ORIGINAL RESEARCH

Effective Use of Dextrose-Prolotherapy within the Scope of Osteopathic Family Medicine

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KEYWORDS:

Prolotherapy

Hyperosmolar Dextrose

Injection Therapy

Tendinopathy

Chronic Musculoskeletal Pain

Background: Chronic pain is prevalent and often managed by family medicine-OMT (FM-OMT) physicians. By triggering the body's own healing mechanisms, prolotherapy embraces Osteopathy's second tenet, "The body is capable of self-regulation, self-healing, and health maintenance." Little has been reported to describe its utilization in FM-OMT or to formally designate its suitability to the scope of practice. **Hypothesis:** When prolotherapy is introduced within an existing FM-OMT practice, it can be delivered safely, pain scores will improve compared to baseline, and patient-preference toward prolotherapy will develop. **Methods:** 43 unique, adult patients (57 treatment areas) were treated with prolotherapy within the scope of practice of a FM-OMT physician over 15 months. The primary outcome measure was change in the 11- point numerical pain rating scale (NPRS). **Results:** 60.5% of participants reported pain improvement. 52.6% of treatment areas improved. 30.2% of participants requested treatment of an additional pain location. When adjusted for attrition, 73.2% of treatment areas improved from a total average NPRS score of 8 (standard error (SE) = 1.41) to 6.5 (SE = 2.83) (p-value <0.001), representing an 18.8% improvement. No significant complications were reported for the 170 treatments. **Conclusion**: Prolotherapy can be safely utilized within the scope of practice of FM-OMT physicians with improvement in patient-reported pain scores compared to baseline. Spontaneous development of patient-preference toward prolotherapy as a treatment for pain occurs. Additional research with a control group is warranted to further explore these outcomes.

INTRODUCTION

As of 2011, the prevalence of chronic pain in the general population of the United States has been estimated to be as high as 116 million adults.[1] If chronic pain is managed medically, it is typically done in the primary care setting. A modality that is underutilized in this setting, which has the potential to improve the care for those with chronic pain, is prolotherapy. Prolotherapy is a complementary injection-based therapy for chronic musculoskeletal pain that requires specialized training[2] and is used by providers of various allopathic and osteopathic specialties to treat pain conditions resulting from ligament and joint laxity,[3] low back pain, osteoarthritis, and tendinopathy.[2] Injections are often guided by palpation. Favorable outcomes have been reported in the treatment of lateral epicondylosis,[4, 5] Achilles tendinosis,[6, 7] groin pain,[8] plantar fasciitis,[9] and knee osteoarthritis.[10] While the exact mechanism of action has not been clearly established, various prolotherapy solutions ("proliferants") exist, and each may have a different mechanism of action. Proposed mechanisms include cellular irritation, chemotaxis of inflammatory mediators, sclerosis of pathologic neovascularity, and release of growth factors.[2, 11] Traditionally, the injection of proliferant has been hypothesized to stimulate localized irritation and inflammation that ultimately promotes healing of tissue and reduction of pain.[2, 3, 5, 7]

Prolotherapy is potentially a useful addition to the scope of practice of FM-OMT physicians. The skill of palpation used by osteopathic physicians utilizing osteopathic manipulative treatment (OMT) in clinical practice is likely to lend itself well to the recognition of ligament-laxity on physical examination, and also to effectively implement prolotherapy. Despite the utility of integrating prolotherapy within the FM-OMT scope of practice, little has been reported in the literature to describe the outcomes of doing so, the safety of implementation, and patient response to the offering. This study serves to describe observations after one year of implementation of dextrose-prolotherapy into an established osteopathic family physician's practice.

METHODS

Dextrose-prolotherapy (15% dextrose in 1% lidocaine) was utilized in an established osteopathic family practice for one year. Participants were enrolled over the course of 12 months as part of the routine family practice. Treatment sessions were completed within the year of the study. Outcomes were recorded for the year of implementation plus an additional three months for the purpose of surveillance of those whose treatment sessions occurred in the latter portion of the year-long study interval. Treatment was offered by

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an osteopathic family physician with specialized training in prolotherapy,[2] † who was a member of a larger family medicine group.

Adults aged 25 to 86 years from the primary care practice were enrolled (Table 1). Inclusion criteria included: the existence of pain conditions secondary to ligament-laxity; tendinopathy; or other indications as noted previously.[2-9] Diagnoses were made clinically by evidence of ligament-laxity on physical examination, tissue-texture abnormality and tenderness at entheses, or by demonstration of tendinosis on imaging. Participants did not have typical absolute contraindications for the implementation of prolotherapy (active local infection, such as cellulitis or abscess) or relative contraindications (acute gouty arthritis or acute fracture).[2] Prolotherapy was offered for all typical treatment locations other than the axial cervical spine.

The primary outcome measure was the amount of change in the 11-point numerical pain rating scale (NPRS) (0 = no pain; 10 = worst pain). This was assessed via paper visual questionnaire or verbal interview. The scale was assessed prior to each treatment session. If the final NPRS for a participant was unknown at the end of the study, the participant was contacted by telephone and asked for a final NPRS value verbally. If a participant reported improvement in the NPRS after prolotherapy, but later required a more definitive procedure, such as surgery, the treatment area was not included in the results section as improved.

Prolotherapy injections were implemented by palpation-guidance; no external modalities were used to assist in needle placement. Treatments were done no more frequently than at intervals of two weeks. Participation was voluntary and data were acquired observationally, not at prescribed intervals. Participants were billed a nominal fee for prolotherapy. No commitment was required to participate in follow-up treatments or evaluations. No incentive was offered for participation. The provider was not incented to perform prolotherapy. All follow-up treatments were initiated at the discretion of the participant and were not directed or requested by the provider. Treatment with prolotherapy did not exclude the continuation of additional concurrent treatment modalities, such as physical therapy or OMT. Avoidance of non-steroidal anti-inflammatory drug (NSAID) use was recommended in the days immediately following prolotherapy sessions.

TABLE 1

Baseline Participant Characteristics
(participants = 43, treatment areas = 57)

Female, n (%); Male, n (%)	27 (62.8%); 16 (37.2%)
Age, years, mean (SD)	52 (4.9)
Female treatment areas, n (%); Male treatment areas, n (%)	35 (61.4%); 22 (38.6%)

RESULTS

Over the course of one year, 43 unique participants aged 25 to 86 years, who had pain that persisted in duration from one week to 35 years, were enrolled into treatment with prolotherapy. 27 participants were female; sixteen were male. Locations of treatment included low-back/pelvis/sacroiliac region, shoulder, knee, hip, elbow, wrist, ankle, hand, and

TABLE 2

Locations of Pain, Number of Areas by Location, Number of Areas by Location with Improvement Compared to Baseline, and Chronic Pain Improvement by Location Compared to Baseline

Location of Pain	Total Number of Pain Areas (by location)	Total Number of Improved Pain Areas (by location) and (n) that were chronic
Low Back/Pelvis/ Sacro-Iliac	20	8 (8)
Shoulder	11	7 (6)
Knee	8	2 (1)
Hip	7	7 (7)
Elbow	6	3 (2)
Wrist	2	1 (0)
Ankle	1	1 (1)
Hand	1	0 (0)
Ribs	1	1 (1)
Total	57	30 (26)

ribs/thoracic spine (Table 2). Pain in each identified body region was individually assessed using the NPRS. The average number of treatments per area was three, and the range of treatments was one to 16. Using 11-point NPRS, 60.5% of participants reported improvement in pain (26 of 43 patients). If a participant requested more than one location be treated, the 11-point NPRS scores for each location were analyzed individually, and the participant accounted for more than one area of treatment. This resulted in a total of 57 unique treatment areas. Thirty-five treatment areas pertained to female participants; twenty-two treatments areas pertained to male participants.

In total, 43 unique participants contributed 57 unique treatment areas to the analysis. Improvement in pain was reported for 30 of the 57 unique treatment areas (52.6%). Acknowledging that a clinically important pain improvement is made when a two-point or greater improvement in the 11-point NPRS11 is achieved, 18 of 57 treatment areas (31.6%) met this criterion. Of the treatment areas that improved, 18 of 30 (60%) were clinically important. Forty-nine of the 57 total treatment areas were areas of chronic pain (86.0%), with chronic pain defined as pain persisting for more than three months. Improvement in pain was reported for 26 of the 49 chronic pain locations (53.1%), while four of eight non-chronic pain areas showed improvement in pain (50.0%) (Table 3). The cumulative number of treatments for the study was 170.

Of the 27 total treatment areas that did not demonstrate improvement compared with baseline, three treatment areas were lost to follow-up (5.3% of total treatment areas), eight treatment areas ultimately had a secondary procedure (14.0%), and four treatment areas were still receiving prolotherapy at the end of the recording period (7.0%). The total number of treatment areas lost to follow-up, receiving secondary treatment, or continuing to receive prolotherapy was 15 (26.3% of total treatment areas) (Figure 1).

When data are adjusted for participants lost to surgery (8), lost to follow up (3), lost to re-injury (2), and those who could not accurately describe initial pain (3), there were 32 unique patients with 41 unique treatment areas. Thirty treatment areas (73.2%) showed improvement (Table 4).

FIGURE 1

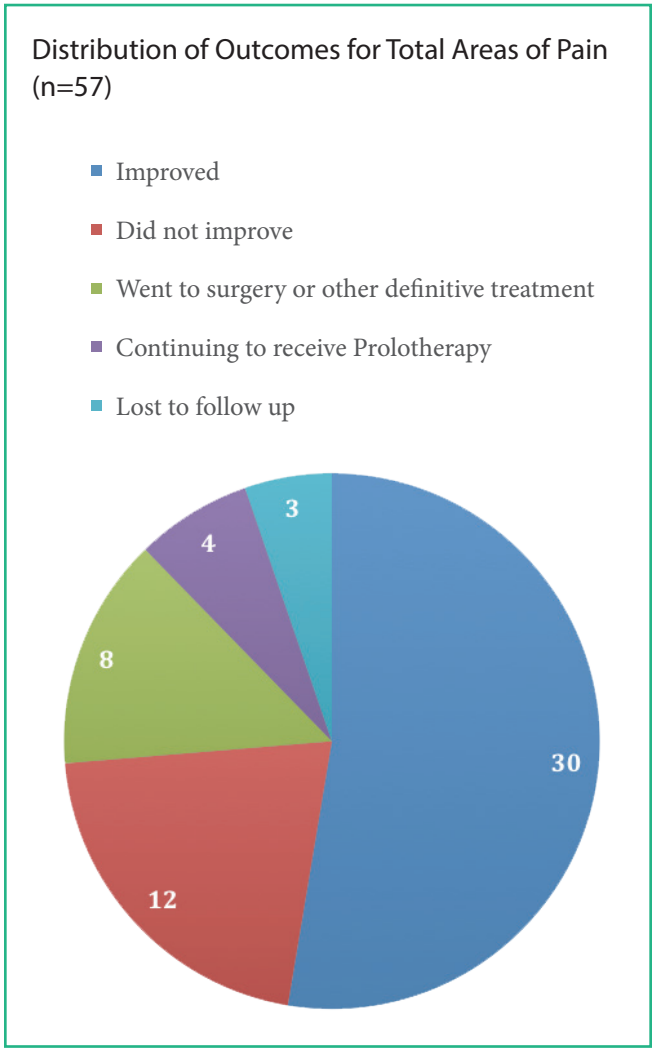

TABLE 3

Number of Treatment Areas of Chronic Pain and Non-Chronic Pain with Reported Improvement Compared to Baseline

	Number of Treatment Areas	Number of Areas with Improvement	Percent of Areas with Improvement
Areas of Chronic Pain	49	26	53.1%
Areas of Non-chronic Pain	8	4	50.0%
Total Areas	57	30	52.6%

TABLE 4

Change in 11-point NPRS Compared to Baseline (after data adjustment)

	Baseline Score	Change in Score Compare to Baseline	p-value
Total Average 11-point NPRS Score and Change in Score, (SE)Areas of Non-chronic Pain	8 (1.41)	-1.5 (2.83)	< 0.001
% total of 11-point NPRS Score Improvement	N/A	18.8%	N/A

During the 15 months the study was observed, there were no significant complications, such as allergic reaction, pneumothorax, nerve injury, infection, or hematoma. Two treatments (1.2% of total treatments) resulted in brief, amplified, post-procedural pain. In both cases, prednisone was prescribed and pain resolved.

Over the course of the study, 13 of the 43 unique participants (30.2%) spontaneously requested treatment with prolotherapy for an additional area of pain other than the treatment area for which he or she was originally enrolled.

DISCUSSION

This uncontrolled, observational study is a report of successful implementation of dextrose-prolotherapy as a general offering for multiple body locations within the scope of the FM-OMT practice setting, and demonstrates a positive effect in this clinical context for treatment of multiple locations of chronic pain on an 11-point NPRS compared with baseline status.

Previous studies suggest that prolotherapy is beneficial when compared with baseline status for several specific pain conditions, and randomized controlled trials continue to emerge.[4, 6-10, 12-15] While most studies are location-specific and utilize various scales for surveillance of treatment outcome, this study serves to suggest a utility of prolotherapy within the context of a typical family practice in which numerous pain conditions present, and highlights the patient-centered simplicity of the NPRS for treatment surveillance, which is common to the routine clinical setting.

Prolotherapy can be safely added to the scope of a FM-OMT practice when the provider has had additional specialized training. The osteopathic skill of palpation that is utilized in OMT lends itself well, logically, uniquely, and safely to diagnose ligament or tendon laxity/injury and to implement prolotherapy. For the duration of the 15 months in which the study took place, only two brief, self-limited complications were noted.

Participants experienced improvement in chronic pain; 86% of the areas treated in this study were areas of chronic pain. At least 53.1% of the total treatment areas had improvement in pain reported; 73.2% showed improvement after data correction. The participants largely enrolled from non-referral sources, and most had not found benefit with standard treatment modalities. Within the context of the FM-OMT setting, there was meaningful improvement of chronic pain compared with baseline that was unlikely to be realized otherwise.

Prolotherapy can become a treatment of choice for those who receive it. Most participants who entered the study had no prior knowledge of prolotherapy–only one participant had received prolotherapy prior to the study. Nearly one-third (30.2%) of participants spontaneously requested treatment with prolotherapy for an additional area of pain other than the treatment area for which they were originally enrolled. These data suggest that those who receive prolotherapy develop confidence in its use as an effective treatment independently of the potential bias of the provider.

DISCUSSION

Dextrose-prolotherapy can be safely utilized within the scope of practice of FM-OMT physicians with improvement in patient-reported pain scores compared with baseline. Patient preference of prolotherapy as a treatment for pain spontaneously occurs. Additional research with a control group is warranted to further explore these outcomes.

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