Research article

Prospective case series of litigants and non-litigants with chronic spinal pain treated with dextrose prolotherapy

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Objectives: To compare outcomes for litigants and non-litigants with chronic spinal pain treated with dextrose prolotherapy.

Methods: One hundred and forty-seven consecutive patients with chronic spinal pain were classified as litigants if they had retained a lawyer for an unresolved claim at the start of treatment, or as non-litigants if they had previously settled claims or sustained non-compensable injuries. Patients were treated with a solution of 20% dextrose and 0.75% lidocaine. One-half milliliter of proliferant was injected into facet capsules of the cervical, thoracic, or lumbar spine. The iliolumbar and dorsal sacroiliac ligaments were also injected for a total of 10 cc in low back pain patients. The Neck Disability Index, Patient Specific Functional Scale, and Roland–Morris Disability Questionnaire scales were administered before treatment and approximately 1 year after treatment. At the 1-year follow-up, patients were also asked to rate their change in symptoms, function, ability to work, willingness to repeat treatment, and need for ongoing medications or other treatment.

Results: Both litigants (71) and non-litigants (76) showed significant improvement from baseline on all disability scales ($P < 0.001$). There were no differences in the percentage of litigants/non-litigants reporting improvement on impression of change scales for symptoms (91/92%), function (90/90%), improved ability to work (76/75%), willingness to repeat treatment (91/93%), ability to decrease medication (82/81%), and decreased need for other treatment (80/84%).

Discussion: Litigants and non-litigants with chronic spinal pain treated with prolotherapy showed statistically and clinically significant improvements in measures of disability, and impression of change scales. Litigation need not be an exclusion factor for future spine prolotherapy studies.

Keywords: Back pain, Dextrose, Litigation, Motor vehicle accident, Prolotherapy

Introduction

Prolotherapy is an injection technique used for over 70 years to treat pain due to lax ligaments.[1] Its proposed mode of action is improved joint stability through the strengthening of stretched or torn ligaments. It involves the repeated injection of tender ligaments and entheses with an irritant solution to induce inflammation followed by the deposition of collagen fibers, thereby strengthening the affected ligament.[2] Laxity of ligaments has been proposed as a specific source of chronic pain since the 1930s.[3] There is some biologic rationale for this. Overstretched ligaments do not regain their original length[4] or strength[5] after injury. Ligaments are known to contain nociceptors that activate with stretch.[6] Biopsy studies in animal models and humans have demonstrated thickening and strengthening of ligaments after injection.[7–9] The effect of injection on nociceptors or other mechanisms of action remains untested.

Multiple studies on spine prolotherapy support ongoing investigation of this technique. There are 26 cohort studies on spinal pain reporting outcomes on a total cohort of 3136 patients.[10] Most of these studies used retrospective impression of change or pain scales as outcomes. In contrast, four of the five randomized controlled trials (RCTs) on chronic low back used validated disability scales. A systematic review of the RCTs failed to show benefit of prolotherapy alone but suggest, when used in conjunction with

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other co-interventions, that prolotherapy is better than placebo.[11] Four of the five RCTs excluded patients with pending litigation, despite the lack of prolotherapy studies demonstrating litigation as a negative prognostic indicator.

The assumption that litigants do not respond as well to treatment has remained since as early as 1961, when litigation neurosis was proposed as an explanation for prolonged symptoms for secondary monetary gains.[12] A review of the literature in 2003 failed to support this concept in whiplash patients.[13] Significant improvements in impairment and disability outcomes for low back and neck pain patients with pending litigation have been noted with treatment.[14,15] However, other studies have shown poorer outcomes in patients involved in litigation compared with those not involved in litigation.[16,17]

Prior to proceeding with a further RCT on spine prolotherapy, we were interested in determining the response of litigants to prolotherapy and whether they could be included in future studies. To this end, we prospectively measured outcomes on disability scales along with retrospective global impression of change questionnaires, to describe the response of a case series of litigant and non-litigant patients with chronic spinal pain, treated with dextrose prolotherapy.

Materials and methods

Study population

The study comprised a prospective case series on consecutive patients referred by manual therapists for prolotherapy for chronic cervical, thoracic, or lumbar pain of over 6 months' duration that had not responded to a trial of exercise, manipulation, and dry needling of trigger points by the therapist, and had signs of laxity in the spinal, iliolumbar, or sacroiliac ligaments on stress testing. Stress tests for laxity, performed in a standardized manner according to the International Federation of Manipulative Therapists,[18] were performed by fixating one side of the joint while applying an anterior, posterior, or rotational force to the other side of the joint. The examiner assessed the quantity of movement, end feel, and whether the test reproduced any symptoms.

Participants were classified as litigants if they had retained a lawyer and had an unresolved claim relating to a motor vehicle collision at the start of the treatment. Non-litigants either had settled previous motor vehicle collision claims, or had symptoms due to non-compensable causes such as pregnancy, normal aging, or self-inflicted injury, such as during a fall.

Participants were treated in a private outpatient prolotherapy practice with ligament injections of a solution of 20% dextrose and 0.75% lidocaine. Injection sites were selected by palpating for areas of tenderness in ligaments and by pain distribution. These sites were concordant with the lax ligaments identified by manual examination. Anatomical landmarks described by Hackett *et al.*[1] guided the placement of injections. Injections were usually given on a weekly basis for up to 3 weeks. A set of three injections was repeated in 1 month if symptoms persisted and ongoing laxity was identified. Depending on subject tolerance, some injections were completed on a monthly basis. One-half milliliter of proliferant was injected into facet capsules of the cervical, thoracic, or lumbar spine. The iliolumbar ligament insertions on the iliac crest and dorsal sacroiliac ligaments were also injected with a total of 10 ml in low back pain patients. During the course of prolotherapy, participants were restricted from taking non-steroidal anti-inflammatory medications for 4 weeks after each treatment. All participants received other co-interventions (exercise, manipulation, dry needling) that remained unchanged before and during the study.

The Conjoint Health Research Ethics Board, associated with the local University, granted ethics approval for this study.

Study measures

Participants completed the Neck Disability Index (NDI) (cervical), Patient Specific Functional Scale (PSFS) (thoracic) for the three most difficult activities, and Roland–Morris Disability Questionnaire (RMDQ) (lumbar), relevant to their affected spinal region or regions, before treatment and approximately 1 year post-treatment. The post-treatment questionnaires also requested the degree of improvement with the five response categories, 'worse', 'same', 'somewhat better', 'moderately better', 'much better', for symptoms (pain, stiffness, or numbness and tingling), function with activities of daily living, and need for medication and other treatment (physiotherapy, massage or chiropractic) with the five response categories of 'no change', 'somewhat decrease', 'moderately decrease', 'significantly decrease', and 'completely stop'. Willingness to repeat treatment, and whether treatment improved ability to work were assessed with a yes/no response.

All patients who completed treatment, returned all pre/post-treatment questionnaires, and had follow-up of over 6-month duration were included in analysis. Minor variations in the duration of follow-up occurred due to variable response times and because post-treatment questionnaires were sent to the cohort in batches at quarterly intervals.

Statistical analysis

We used descriptive statistics and plots to assess the distributions of continuous variables. Continuous variables that were approximately symmetrical are

summarized as means with standard deviations, and otherwise are reported as medians and quartiles. Categorical and binary (yes/no) variables are reported as percentages. To assess the potential for selection bias, our initial analysis compared baseline demographic and clinic characteristics for participants included in the final analysis with patients excluded from the final analysis. The included participants were then stratified into litigants and non-litigants for further comparison. For binary and categorical variables, we used corrected chi-square tests to compare groups. If continuous variables had approximately symmetrical distributions in each group and similar standard deviations, we used *t*-tests to compare groups. Differences in categorical outcomes for the improvement of symptoms, function, ability to work, treatment satisfaction, RMDQ, PSFS, and NDI scores were compared for litigants and non-litigants using chi-square tests.

Results

Description of cohort

Over a 2-year period, 260 consecutive patients consented to prolotherapy treatment. Analysis was not possible on patients who did not complete intake questionnaires (29) or follow-up questionnaires (28), or did not complete treatment. Twenty patients had valid reason for not completing treatment such as moved, pregnant, lost funding, re-injury severe enough to require restarting treatment, and 10 dropped out for unknown reasons. The study ended at 2 years when an adequate number of thoracic and lumbar participants were recruited. Follow-up was not done on 21 subjects still receiving treatment at the end of the study. Five patients with less than 6 months follow-up were excluded. This left 147 participants for analysis.

Of the 147 participants, 75% were female. The mean age was 39.0 (SD 9.0) years. Duration of symptoms ranged from 6 months to 30 years with a median of 2.5 years (interquartile ratio — IQR 4.0) and a mean of 4.3 years (SD 5.1), skewed by 12 subjects with over 10 years of symptoms. Ninety-six participants received treatment in one spinal region, 46 in two spinal regions, and 5 in three spinal regions, for a total of 100 lumbar, 74 thoracic, and 29 cervical treatments.

The patients excluded from analysis had similar gender, regional distribution, and numbers of regions treated, but were somewhat younger (35.0 years, SD 10.3, $P = 0.01$) with a shorter duration of symptoms (mean 2.9 years, SD 3.2, $P = 0.002$) and were predominantly litigants (79 out 84 patients where litigation status was known) (Table 1).

Seventy-one of the participants were litigants and 76 were non-litigants. There were no differences between these groups in gender, age, or length of follow-up.

Table 1 Demographic and clinical characteristics of participants vs. excluded patients

	Participants ($n = 147$)	Excluded ($n = 113$)	*P* value
Female	111 (75%)	77 (68%)	0.35
Mean age in years (SD)	39.0 (9.0)	35.0 (10.3)	0.01
Mean duration of symptoms in years (SD)	4.3 (5.1)	2.9 (3.2)	0.002
Spinal regions treated			
Lumbar	100 (68%)	64 (57%)	0.08
Thoracic	74 (50%)	71 (63%)	0.07
Cervical	29 (20%)	24 (21%)	0.66
Treated single region	96 (65%)	72 (64%)	0.97
Treated two regions	46 (31%)	36 (32%)	0.89
Treated three regions	5 (3%)	5 (4%)	0.67

The duration of symptoms in litigants was shorter, with a median of 1.63 years (IQR 2.0) and a mean of 2.1 years (SD 0.2, $P < 0.0001$), compared with non-litigants with a median of 4.0 (IQR 8.0) and a mean of 6.3 years (SD 6.3), skewed by the 12 subjects with long-term symptoms. There were more litigants with neck and thoracic symptoms and with multiple areas of treatment ($P < 0.0001$) (Table 2).

Disability questionnaire outcomes

Lumbar disability data were obtained for 97 participants, including 35 litigants and 62 non-litigants. Pre-treatment disability scores were significantly higher in litigants ($P = 0.001$). Both groups showed significant improvement post-treatment ($P < 0.001$), with no difference between groups in the degree of improvement ($P = 0.46$) (Table 3). Non-litigants had a higher percentage of patients reporting over 50% improvement on the RMDQ scale (54.3% non-litigants vs. 43.3% litigants), but this difference was not significant ($P = 0.302$).

Thoracic disability data were obtained on 70 participants, including 50 litigants, and 20 non-litigants.

Table 2 Demographic and clinical characteristics of litigant vs. non-litigant participants

	Litigants ($n = 71$)	Non-litigants ($n = 76$)	*P* value
Female	53 (75%)	58 (76%)	0.81
Age in years (SD)	38.7 (1.12)	39.3 (0.99)	0.73
Mean duration of symptoms in years (SD)	2.1 (0.2)	6.3 (6.3)	<0.0001
Length of follow-up in months (SD)	13.6 (0.6)	13.9 (0.5)	0.72
Spinal regions treated			
Lumbar	37 (33%)	63 (70%)	<0.0001
Thoracic	53 (46%)	21 (24%)	<0.0001
Cervical	24 (21%)	5 (6%)	<0.0001
One region	32 (45%)	64 (84%)	<0.0001
Two regions	35 (49%)	11 (15%)	<0.0001
Three regions	4 (6%)	1 (1%)	0.15

Table 3 Mean (SD) pre/post-treatment scores for litigants vs. non-litigants

	Litigants	Non-litigants	*P* value
Lumbar spine $N = 97$ (missing 3)			
RMDQ (range 0–24)	$n = 35$	$n = 62$	
Pre-treatment	12.3 (4.5)	8.9 (4.9)	0.001
Post-treatment	7.1 (5.9)	4.3 (5.1)	0.02
Mean change	5.2 (4.5)	4.6 (5.4)	0.46
Thoracic spine $N = 70$ (missing 4)			
Patient specific functional scale (range 0–10)	$n = 50$	$n = 20$	
Pre-treatment	3.0 (1.5)	4.7 (2.0)	0.0003
Post-treatment	5.9 (2.2)	6.7 (2.0)	0.27
Mean change	2.9 (2.0)	2.0 (2.2)	0.05
Cervical spine $N = 26$ (missing 3)			
NDI scores (range 0–50)	$n = 23$	$n = 3$	
Pre-treatment	22.3 (6.8)	20.3 (4.0)	0.63
Post-treatment	14.3 (9.2)	10.7 (4.9)	0.49
Mean change	8.0 (5.7)	9.6 (4.9)	0.59

$P < 0.001$ for all comparisons of pre- and post-treatment scores within groups.
Lower disability is indicated by a reduction in the Roland–Morris and NDI scores and an increase in PSFS score.

Litigants started with lower function ($P = 0.0003$). Both groups showed significant improvement on PSFS ($P < 0.001$); however, litigants showed significantly greater improvement ($P = 0.05$) (Table 3), and had more patients with over 50% improvement ($35/50 = 70\%$ litigants and $9/20 = 45\%$ non-litigants, $P = 0.05$).

Cervical disability data were obtained on 26 participants, including 23 litigants and 3 non-litigants. The low number of non-litigants limits statistical comparison between groups. Both groups showed significant improvement ($P < 0.001$) (Table 3). Two-thirds of litigants had over 50% improvement on NDI.

Impression of change outcomes

There were no significant differences at 12 months for litigants vs. non-litigants in reporting improvement in symptoms (91 vs. 92%), function (90 vs. 90%), ability to work (76 vs. 75%), willingness to repeat treatment (91 vs. 93%) (Table 4), and decreased need for medications (82 vs. 81%) or other treatment (80 vs. 84%) (Table 5).

Adverse events

Participants generally found the injections uncomfortable and reported 1–2 days of stiffness afterward. No serious or prolonged complications such as nerve damage, pneumothorax, or infection were encountered with the treatments administered in this cohort.

Discussion

This study is the first to document the outcomes of prolotherapy in a consecutive case series of litigants and non-litigants. Improvement in both groups was seen with prospective disability scales and retrospective impression of change scales. Despite higher

Table 4 Impression of change responses for litigants and non-litigants following prolotherapy

	Litigants ($n = 71$)	Non-litigants ($n = 76$)	*P* value
Symptoms			
Worse	1 (1%)	2 (3%)	
Same	5 (7%)	4 (5%)	
Somewhat better	16 (22%)	12 (16%)	
Moderately better	22 (32%)	21 (28%)	
Much better	25 (36%)	37 (48.7%)	
Missing	2	0	
Total better	63 (91%)	70 (92%)	0.39
Function			
Worse	0	2 (3%)	
Same	7 (10%)	6 (8%)	
Somewhat better	17 (25%)	10 (13%)	
Moderately better	19 (28%)	21 (28%)	
Much better	25 (37%)	37 (49%)	
Missing	3	0	
Total better	61 (90%)	68 (90%)	0.10
Work			
Improved	41 (76%)	48 (75%)	0.54
Not improved	13	16	
Not applicable	17	12	
Repeat treatment			
Yes	57 (91%)	70 (93%)	0.54
No	6	5	
Missing	8	1	

Percentages are expressed as percentage of total *n* minus missing or not applicable scores. *P* values relate to the total percentage of patients reporting improvement in each category.

Table 5 Change in need for medication and other treatment for litigants and non-litigants following prolotherapy

Response	Litigants ($n = 71$)	Non-litigants ($n = 76$)	*P* value
Medication			
No change	9 (18%)	9 (19%)	
Somewhat decrease	8 (16%)	2 (4%)	
Moderate decrease	10 (20%)	5 (11%)	
Significant decrease	17 (33%)	18 (38%)	
Completely stop	7 (14%)	13 (28%)	
Not applicable	9	22	
Missing	11	7	
Total decrease	42 (82%)	38 (81%)	0.85
Other treatment			
No change	12 (20%)	11 (16%)	
Somewhat decrease	14 (24%)	5 (7%)	
Moderately decrease	12 (20%)	11 (16%)	
Significant decrease	17 (29%)	29 (42%)	
Completely stop	4 (7%)	13 (19%)	
Missing	12	7	
Total decrease	47 (80%)	58 (84%)	0.52

Percentages are expressed as percentage of total *n* minus missing and not applicable scores. *P* values relate to the total percentage of patients reporting improvement in each category.

disability scores and more treatment areas, litigants showed equal or greater improvements in outcomes compared with non-litigants. The reported changes in disability questionnaires for both groups in this study meet or exceed the minimum detectable change (MDC) and minimal clinically important change (MCIC) reported for RMDQ,[19,20] PSFS,[21–23] and NDI.[24] The improvements reported on impression of change scales in this study are similar to those reported in a previous retrospective study on chronic spinal pain treated with dextrose prolotherapy which reported outcome did not depend on gender, duration of symptoms, or traumatic vs. atraumatic cause of symptoms.[25]

Our findings concur with studies of neck pain patients treated with radiofrequency neurotomy, a procedure targeted specifically to facet joint pain, that sustained improvement is independent of litigation status.[26,27] In these studies, both the selection criteria (a positive response to a medial branch block) and the treatment are more targeted than with prolotherapy in the present study, but the results in litigant and non-litigant patients are very similar.

The generalizability of this study is limited by the differences between the included/excluded patients. Excluded patients were slightly younger in age and had a shorter duration of symptoms compared with participants. However, previous research showed no difference in outcome for duration of symptoms.[25] Both the generalizability and internal validity of the study are threatened by the high number and large proportion of litigants in the excluded group whose outcomes are not known. Litigants may have feared that documentation of their progress over time would have a negative influence on the results of their claims. Sapir and Gorup[27] argued that the potential secondary gain in litigant patients from documenting responses to treatment can work either way — a positive response to treatment can support the existence of an injury, whereas a poor response could also support the severity of the injury and lead to a higher settlement.

Differences in the distribution and number of spinal regions affected within the litigant and non-litigant groups may also have confounded the study findings. Cervical and thoracic problems were dominant in the litigant group, whereas lumbar problems were dominant in the non-litigant group. The effects of this are not clear, but a previous study comparing the outcomes of a functional restoration program in chronic cervical and lumbar spinal problems similar in severity to our cohort showed no difference in outcomes between regions.[28] Previous retrospective data[25] found less favorable outcomes for cervical compared with lumbar or thoracic prolotherapy, which might lead to an expectation of better outcomes for non-litigants in this study. Litigants in our cohort were also more likely to have two regions affected. This might have made litigants less likely to achieve improvements in many of the outcomes we measured but, despite this, their outcomes were no different to those of the non-litigants.

To take into account the baseline imbalance we ran an analysis of covariance. There was no significant effect of change in RMDQ ($P = 0.68$) or PSFS ($P = 0.74$) scores for lumbar and thoracic litigants after controlling for baseline characteristics.

The sample size for this study was based on enrolling available cases within a 2-year period, and we did not perform *a priori* power calculations to inform the sample size. Using the obtained standard deviations and an alpha level of 0.05, our study had an 80% power to detect a 3.1-point difference in change in the RMDQ between litigant and non-litigant groups, and for thoracic patients had an 80% power to detect a 1.6-point difference in change in the PSFS. These detectable differences are smaller than the MDC and MCIC reported for the RMDQ,[19,20] and PSFS.[21–23]

As this study is limited by lack of a comparison group that did not receive injections, it is not known how many patients would have improved over time without treatment. However, given the duration of symptoms, and failed conservative treatment, the literature would suggest that chronic spine pain over 1 year is likely to continue.[29–31]

Therefore, the implication of this study for future studies on prolotherapy considering involvement of non-litigants only is that the inclusion of litigants who are willing to consent to long-term monitoring of outcomes, is unlikely to affect the mean outcomes of the cohort as a whole. However, the favorable outcomes of litigants in this study cannot be generalized to the equally large group of litigants who did not consent to monitoring of outcomes.

Commonly used disability measures for each area of spine were selected to allow comparison to other region-specific studies, and to confirm these scales were as responsive as impression of change ratings. In the future, a validated disability outcome measure that covers all three regions of the spine, such as the Aberdeen back pain scale could be used to allow more powerful analysis using the whole sample.[32]

Future studies may also need to consider the effect that local jurisdiction, and the definition chosen for litigant, can have on whether a patient would be classified as a litigant at any particular point in the legal or treatment process. In this cohort, all legal claims must be made by 2 years, usually preceding initial consultation, and rarely settle until all treatment is complete. There were insufficient numbers to further classify litigants into those who started litigation during treatment, or had settled their claim prior to, or during treatment.

Notwithstanding the lack of a formal economic analysis in this study, the reported decreases for medications and other treatment in both litigant and non-litigant groups provide some indication of decreased health resource utilization after treatment. Cost-minimization and cost-effectiveness analyses are warranted in future studies of prolotherapy for spinal pain. Decreased resource utilization and improvements in litigants should be of interest to insurance companies.

Conclusions

Litigants and non-litigants with chronic spinal pain treated with prolotherapy showed statistically and clinically significant improvements in measures of disability and impression of change scales. Results should be interpreted in the context of a more diffuse spinal injury pattern and a lower study participation rate amongst litigants. Further prolotherapy studies may therefore be able to include litigants with little effect on overall outcomes.

Disclosures

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