism.2009.057968.

ABSTRACT SUMMARY

Yelland, et. al., compared Prolotherapy of Achilles tendinosis to the efficacy of eccentric loading exercises (ELE). Subjects were randomly selected for one of three groups: 1) a 12-week program of hypertonic glucose Prolotherapy injections (n=14); 2) a 12-week program of ELE (n=15), and 3) a 12-week program of combined Prolotherapy and ELE treatment (n=14). Prolotherapy was administered by delivering injections of hypertonic glucose diluted with lignocaine and delivered alongside (parallel to) the affected tendon. Long term outcome was assessed over the ensuing 12 months by measuring the proportions of participants achieving a minimum clinically important change (MCIC) for VISA-A questionnaire

scores. The symptoms of pain, stiffness, and limitation of activity, along with treatment costs, were also periodically assessed over that 12 month period.

At 12 months, Prolotherapy (compared to ELE) demonstrated earlier reductions of stiffness and activity limitation. Combined treatment demonstrated even earlier reductions of pain, stiffness, and activity limitation—as well as lowest incremental cost. (Study design: Single-blinded, randomized clinical trial: Level 1 evidence)

JOP COMMENTARY

Currently, there are relatively few clinical reports on the use of Prolotherapy specifically as treatment for sports injuries. And ... most of those reports are at the lowest level of quality of evidence.

Evidence-based medicine has become a cornerstone of modern medical practice, attempting to apply the best available scientific evidence to medical decision making. Good evidence is the fundamental basis upon which therapies are judged as most appropriate and necessary by the medical community (i.e., clinically effective and efficient) and deemed reimbursable by insurance programs.¹

Existing clinical evidence can be collected and ascertained for quality by scientific, engineering, and statistical methods. Several evidence grading systems are available. One example is that of the New Zealand Guidelines Group (NZGG), which has developed a system for grading the quality of evidence and is often referenced. These levels of evidence (or levels of confidence) are summarized in *Table 1*.²

If there were a level 5, it would incorporate anecdotal reports that might be based on empirical experience but are undocumented, totally hearsay, and subjective, providing no weight of evidence, whatsoever.

It has been pointed out by many observers, including the National Institutes of Health Center for Complementary and Alternative Medicine,³ that the beneficial effects of Prolotherapy may be much more complex than first thought. Aside from the inflammatory stimulation of fibroblastic ligament or tendon regeneration, the individual elements of Prolotherapy may have their own specific effects. The needling, itself, may have some acupuncture effect on pain. The anesthetic (i.e., procaine,

Table 1. New Zealand Guidelines Group (NZGG) levels of evidence of medical efficacy.²

Reliability Level of Evidence	Source of the Evidence
1. Evidence that has a high degree of proven reliability leaving little question to debate.	Trial studies that use well-tested methods (including comparable control groups) to make comparisons in a fair way and produce results that leave very little room for uncertainty. Example: Usually Level 1 evidence is from 1) systematic reviews or meta-analyses with consistent findings or 2) large, high-quality randomized controlled studies.
2. Evidence that has significant reliability but is still open to some debate.	Trial studies that use well-tested methods (including comparable control groups) to make comparisons in a fair way but where the results leave some room for uncertainty. For example, the size of the study may be small enough to cause significant losses to follow-up or the experimental design precludes adequate selection of groups for comparison. Example: Usually Level 2 evidence is from 1) systematic reviews without consistent findings, 2) randomized controlled trials in which significant numbers of subjects are lost, or 3), small randomized controlled studies.
3. Evidence that has some weight of clinical significance but is without a high degree of proven reliability.	Trial studies that use an experimental design that does not guarantee that fair comparisons can be made, thus, producing results that are doubtful. Example: Usually Level 3 evidence is from 1) systematic reviews of case-control studies or 2) individual case-control studies.
4. Evidence that has some weight of clinical significance but is based on reports of empirical experience without any comparable groups.	Trial studies that use an experimental design without comparable (control) groups that produce a high probability of results being due to chance or because the groups compared were different at the outset of the study. Example: Usually Level 4 evidence is from 1) cohort or case-control studies where the groups were not really comparable or 2) totally uncontrolled case-series reports.

lidocaine, lignocaine) used for diluting the dextrose and other proliferant components may have a Neural Therapy effect on local sympathetic enervation and lymphedema.

Additionally, we have yet to prove the differences between the various proliferant combinations that are in use around the country. Varying concentrations of dextrose (glucose) are being used. Other proliferant solution constituents are being used, including phenol and glycerin (P2G solution is phenol, glucose and glycerin), sodium morrhuate, and testosterone. Also, some say that tendons deserve different proliferant concentrations and constituents compared to ligaments.

All of the variations of Prolotherapy and their respective effects need to be carefully documented and analyzed in the private treatment room as well as the academic

research clinic. Well-designed case studies can be a very beneficial contribution to the total body of evidence—though not as weighty as randomized controlled studies.

Currently, the body of Level 1 and 2 evidence of Prolotherapy efficacy is still meager. But, the vastly more preponderant Level 3 and 4 private-practice therapeutic evidence still provides an unwavering weight of overall support for the efficacy of Prolotherapy in treating injuries of all types, including those that are sport-related.

There are many articles on sports injuries of all types that do not address Prolotherapy as a major therapeutic consideration. Instead, there is a plethora of reports on failed physical, medical, and surgical treatments that permeate throughout the professional channels of information. We have to show that Prolotherapy can make a difference. However, to prove the truth to the medical community at-large and the healthcare insurance companies, we need more Level 1 and 2 evidence. The work of Scarpone, et. al., and Rabago, et. al., are most recent examples of the quality of work that needs to be accomplished.^{4,5}

Yelland, et. al., cited earlier, have provided an excellent example of Level 1 evidence for the efficacy of Prolotherapy. An “efficacious” treatment, by definition, is both therapeutically effective in resolving the cause of the patient’s symptoms and, also, therapeutically efficient, i.e., cost-effective. As time goes on, there will be more and more Level 1 and 2 evidence proclaiming the therapeutic efficacy of Prolotherapy. However, it will take disciplined and concerted effort, time, and money to reach the needed preponderance of compelling clinical evidence to convince Medicare and private healthcare insurance companies to reimburse for Prolotherapy.

Case Study (continued): *Over the evening, Roy’s knee had been put at rest, iced, wrapped (compressed) and elevated (i.e., R.I.C.E. therapy). The very next day following his injury, he visited a local musculoskeletal pain specialist for diagnosis and treatment.*

Physical examination revealed a clearly demarcated, swollen medial collateral ligament (MCL), which was exquisitely sensitive to palpation at its proximal and distal attachments. There were no findings of meniscal, coronary ligament, cruciate ligament, or other structural damage upon specific physical testing. Due to joint stability and isolation of a discrete injury, radiography was not necessary.

Initial treatment consisted of Neural Therapy,⁶ performing intradermal injections of procaine circumferentially around the edge of the clearly demarcated medial collateral swelling. The edematous swelling began to subside during the injections and was essentially gone by the time that the injections were completed. Roy reported significant pain relief. He was asked to return in one week and urged to continue R.I.C.E. as much as possible and crutches until all pain had subsided—along with restriction from the skating rink. He was placed on a mild physical therapy program to maintain strength and range of motion.

At Roy's second visit the next week, his MCL was nonswollen but still slightly tender at both the proximal and distal MCL attachments. P2G Prolotherapy was performed at both the proximal and distal MCL. Roy was taken off crutches, continued on a moderate physical therapy program, and cautioned to participate in only mild skating. Any physical activity was to be limited by the occurrence of any MCL pain.

Roy's team trainer claimed that his recovery was "miraculous!" ... "What is this Prolotherapy thing?!" Three weeks following the accident, Roy played in the final game. The coach saved him for the third period. His team broke a tie with Roy's winning a hat trick in the last five seconds. His last clinic visit in the following week showed full recovery of the MCL. ■

BIBLIOGRAPHY

1. Evidence-based medicine. Wikipedia. <http://en.wikipedia.org>.
2. Levels of Evidence. New Zealand Complementary and Alternative Medicine. www.cam.org.nz/levelsofevidence.
3. Prolotherapy. National Center for Complementary and Alternative Medicine. <http://nccam.nih.gov>.
4. Scarpone M, et al. The efficacy of prolotherapy for lateral epicondylitis: a pilot study. *Clinical Journal of Sports Medicine*. 2008 May;18(3):248-54.
5. Rabago D, et al. The systematic review of four injection therapies for lateral epicondylitis: prolotherapy, polidocanol, whole blood and platelet rich plasma. *British Journal of Sports Medicine*. 2009 Jan 21.
6. Neural Therapy. Wikipedia. <http://en.wikipedia.org>.

708.848.5011 www.benuts.com



Help Maximize the effect of Prolotherapy Treatments

Prolo Max may be used to support connective tissue growth such as ligaments, tendons, and collagen. It may help sports injury healing, musculoskeletal pain, after Prolotherapy, muscle cramps, and in connective tissue injury.

AVAILABLE AT BENUTS

BEULAH LAND NUTRITIONALS MEDICAL ARTS BUILDING, 715 LAKE ST., 6TH FLOOR, OAK PARK, IL 60301