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Hypertonic dextrose injection (prolotherapy) for knee osteoarthritis: Long term outcomes

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Summary
Objective: Knee osteoarthritis (OA) is a common, debilitating chronic disease. Prolotherapy is an injection therapy for chronic musculoskeletal pain. Recent 52-week randomized controlled and open label studies have reported improvement of knee OA-specific outcomes compared to baseline status, and blinded saline control injections and at-home exercise therapy ($p < 0.05$). However, long term effects of prolotherapy for knee OA are unknown. We therefore assessed long-term effects of prolotherapy on knee pain, function and stiffness among adults with knee OA.
Design: Post clinical-trial, open-label follow-up study.
Setting: Outpatient; adults with mild-to-severe knee OA completing a 52-week prolotherapy study were enrolled.
Intervention and outcome measures: Participants received 3–5 monthly interventions and were assessed using the validated Western Ontario McMaster University Osteoarthritis Index, (WOMAC, 0–100 points), at baseline, 12, 26, 52 weeks, and 2.5 years.
Results: 65 participants (58 ± 7.4 years old, 38 female) received 4.6 ± 0.69 injection sessions in the initial 17-week treatment period. They reported progressive improvement in WOMAC scores at all time points in excess of minimal clinical important improvement benchmarks during the initial 52-week study period, from 13.8 ± 17.4 points (23.6%) at 12 weeks, to 20.9 ± 2.8 points, ($p < 0.05$; 35.8% improvement) at 2.5 ± 0.6 years (range 1.6–3.5 years) in the current follow-up analysis. Among assessed covariates, none were predictive of improvement in the WOMAC score.

Abbreviations: RCT, randomized controlled trial; BMI, body mass index; WOMAC, Western Ontario McMaster University Osteoarthritis Index; KPS, knee pain scale; MCII, minimal clinical important improvement.

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Conclusions: Prolotherapy resulted in safe, significant, progressive improvement of knee pain, function and stiffness scores among most participants through a mean follow-up of 2.5 years and may be an appropriate therapy for patients with knee OA refractory to other conservative care.
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Introduction

Knee osteoarthritis (OA) is a chronic disease; knee pain, stiffness, and functional impairment are common sequelae. Knee OA is common and age-related;[1] 33.6% of those over 65 years of age will have knee OA,[2] conferring substantial expense for patients and society. The etiology of knee OA pain is multifactorial; pain generators include both intra-articular and supportive extra-articular structures.[3,4] Standard-of-care is multidisciplinary; however, a recent systematic review reported no clear benefit of commonly used therapies.[5] The Institute of Medicine has identified assessment of knee OA treatment strategies as a ''top 100'' comparative effectiveness research priority[6] and the Agency for Healthcare Research and Quality has called for the development of new therapies to treat knee OA.[5]

Prolotherapy is a complementary and alternative medical (CAM) injection therapy for chronic musculoskeletal pain, including knee OA.[7–9] It has been categorized as a regenerative injection techniques for musculoskeletal pain by some researchers.[10] Small volumes of an irritant solution are injected at multiple tender ligament and tendon attachments and in adjacent joint spaces during several treatment sessions.[7] The earliest description of prolotherapy to appear in the allopathic medical literature was in 1937 in a case report for temporomandibular joint, in which the modality was called 'sclerotherapy' due to the scar-forming properties of early injectants.[11] Contemporary injection techniques date from the 1950s when the more commonly used term 'prolotherapy' (from 'proliferant therapy') was adopted based on the observation that ligamentous tissue exhibited larger cross-sectional area after prolotherapy injections in animal models.[12] The mechanism of action remains unclear. Hypotheses include stimulation of local healing through inflammatory or sensorineural mechanisms,[13–15] but definitive evidence is lacking.[7] Hypertonic dextrose is the most commonly used injectant.[7] Prolotherapy may be well-suited to address the multifactorial etiology of symptomatic knee OA because injections target multiple potential pain-generating sites in and around the knee joint; positive one-year outcomes have been reported in three studies,[16–18] however the long term effects of prolotherapy in participants with knee OA are not known. We therefore enrolled participants from one completed 52-week randomized controlled clinical trial[18] and two completed 52-week non-controlled trials[16,17] in an open-label follow-up study to assess the hypothesis that adults with symptomatic knee OA who received prolotherapy will report progressive improvement on a validated assessment of knee pain, stiffness and function up to 3.5 years after initiating treatment.

Materials and methods

Context

The study protocol is part of a larger body of work; each individual study was approved by the University of Wisconsin Health Institutional Review Board. The clinical trials identifier of the project as a whole is NCT00085722. In two 52-week uncontrolled open label studies and one randomized controlled study, our group has reported improvement in self-reported knee OA-specific pain, function and stiffness compared to baseline status,[16,17] and blinded saline control injections and at-home exercise therapy,[18] in reponse to prolotherapy. The eligibility criteria and injection protocols of the three prior trials were nearly identical; the primary outcome measure in each was the Western Ontario McMaster University Osteoarthritis Index (WOMAC) questionnaire, a validated, responsive questionnaire evaluating knee OA severity using pain, stiffness, and function subscales.[19] The improvement among participants receiving prolotherapy in each study was similar: 15.9 ± 2.5 points in ''Open Label 1'',[16] (Fig. 1) 12.4 ± 3.5—19.4 ± 7.0 points in Open Label 2,[17] and 15.3 ± 3.5 points in the randomized controlled trial.[18]

Study design

Post clinical-trial open-label follow-up study assessing self-reported outcomes among participants up to 3.5 years after enrollment in three prior studies.

Participants

The primary inclusion criteria for the current study were: receiving prolotherapy in one of three prior studies of prolotherapy for mild-to-severe knee OA;[16–18] completion of 52 week follow-up assessment in those studies, and being 1.5 to 3.5 years from initial enrollment in those studies (Fig. 1). Details of the eligibility criteria of the prior studies have been published.[16–18] Briefly, they included a diagnosis of knee OA based on clinical criteria,[20] augmented by radiologically demonstrated knee OA identified by a radiologist on an existing radiograph obtained within five years prior to initial enrollment; tenderness of one or more anterior knee structures on physical exam conducted by the first author (DR); and self-reported moderate-to-severe knee pain for at least 3 months, defined as a score of ''3'' or more in response to the question ''What has been the average level of your left/right knee pain over the last week?'' (0—6 ordinal response scale). Potential participants were contacted sequentially, based on their 52-week exit date, from their

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