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Alternative Medicine

Prolotherapy Pinpoints Patients' Pain

Injections trigger short-term inflammation to jump-start the healing process.

By Dan Krotz

Philip Greenman's knee sometimes buckled when he walked. The 73-year-old had torn his meniscus 30 years earlier while playing basketball and the cartilage had not healed properly. He also suffered weekly headaches thanks to whiplash sustained in a childhood tobogganing accident.

He twice scheduled knee surgery and relied on nonprescription painkillers for his headaches. But he kept postponing surgery and his headaches persisted.

Then he tried a little-known treatment called prolotherapy. His doctor stuck a needle in his knee and injected a sugary solution designed to spur short-term inflammation. For his headaches, a similar series of injections was administered in his neck. In all, he underwent three sessions in two years.

"My knee is much stronger and I haven't had a headache in more than a year," Greenman said. "I play golf, my gait is fine, and I'm putting knee surgery on hold."

Greenman isn't surprised a cure finally came with a few shots and a bit of swelling. As a professor of osteopathic medicine at Michigan State University, he appreciates the power of simple remedies. And he joins a small but growing number of doctors—including former surgeon general C. Everett Koop, MD—who contend that prolotherapy is an effective and risk-free treatment for chronic joint pain.

How It Works

Prolotherapy proponents believe most joint pain can be traced to weakness in ligaments, tendons, and cartilage. Strengthen this tissue and stop the pain. But instead of coddling weak tissue with rest and anti-inflammatory medication, prolotherapy jump-starts the body's self-repair process through mild aggravation.

In a typical session, ligaments are injected with a local anesthetic and an irritant, most commonly a nontoxic dextrose solution but sometimes phenol or glycerin. The number of injections per session varies. Some lower back and shoulder treatments require up to 40 injections, while a wrist can get by with only three. Between two and four sessions are repeated every four to six weeks.

Back pain, fibromyalgia, tendinitis, plantar fasciitis, tennis elbow, bursitis, headaches, knee and shoulder arthritis—name the pain and prolotherapy has been used to treat it. Mark T. Wheaton, MD, a physiatrist in private practice in Minnetonka, MN, remembers treating a woman who severely tore her upper ankle ligaments on the set of American Gladiators. Five years after the injury, she still could not run.

"We gave her prolotherapy and now her ankle is much stronger. She can run," he said.

Wheaton has witnessed a number of such success stories in the five years he has administered prolotherapy. He credits the technique's effectiveness to a three-step process that he says helps connective tissue repair itself.

Start To Finish

First, the injection site is inflamed for up to three days. This is followed by a six-week growth phase, in which fibroblasts respond to the inflammation by producing collagen, which gives ligaments tensile strength, mass, and elasticity. The procedure was formerly called sclerotherapy, but today's practitioners prefer "prolotherapy" because it underscores their assertion that it promotes this tissue proliferation and rejuvenation. Scar tissue is not formed, Wheaton said.

Finally, there's the two-year maturation phase, in which cells combine and realign to form healthy tissue fiber. Because these fibers have to align along the line of physical stress for the tissue to form properly, exercise is important, Wheaton said. The body doesn't intuitively know how to align fiber; it must be taught through motion, he said.

In the U.S., about 400 doctors of osteopathy and other physicians administer prolotherapy. Many, like Brad Sandler, DO, vice president of Corrective Care, a pain treatment clinic in Mishawaka, IN, have a packed schedule. His clinic sees patients from several adjacent states and he and his partner are often booked three weeks in advance, charging between \$300 and \$1000 for two to six sessions.

He credits his busy practice to the nation's huge chronic pain population, the growing demand for nonsurgical treatments, and an increasing number of physician-based referrals. He also defers to prolotherapy's simplicity.

"It's tissue healing 101," Sandler said. "Where the ligament and tendon attach to the bone, there are naturally very few fibroblasts. Prolotherapy turns on the fibroblasts, which deposit collagen, which in turn strengthens tissue."

And The Study Says...

But critics contend there's not enough research. Only five randomized, placebo-controlled studies have been conducted, four of which support the technique.

"There are risks whenever you use something that isn't backed by convincing research," said Kevin Coupe, MD, an orthopedic surgeon with the University of Texas Houston Health Science Center. "I don't know too much about prolotherapy, but I'm skeptical about something that promotes rather than fights inflammation. We need more data."

Health Care Financing Administration officials agree. Although some insurance companies cover the treatment, the agency denied Medicare coverage for prolotherapy to treat low back pain. (The treatment is not covered for any indications.) In a September 1999 decision memo, the agency poked holes in two studies touted by many prolotherapy advocates as proof the procedure works.

The first and best-known study was conducted by researchers at the Sansum Medical Clinic in Santa Barbara, CA, and published in *The Lancet* in 1987 (Ongley MJ, Klein RG, Dorman TA, et al. A new approach to the treatment of chronic low back pain. *Lancet* 1987;2[8551]:143-146). Eighty-one patients with low back pain were divided into two groups; half received prolotherapy and half received an injection that replaced the dextrose irritant with a saline-based placebo. Six months later, the experimental group reported less pain. The second study, conducted at the same institution, was published in 1993 in the *Journal of Spinal Disorders* (Klein RG, Eek BC, DeLong WB, Mooney V. A randomized double-blind trial of dextrose-glycerine-phenol injections for chronic, low back pain. *J Spinal Disord* 1993;6[1]:23-33). It involved 79 patients and also determined that prolotherapy alleviates lower back pain. But HCFA officials were unimpressed, citing among other reasons that neither study had enrolled enough patients to support a national coverage policy.

Continuing Research

More data is trickling in, however. Since the HCFA decision, three more studies have been conducted; two by K. Dean Reeves, MD, research director of Middlebrook Rehabilitation Hospital in Gardner, KS.

In his first study, published in the March 2000 issue of *Alternative Therapies in Health and Medicine*, Reeves conducted a placebo-controlled trial on 38 osteoarthritic knees (Reeves KD, Hassanein K. Randomized prospective double-blind placebo-controlled study of dextrose prolotherapy for knee osteoarthritis with or without ACL laxity. 2000;6[2]:68-74, 77-80). Knees treated with prolotherapy exhibited less swelling, pain, and buckling than the control group (Figure 1). Reeves turned his attention to finger osteoarthritis in a second study, published in the August 2000 *Journal of Alternative and Complementary Medicine* (Reeves KD, Hassanein K. Randomized, prospective, placebo-controlled double-blind study of dextrose prolotherapy for osteoarthritic thumb and finger [DIP, PIP, and trapeziometacarpal] joints: evidence of clinical efficacy. 2000;6[4]:311-320). Based on an experimental group of 13 and a control group of 14, he determined that dextrose-based prolotherapy is a safe and effective treatment for mitigating finger joint pain.

Hoping to net a larger patient population, Reeves is also initiating two multicenter studies. The first will examine prolotherapy's effectiveness in treating patients with knee osteoarthritis who are not candidates for knee surgery; the second will examine its effectiveness in treating ACL-deficient patients who are also not surgical candidates.

It will take large studies like these to hold the medical community's attention. Several physicians who specialize in osteoarthritis contacted for this article either had never heard of prolotherapy or didn't know enough to comment. And Coupe, who's from a research university and considers himself open-minded when it comes to innovative techniques, cautioned that doctors should be conservative when using a procedure that isn't backed by convincing research.

Uphill Battle

"I suspect orthopedic surgeons and sports medicine physicians will come down on us," said Ross A. Hauser, MD, medical director of Caring Medical and Rehabilitation Services in Oak Park, IL, and author of two books on prolotherapy.

Hauser believes prolotherapy would gain wider acceptance if it were taught in medical school. Wheaton agrees, pointing out that even his 2000-page physical medicine and rehabilitation textbook has only three lines devoted to prolotherapy.

The problem, Wheaton said, is there isn't much money to be made from a procedure using off-the-shelf dextrose solutions that can't be patented. No money means no industry-funded research. No research means no acceptance.

"It's David versus Goliath," Wheaton said.

Wheaton listed more strikes against prolotherapy: Many insurance companies don't cover it. Surgeons don't care for it because it eliminates surgeries. Chiropractors don't like it because it siphons away patients. And pharmaceutical companies, which have a powerful lobby with the American Medical Association and the Food and Drug Administration, make billions of dollars selling anti-inflammatory drugs.

And most practitioners don't have the time or resources to conduct research. Reeves financed his two studies out of his own pocket at a cost of \$90,000, a fundraising technique not likely to become a trend. And Hauser's practice is thriving. His clinic receives about 1000 new patients per year, which, along with returning patients, breaks down to about 50 patients a day.

In addition, prolotherapy practitioners contend there's already ample proof. There are the several placebo-controlled studies, and there's the ever-growing mound of anecdotal evidence. Hauser's clinic, for example, boasts a 90% success rate with patients who've been told they need surgery but come to him first, and an 85% success rate in treating patients with chronic pain for whom prolotherapy is the last stop in a long line of noninvasive and surgical treatments.

Buoyed by these numbers, Hauser doesn't believe winning over the medical establishment is a make-or-break imperative. Instead, he foresees a grassroots push toward acceptance.

"We're hoping that with the Internet and better information dispersal, the general population will ask for more natural remedies like prolotherapy," Hauser said.

Too Good To Be True?

Critics, however, also argue that one procedure can't possibly soothe the pain associated with so many disparate pathologies.

"Each injury and each patient must be treated differently," said Patrick J. Nunan, DPM, vice president of the American Academy of Podiatric Sports Medicine and team podiatrist at Wilmington College in Wilmington, OH. "In my experience, any procedure that's administered to a wide range of patients and problems isn't good."

Nunan used plantar fasciitis as an example. The factors that determine both its causes and the most appropriate treatments vary from person to person. Body weight, the patient's daily activities, biomechanics, shoe type, muscle strength, and flexibility must be taken into account, he said.

"Using one technique to cure so many types of pain is ludicrous," added Robert S. Baratz, MD, assistant clinical professor in Boston University's departments of medicine and emergency medicine.

Baratz frequently assists medical boards in the prosecution of physicians who violate professional standards.

Consider low back pain, he said. It can be caused by everything from tuberculosis of the spine to bone spurs to something as mundane as a rough game of racquetball. Obviously, each of these problems requires a different treatment, he said.

Baratz also referred to the underpinnings of modern medicine: Identify the problem, associate the pain with the problem, and finally treat the pain by (hopefully) eliminating the problem. This process is subverted in procedures like prolotherapy, which may tempt a practitioner to administer shots without fundamental workups, he said.

Quality Control

There have been no prolotherapy-related deaths since the 1950s, when two patients died and three were paralyzed. Today, improved physician training and milder irritant solutions make prolotherapy safe, Reeves said, although he added that extremely rare complications occur when phenol is accidentally injected into the spinal canal.

"Anytime you inject someone there is risk," noted Wheaton. "The doctor must be skilled, and obviously injecting the ankle is not as risky as injecting the neck."

Prolotherapy complications are indeed few and far between, according to a 1993 survey of 95 practitioners published in the *Journal of Orthopaedic Medicine* (Dorman T. Prolotherapy: a survey. 1993;15). Out of the 494,845 patients represented in the study (most for low back pain), only 14 major complications were reported, defined as either hospitalization or nerve damage. Only 66 minor complications were reported, which included 24 allergic reactions and 29 punctured lungs. This clean record is further corroborated by a watchdog group, which reports only minor complications.

"We have encountered a few cases in which people who've received prolotherapy develop painful scar tissue," said Stephen Barrett, MD, a retired psychiatrist and vice president of the National Council Against Health Fraud.

For now, ensuring patient safety is up to each practitioner. There are no prolotherapy certification programs, according to Maelu Fleck, executive director of the American Association of Orthopedic Medicine. Although AAOM officials explored the feasibility of establishing such a program, the project was derailed by the AMA's reluctance to support independent board certification programs in prolotherapy or any new specialty, Fleck said.

Instead, the AAOM hopes to include prolotherapy-specific questions in the certification programs of specialties such as physiatry, orthopedic surgery, or anesthesiology, Fleck said.

The AAOM does, however, offer several continuing medical education (CME) classes each year, which have been completely filled in recent years, Fleck said. In addition, the American College of Osteopathic Sclerotherapeutic Pain Management, which is associated with the American Osteopathic Association, offers two prolotherapy-related CME classes per year that each draw between 50 and 110 physicians.

Slow Growth

Until prolotherapy earns more than a few lines in medical textbooks, its use will likely grow one CME class at a time, and its reputation will likely spread one successful treatment at a time. High-profile patients don't hurt either.

Hauser recalls treating Kendall Gill, a starting guard for the New Jersey Nets, who suffered from debilitating headaches. Several seasons of taking elbows above the neck were taking their toll. Since 1994, Gill has received three series of shots, and his headaches are gone.

And there's Gregg Hill, who in 1995 was a top-ranked junior tennis player. At age 18 he suffered a wrist injury and underwent cortisone shots and surgery, but nothing worked. By the time Hill came to Hauser, he was also plagued with knee and elbow tenderness, which Hauser attributed to his anti-inflammatory medication preventing proper recovery after workouts. He was scheduled to play his first tournament on the Association of Tennis Professionals (ATP) tour in March.

"He needed a lot of prolotherapy, but it worked," Hauser said. "He's now back on tour."

Dan Krotz is a freelance writer based in San Francisco.

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