FANTASTIC FINDINGS

A Retrospective Observational Study on Hackett-Hemwall Dextrose Prolotherapy for Unresolved Foot and Toe Pain at an Outpatient Charity Clinic in Rural Illinois

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ABSTRACT

To study the efficacy of Hackett-Hemwall dextrose Prolotherapy for foot and toe pain, a retrospective observational study was commissioned using the data obtained at a charity health clinic in rural Illinois. Foot and toe pain is a common complaint affecting the lives of millions. Nearly 25% of the population suffers from foot and toe pain at any one time. The diagnoses given to these patients by their medical doctors and podiatrists are many and varied. Some of the most common are hallux rigidus and hallux malleus. Prolotherapy is an injection treatment used to initiate a healing response in injured connective tissues such as tendons and ligaments, common in painful foot and toe conditions. This retrospective study documents the improvements the subjects obtained after receiving Prolotherapy treatments, which included reduction of their pain and an increase in quality of life measures.

Objective: *To investigate the outcomes of patients undergoing Hackett-Hemwall dextrose Prolotherapy treatment for unresolved foot and toe pain.*

Design: *Nineteen patients who had been in pain an average of 54 months were treated quarterly with Hackett-Hemwall dextrose Prolotherapy. This included a subset of eight patients who were told by their medical doctor(s) that there were no other treatment options for their pain. Patients were contacted an average of 18 months following their last Prolotherapy session and asked questions regarding their levels of pain, physical and psychological symptoms, as well as activities of daily living, before and after their last Prolotherapy treatment.*

Results: *In these 19 patients, all 100% had improvements of their pain and stiffness. Eighty-four percent experienced 50% or more pain relief. Dextrose Prolotherapy helped the patients make large improvements in walking and exercise ability, as well as produced decreased levels of anxiety and depression. One-hundred percent of patients said Prolotherapy changed their lives for the better.*

Conclusion: *In this retrospective observational study, Hackett-Hemwall dextrose Prolotherapy helped cause large decreases in pain and stiffness and improved clinically relevant quality of life parameters in people with unresolved foot and toe pain.*

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KEYWORDS: bunion, cuneiform, hallux rigidus, metatarsal, metatarsalgia, metatarsal ligaments, navicular, phalanges, Prolotherapy.

INTRODUCTION

Chronic foot and toe pain is a common condition affecting approximately 25% of the population at any given time.[1] The average person spends four hours on their feet and takes between 8,000 and 10,000 steps each day. Each step generates a force, more than 50% the person's body weight.[2] Jumping and running adds a force many times the person's body weight with each stride.[3] Thus, during an average day the feet support a combined force equivalent to several hundred tons. It is not surprising, then, that about 75% of Americans experience foot pain at some point in their lives.

The causes of many incidents of metatarsalgia, or forefoot pain, are mechanical, including poorly fitting shoes and improper foot mechanics with walking or running, although the nature and mechanism underlying many types of foot and toe pain is not clearly understood.[4] Other factors that can lead to foot pain are intense training, certain

foot shapes such as high or fallen arches, degenerative arthritis, and excess weight.[5] For the purpose of this study, the phalanges (toes) are included, as painful conditions involving the toes which can arise from problems in the forefoot or metatarsal region. Bunions, otherwise known as hallux rigidus, and hammertoes (hallux malleus), are two common diagnoses for toe pain whose etiologies can be related to the structures of the forefoot. A multitude of diagnoses can be arrived at for foot/toe pain, though many times the underlying problem, a weakness or injury in the ligaments, tendons or cartilage, is the culprit. For example, hallux rigidus (bunion) "is poorly understood but is thought to be secondary to both hereditary and environmental factors. The fact that bunions occur commonly in families suggests a genetic predisposition from ligamentous laxity and hyperpronation of the foot."[6] First ray hypermobility and pes planus (flat feet) are conditions that can lead to bunions.[7] A study done at the University of Pittsburgh's Orthopaedic Foot Research Clinic came up with 23 different diagnoses for 98 patients with forefoot pain.[8] Joint instability and/or hypermobility is what happens when the ligament structure in an area is damaged. This can result in a hallux rigidus, pes planus (flat feet) or other painful maladies such as Morton's neuroma that can be traced back to an original ligament injury or weakness. Morton's neuroma, a neuropathy that usually occurs between the 3rd and 4th metatarsals, is not traditionally thought of as being an instability problem. But, "excessive motion between these metatarsals …can result in significantly enlarged 3rd common digital nerve. This enlargement can cause further trauma, worsening the symptoms," which can be quite severe.[9]

Standard treatment for foot pain is generally conservative, beginning with having the patient wear properly fitting shoes and/or orthotics. If the pain does not resolve, NSAIDs are often prescribed along with some physiotherapy. Patients that do not respond to conservative treatment for foot and toe pain are often considered to be surgical candidates. These procedures include but are not limited to arthrodesis, commonly known as a "fusion;" arthroplasty, which restores the joint, often with some type of implant; chondroplasty, which is the reshaping of the cartilage in the joint; and osteotomy, defined as a bone division to correct a deformity.[10] Despite these measures, a large percentage of foot pain remains, especially in the elderly.[11] Because of the limited response of chronic foot and toe pain to traditional therapies, many people are turning to alternative therapies including Prolotherapy for pain control, because it addresses the underlying cause of the problem, ligament injury or weakness.[12, 13]

The foot, if we include the toes and ankle, contains 26 bones, 33 joints and more than 100 muscles, tendons and ligaments. The function of cartilage is to provide a cushion and allow ease of motion between these various joints. When there is insufficient ligament support to stabilize joint motion, the resultant increase in joint laxity leads to the development and acceleration of articular cartilage injury, commonly known as osteoarthritis, another frequent diagnosis related to foot and toe pain. (Degenerative joint disease is a more apt description as this process of cartilage breakdown is not inflammatory in nature.) Other joints susceptible to degenerative joint disease include the knees, hips, shoulders, fingers and spine due to their supportive ligament structures that can become damaged.[14]

Prolotherapy is becoming a widespread form of pain management in both complementary and allopathic medicine. Its primary use is in the pain management associated with tendinopathies and ligament sprains in peripheral joints.[15, 16] It is also being used in the treatment of spine and joint degenerative arthritis.[17, 18] In double-blinded human studies the evidence on the effectiveness of Prolotherapy is still being debated, with promising but mixed results being reported.[19-21]

George S. Hackett, MD coined the term Prolotherapy.[22] As he described it, "The treatment consists of the injection of a solution within the relaxed ligament and tendon which will stimulate the production of new fibrous tissue and bone cells that will strengthen the 'weld' of fibrous tissue and bone to stabilize the articulation and permanently eliminate the disability."[23] Dr. Hackett introduced Prolotherapy to Gustav Hemwall, MD in the mid 1950s. Dr. Hemwall continued Dr. Hackett's work after his death in 1969, and trained the majority of physicians who practiced the technique, over the next 30 years. Hence, the designation Hackett-Hemwall Prolotherapy was born.

Animal studies have shown that Prolotherapy induces the production of new collagen by stimulating the normal inflammatory reaction.[24, 25] In addition, animal experiments have shown improvements in ligament and tendon diameter and strength, as evidenced upon post-mortem exam.[26, 27] While Prolotherapy has a long

history of being used for unresolved foot and toe pain,[28] no study has been done to date to show its effectiveness. This observational study was undertaken to evaluate the effectiveness of Hackett-Hemwall dextrose Prolotherapy in regard to reducing the subjects' previously unresolved foot and toe pain, stiffness, and their need for medications, in addition to improving other quality of life measures.

Patients And Methods

FRAMEWORK AND SETTING

In October 1994, the primary authors (R.H., M.H.) started a Christian charity medical clinic called Beulah Land Natural Medicine Clinic in an impoverished area in southern Illinois. The primary modality of treatment offered was Hackett-Hemwall dextrose Prolotherapy for pain control. Dextrose was selected as the main ingredient in the Prolotherapy solution because it is the most common proliferant used in Prolotherapy, is readily available, inexpensive (compared to other proliferants), and has a high safety profile.[29] The clinic met every three months until July 2005. All treatments were given free of charge.

PATIENTS

Patients who received Prolotherapy for their unresolved foot and toe pain in the years 2002 to 2005 were called by telephone and interviewed by a data collector (D.P.) who had no prior knowledge of Prolotherapy. General inclusion criteria were an age of at least 18 years, having an unresolved foot or toe pain condition that typically responds to Prolotherapy, and a willingness to undergo at least four Prolotherapy sessions, unless the pain remitted with fewer Prolotherapy sessions. The foot, for purposes of this study, included the area in front of the ankle (cuneiform, navicular) to the metatarsals, metatarsal heads and phalanges. It did not include the heel (calcaneous) or ankle (tibia and fibula). Conditions that typically respond to Prolotherapy include metatarsalgia, degenerative arthritis, as well as tendon and ligament injuries of the foot.

INTERVENTIONS

The Hackett-Hemwall technique of Prolotherapy was used. Each patient received 10 to 30 injections of a 15% dextrose, 0.2% lidocaine solution with a total of 6 to 40 cc of solution used per foot and toe. Injections were given into and around the areas on the foot that were painful and/or tender to touch. The typical areas injected each with 0.5 to 1cc of solution can be seen in *Figure 1*. Tender areas injected included the metatarsal joints, metatarsal, cuneiforms, and navicular bones, as well as ligament and tendon attachments on the foot. In regard to toe pain, the metatarsophalangeal joints, the proximal interphalangeal joints and the proximal interphalangeal joints were injected if painful and/or tender to the touch. If applicable, the patients were asked to decrease or stop pain medications and therapies they were using, as much as the pain would allow.

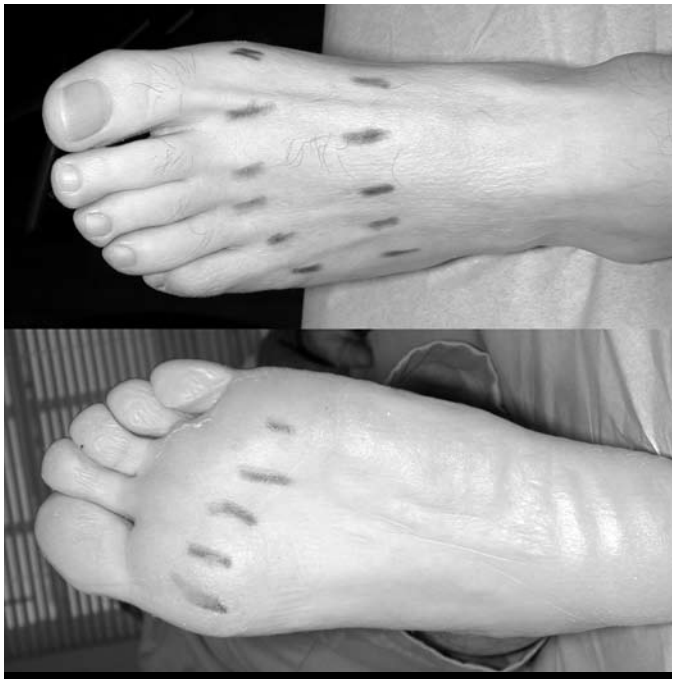

Figure 1. Typical Prolotherapy injection sites for Hackett-Hemwall dextrose Prolotherapy of the foot.

OUTCOMES

D.P. was the sole person obtaining the patient information during the telephone interviews. The patients were asked a series of questions about their pain and previous treatments before starting Prolotherapy. Their response to Prolotherapy was also detailed with an emphasis on the effect Prolotherapy had on their need for subsequent pain treatments and their quality of life. Specifically, patients were asked questions concerning length of pain, pain intensity, stiffness, number of physicians seen and medications taken, quality of life concerns, psychological factors and whether the response to Prolotherapy continued after the Prolotherapy session stopped.

Analysis

For the analysis, patient percentages of the various responses were calculated. These responses gathered from patients before Prolotherapy were then compared with the responses to the same questions after Prolotherapy. The patient percentages were also calculated for clients who answered "*Yes*" to the following question: "*Before starting Prolotherapy it was the consensus of the my MD(s) that there were no other treatment options that he knew of to get rid of my chronic pain?*"

PATIENT CHARACTERISTICS

Complete data was obtained on a total of 19 feet who met the inclusion criteria. Of these, 74% (14) were female and 26% (5) were male. The average age of the patients was 56 years-old. Patients reported an average of four years, six months of pain and on average they saw 2.6 MD's before receiving Prolotherapy. The average patient was taking 1.1 pain medications. Forty-two percent (8) stated that the consensus of their medical doctor(s) was that there were no other treatment options for their chronic pain. The demographics of the patients can be seen in *Table 1*.

Table 1. Foot patient demographics.

Foot patients	19
Average age of foot patients	56
Average number of MD's seen	2.6
Average years of pain	4.5
Average number of pain meds prior to Prolotherapy	1.1
Average number of pain meds after Prolotherapy	0.2
Percentage of male patients	74%
Percentage of female patients	26%

TREATMENT OUTCOMES

Patients received an average of 3.1 Prolotherapy treatments per foot/toes. The average time of follow-up after their last Prolotherapy session was 18 months.

Patients were asked to rate their pain and stiffness levels on a scale of 1 to 10 with 1 being no pain/stiffness and 10 being severe crippling pain/stiffness. All 19 patients reported pain as a symptom, 10 of the 19 reported stiffness as a symptom. The patients had an average starting pain level of 7.1 and stiffness level of 7.0. The average ending pain and stiffness levels were 2.3 and 2.8 respectively. Sixty-three percent had a starting pain level of 7 or greater, while none had a starting pain level of three or less, whereas after Prolotherapy only 6% (one patient) had a pain level of 7 or greater, while 79% had a pain level of three or less. One-hundred percent of the 9 patients reporting stiffness as a symptom had a stiffness level of 5 or greater before Prolotherapy. (*See Figure 2.*)

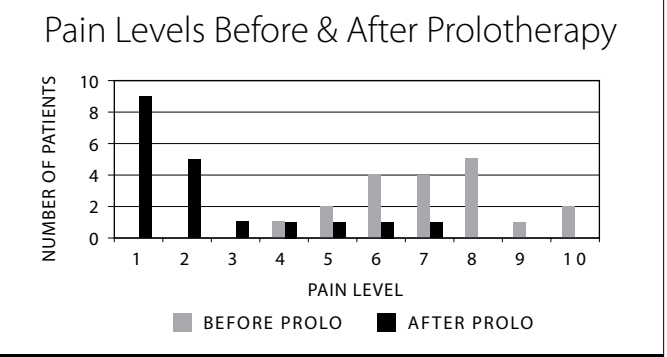

Figure 2. Pain levels before and after receiving Hackett-Hemwall dextrose Prolotherapy in 19 patients with unresolved foot pain.

One-hundred percent of patients stated their pain and stiffness were improved after Prolotherapy. Over 73% percent said the improvements in their pain and stiffness since their last Prolotherapy session have continued 100%. Eighty-four percent of patients stated Prolotherapy relieved at least 50% of their pain. Sixty-three percent received greater than 75% pain relief. All 100% of patients experienced at least 25% pain relief with Prolotherapy. In regard to pain medication usage, before Prolotherapy the average patient was taking 1.1 pain medications but this decreased to 0.2 medications after Prolotherapy.

In regard to quality of life issues prior to receiving Prolotherapy, 58% of patients had a compromised walking ability, but this decreased to 26% after Prolotherapy. Specifically, 37% could walk 3 blocks or less before Prolotherapy, decreasing to 5% (1 patient) that could only walk 3 blocks or less after Prolotherapy. (*See Figure 3.*)

In regard to exercise or athletic ability prior to Prolotherapy, 74% said it was compromised, but after Prolotherapy this decreased to 63%. Before Prolotherapy, only 58%

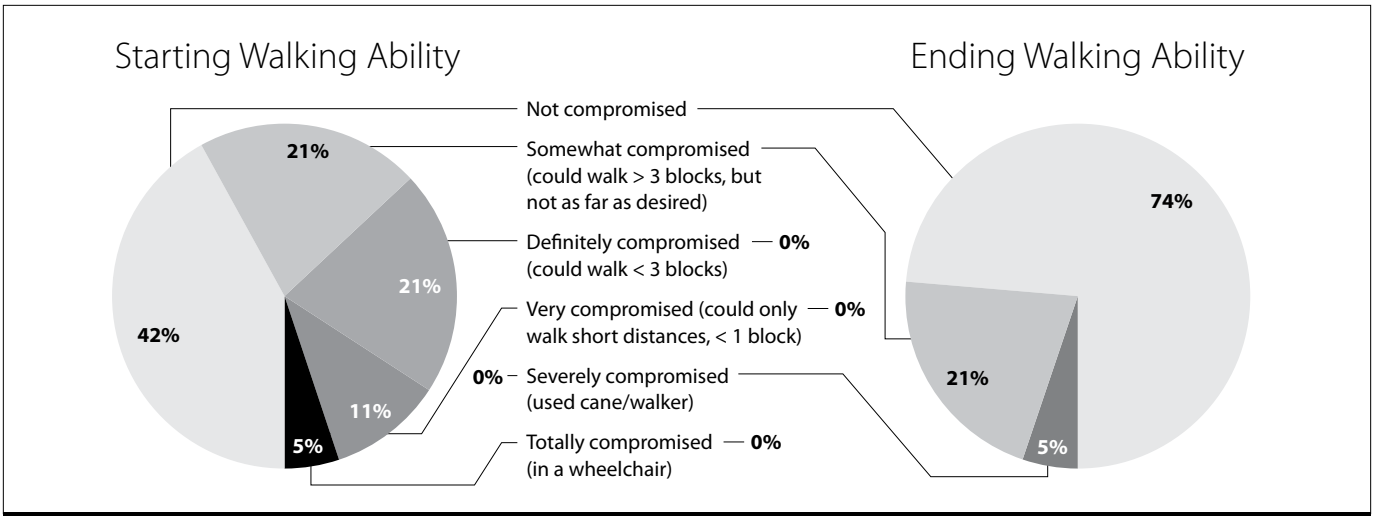

Figure 3. Walking ability before and after Hackett-Hemwall dextrose Prolotherapy in 19 patients with unresolved foot pain.

could do 30 minutes or more of exercise, whereas after Prolotherapy this increased to 95%. (*See Figure 4.*)

Prior to Prolotherapy, 48% of patients had feelings of depression and 58% had feelings of anxiety. After Prolotherapy, only 16% had depressed feelings and 16% had feelings of anxiety. (*See Figures 5 & 6.*)

In regard to sleep, 53% of patients felt their foot/toe pain interrupted their sleep. After Prolotherapy, 90% of this group had improvements in their sleeping ability.

To a simple yes or no question "*Has Prolotherapy changed your life for the better?*" 100% of patients treated answered "*Yes.*" Eighty-four percent of patients rated the Prolotherapy as successful for them (50% or greater pain relief). Sixty-three percent rated it as very successful (75% or greater pain relief). Sixty-eight percent stated that the results from Prolotherapy have very much continued to this day (75% or greater). Ninety-five percent of patients knew someone who had received Prolotherapy. Seventy-nine percent came to receive their first Prolotherapy session because of the recommendation of a friend. One-hundred percent of patients have recommended Prolotherapy to someone.

RESULTS FOR THOSE WHOSE MD'S SAID NO OTHER TREATMENT OPTION AVAILABLE

As previously noted, 42% of patients (8 in number) prior to Prolotherapy were told that there were no other treatment options for their pain. As a group, they suffered with pain on average 54 months. In analyzing these patients, they had a starting average pain level of 7.4 and after Prolotherapy of 3.2. Prior to Prolotherapy, 88% of the patients rated their pain as a level 8 or higher and none rated it a 4 or less. Prior to Prolotherapy, they rated their foot stiffness as a 5.0 and ending of 2.5. All eight patients had improvements in pain and stiffness levels. Six of the eight (75%) had 50% or greater pain relief. All had 25% or greater pain relief. As a group, they were on an average of 2.5 pain medications before Prolotherapy, but this decreased to 0.3 medications after completing treatment.

Discussion

PRINCIPLE FINDINGS

The results of this retrospective, uncontrolled observational study demonstrate that Hackett-Hemwall dextrose Prolotherapy helps decrease pain and improve the quality of life of patients with unresolved foot and toe pain. This treatment gave 63% of patients greater than 75% pain relief, and 84% of patients achieved 50% or more pain relief. One-hundred percent of patients stated their pain and their life in general was better after receiving Prolotherapy. Notable improvements in other quality of life issues included depression, anxiety, sleep, walking ability, exercise ability and medication usage.

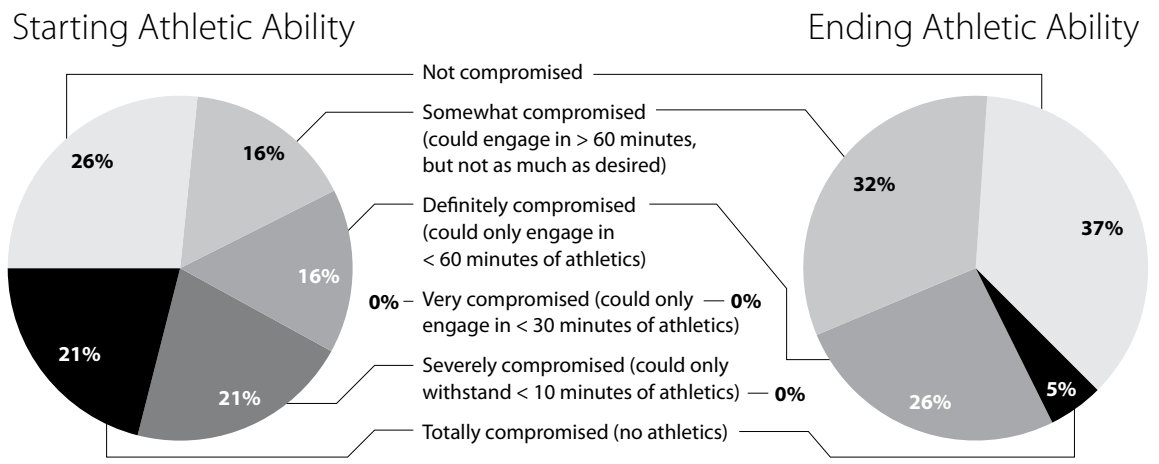

Figure 4. Athletic ability before and after Hackett-Hemwall dextrose Prolotherapy in 19 patients with unresolved foot pain.

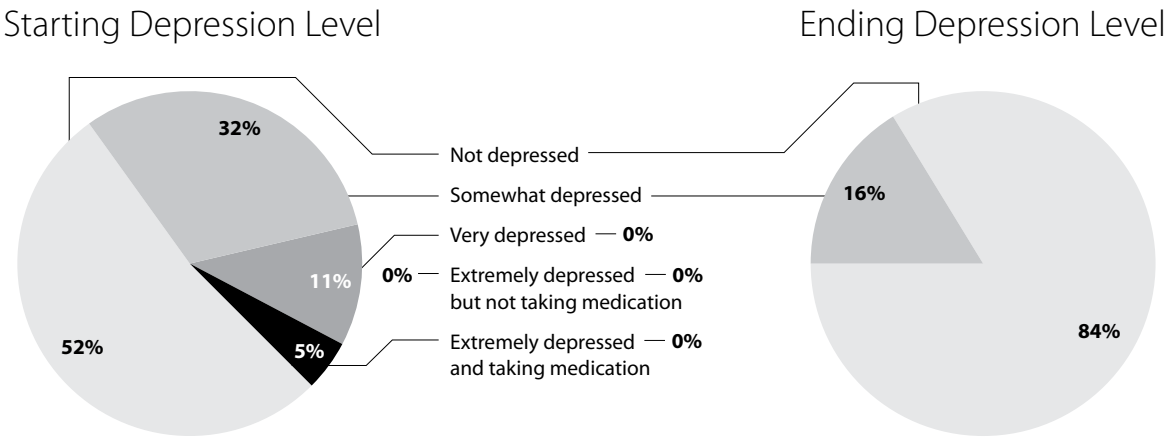

Figure 5. Depression level before and after Hackett-Hemwall dextrose Prolotherapy in 19 patients with unresolved foot pain.

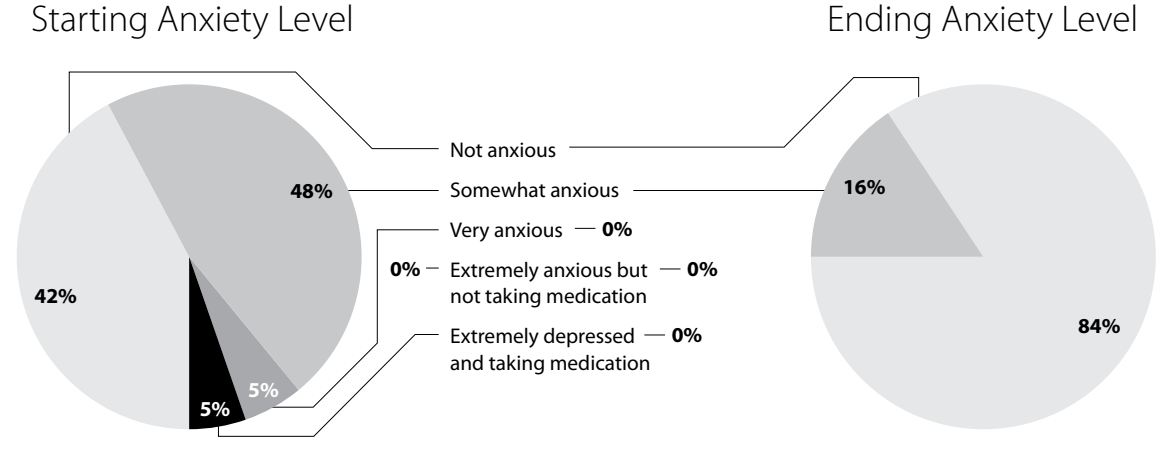

Figure 6. Anxiety level before and after Hackett-Hemwall dextrose Prolotherapy in 19 patients with unresolved foot pain.

For the 42% (8) of patients who stated their doctors said no other treatment options were available for their pain, the results were very similar. Clinically relevant decreases in pain and stiffness were also seen in this subgroup.

STRENGTHS AND WEAKNESSES

Our study cannot be compared to a clinical trial in which an intervention is investigated under controlled conditions. Instead, it is aimed to document the response of patients with unresolved foot and toe pain to the Hackett-Hemwall technique of dextrose Prolotherapy at a charity medical clinic. Clear strengths of the study are the numerous quality of life parameters that were examined. Such quality of life issues as walking ability, stiffness, athletic (exercise) ability, sleep, anxiety and depression, in addition to pain level, are important factors affecting the person with unresolved foot/toe pain. Decreases in medication usage were also documented. The improvement in such a large number of variables treated solely by Prolotherapy is likely to have resulted from Prolotherapy. So while there is no medical test to document pain improvement or the progress with Prolotherapy, an increased ability to walk, exercise, work and use less medications are objective changes.

The quality of the cases treated in this study is also a strength. The average person in this study had unresolved foot or toe pain for four years six months, and eight (42%) of the patients were either told by their MD(s) that there was no other treatment option for their pain. So clearly this patient population represented *chronic* unresponsive foot and toe pain. A follow-up since their last treatment of an average of eighteen months since their last Prolotherapy session was also a strength.

Because this was a charity medical clinic with limited resources and personnel, the only therapy that was used was Prolotherapy. The Prolotherapy treatments could only be given every three months. In private practice, the Hackett-Hemwall technique of dextrose Prolotherapy is typically given every four to six weeks. If a patient is not improving or has poor healing ability, the Prolotherapy solutions may be changed and/or strengthened or the patient is advised on additional measures to improve their overall health. This can include advice on diet, supplements, exercise, weight loss, changes in medications, additional blood tests, and/or other medical care. Often patients are weaned immediately off of anti-inflammatory and narcotic medications that inhibit the inflammatory response that is needed to produce a healing effect from Prolotherapy. Since this was not done in this study, the results at this charity clinic are an indication of the lowest level of success with Hackett-Hemwall dextrose Prolotherapy. This makes the results even that much more impressive.

A shortcoming of our study is the subjective nature of some of the evaluated parameters. Subjective parameters of this sort included pain, stiffness, anxiety, and depression levels. The results relied on the answers to questions by the patients. Changes in these parameters that occurred with Prolotherapy were analyzed by an independent data analyst. No X-ray and MRI correlation for diagnosis and response to treatment was observed. Lack of documentation in the patients' charts of physical examinations made categorization of the patients into various diagnoses categories impossible.

INTERPRETATION OF FINDINGS

Hackett-Hemwall dextrose Prolotherapy was shown to be very effective in eliminating pain and improving the quality of life in this group of patients with unresolved foot and toe pain. This included the subgroup of patients who were told by their MD(s) that no other treatment options were available for their pain. Current conventional therapies for unresolved foot pain include medical treatment with analgesics, non-steroidal anti-inflammatory drugs, anti-depressant medications, steroid shots, trigger point injections, muscle strengthening exercises, physiotherapy, weight loss, rest, massage therapy, manipulation, orthotics, surgical treatments including fusions, multidisciplinary group rehabilitation, education and counseling. The results of such therapies often leave the patients with residual pain.[30-32] Because of this, many patients with chronic foot pain are searching for alternative treatments for their pain. Searching for alternatives, simply put, are patients who either cannot find relief with traditional therapies or do not like the options, especially if surgery is recommended. One of the treatments that chronic foot/toe pain patients are trying instead of surgery is Prolotherapy.[33]

Prolotherapy is the injection of a solution for the purpose of tightening and strengthening weak tendons, ligaments or joint capsules. Damage to connective tissues such as these can cause misalignment of the joint surfaces. Metatarsophalangeal (forefoot/toe) pain most commonly results from misalignment of the joint surfaces with

altered foot biomechanics, causing joint subluxations, capsular impingement and joint cartilage destruction (osteoarthrosis).[34] Many forefoot deformities such as hallux rigidus (bunion) result from the failure of deep transverse ligaments in the sole of the foot, allowing for an abnormal "splay" of the forefoot which progressively worsens, causing the big toe (hallux) to drift and become deformed.[35] Prolotherapy works by stimulating the body to repair these soft tissue structures. It starts and accelerates the inflammatory healing cascade by which fibroblasts proliferate. Fibroblasts are the cells through which collagen is made and by which ligaments and tendons repair. Prolotherapy has been shown in one double-blinded animal study in a six-week period to increase ligament mass by 44%, ligament thickness by 27% and the ligament-bone junction strength by 28%.[36] In human studies on Prolotherapy, biopsies performed after the completion of Prolotherapy showed statistically significant increases in collagen fiber and ligament diameter of 60%.[37, 38] Ligament injury has been implicated as the cause of degenerative osteoarthritis in joints.[39] This is significant since a potential cause of unresolved foot pain is ligament weakness, such as in the calcaneonavicular (spring) ligament, which can lead to flattening of the arch and degenerative osteoarthritis. Ligament injury is also a potential cause of metatarsalgia.[40] Thus, Prolotherapy has the potential to stop the degenerative joint disease process and some preliminary and anecdotal evidence shows that in some cases it can reverse it.[41]

Conclusions

The Hackett-Hemwall technique of dextrose Prolotherapy used on patients who had an average duration of four years of unresolved foot pain, who were eighteen months out from their last Prolotherapy session, was shown in this observational study to improve quality of life. The patients reported less pain, stiffness, depressed and anxious thoughts, medication usage, as well as improved walking ability, sleep and exercise ability. This included patients who were told by their medical doctor(s) there were no other treatment options for their unresolved foot pain. Further research is needed to confirm the results found in this retrospective study. Although studies with larger patient populations in more controlled settings are needed to properly document the efficacy of Hackett-Hemwall dextrose Prolotherapy, this treatment should be seriously considered for people suffering with unresolved foot and toe pain based on risk/reward parameters. ■

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