

The Effect of Prolotherapy for Joint Pain on Pain Control and Quality of Life Improvement: A Six-year Retrospective Comparative Observational Study

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Introduction

The existence of connective tissue disorder and hypermobile joints syndrome plays a significant role in sacroiliac (SI) joint dysfunction. Extra-articular elements, such as ligamentous injuries and enthesopathy, likely the most frequent sources of joint dysfunction and potential hypermobility (1,2).

Prolotherapy is not a new treatment in medicine. However, the results of prolotherapy and the effect of this intervention to reduce the narcotic consumption and improvement in the quality of life have not been appropriately shown in the past. Available studies that assessed the outcome of prolotherapy either had a small sample size or rigid patient selection criteria.

The concept of creating irritation or inflammation to simulate healing was described as early as the fifth century BC. During this time, Hippocrates treated unstable joints by poking the ligaments with a hot metal rod. Although the procedure was rudimentary and experimental, Hippocrates hypothesized that causing inflammation of injured ligaments would lead to selfrepair.

This was one of the first steps towards using the body's own healing potentials to repair injured connective tissues. During prolotherapy, small amounts of an irritant solution are injected into the damaged tendon insertions, joints, ligaments, and adjacent to joint spaces to promote tissue repair or growth (3).

Methods

This is a retrospective observational study of 266 patients who were diagnosed with SI joint dysfunction and had prolotherapy from 2013 to 2018 at the Allevio Pain Management clinic. The request for follow-up resulted in 222 patient respondents.

To evaluate quality of life improvement, we used a BPI questionnaire. Other information like pain free intervals, return to work, changes in narcotic consumption after procedure, as well as descriptive statistics were presented as mean (SD) and median (Interquartile Range [IQR]) for continuous variables and frequency (%) for categorical variables.

Analysis of individual changes on narcotics use and changes of BPI per item before and after treatment were analyzed by a paired t-test. Effects of lidocaine and ketamine use were analyzed separately by items using a paired t-test, and by univariate linear regression using lidocaine and ketamine as explanatory variables. Changes in BPI scores as outcomes. Similarly, univariate linear regression models were also applied to analyze the association between BPI score changes with sex and age as explanatory variables.

Table 1. Patient Characteristics at Baseline

Variable	Total (n=246)
Age (mean, SD)	54.22 (14.90)
Gender (%)	
Male	60 (24.4)
Female	186 (75.6)
Number of Prolotherapy treatments	
Mean (SD)	4.91 (2.74)
1	2 (0.8)
2	6 (2.4)
3	36 (14.7)
4	66 (26.9)
5	75 (30.6)
6	44 (18.0)
7	16 (6.5)
Chiropractic (%)	
No	97 (39.6)
Yes	148 (60.4)
Osteopathy (%)	
Yes	26 (10.6)
No	219 (89.0)
Narcotic use before intervention (yes, %)	68 (28.1)
Narcotic use after intervention (yes, %)	22 (10.0)
Non-narcotic pain medication (reduction, %)	84 (41.0)
Retired (yes, %)	82 (34.5)
Returned to work after intervention (yes, %)	99 (43.8)

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Results

A total of 246 patients (186 females, 60 males) that underwent two to seven prolotherapy sessions between January 2013 and December 2018 were recruited for this study. The mean age was 54.2 (14.9) years.

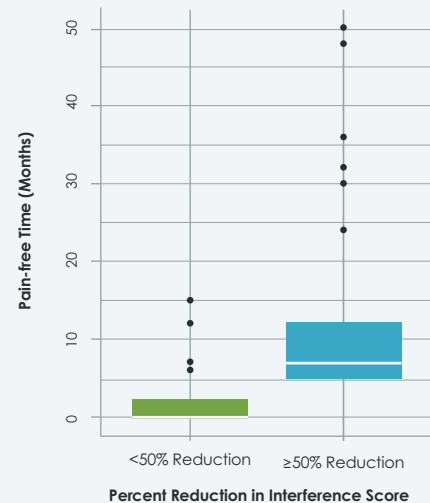
According to our data, at the time of prolotherapy, 156 (65.5%) of patients were working and 82 patients (34.5%) were retired. Of those 156 patients, 99 (63.4%) reported that they returned to work after intervention. Meanwhile, 68 patients reported usage of narcotics, ranging from 0.18mg to 27mg (morphine equivalent), with the exception of three patients who reported usage of 109mg or more (morphine equivalent). In addition, 174 patients reported no use of narcotics before intervention.

After prolotherapy, only 22 patients reported narcotic use, ranging from 0.18mg to 25mg (morphine equivalent), while 199 reported no use (Table 1). A total of 221 patients had available narcotic data at both timepoints, and of these 221 patients, a significant reduction in narcotic use after intervention was observed (Wilcoxon rank-sum-value<0.001), with only one patient reporting increased consumption following prolotherapy (Figure 1, Table 1). For in patients who reported more than 50% improvement in BPI after prolotherapy, the proportion of narcotics consumption was significantly lower (Table 2). With respect to non-narcotic pain drugs, 84 (34.1%) patients reported a decrease in use, while 121 (49.2%) reported no change. No patients reported on increase in use of non-narcotics medication. More than half of the patients (61.1%) in the group with 50% or more improvement in BPI had a statistically significant decrease in use of nonnarcotics (Table 2, Figure 3).

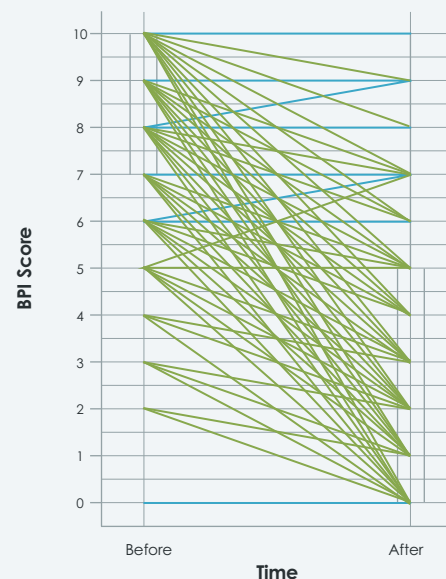
Table 2. Patient Characteristics by Groups of Interference Scores Reduction

	Less 50% reduction (n=68)	50% or more reduction (n=178)	P-value
Age in years	54.97 (15.48)	53.94 (14.70)	0.628
Age categories (%)			0.786
20-39	14 (20.6)	32 (18.0)	
40-59	30 (44.1)	87 (48.9)	
60+	24 (35.3)	59 (33.1)	
Gender (male, %)	16 (23.5)	44 (24.7)	0.977
Chiropractic (yes, %)	38 (55.9)	110 (62.1)	0.452
Osteopathy (yes, %)	6 (8.8)	20 (11.3)	0.740
Narcotic use before intervention (yes, %)	23 (35.9)	45 (25.3)	0.143
Pain free time (months)	0.0 [0.0, 2.0]	7.0 [5.0, 12.0]	<0.001
Chiropractic & Osteopathy			0.02
None	28 (41.2)	50 (28.2)	
Both	4 (5.9)	3 (1.7)	
Either (only one)	36 (52.9)	124 (70.1)	
Narcotic use after intervention (yes, %)	9 (20.9)	13 (7.3)	0.017
Non-narcotic pain medications (yes, %)	5 (12.2)	79 (48.2)	<0.001
Retired (yes, %)	21 (35.0)	61 (34.3)	>0.999
Returned to work after intervention (yes, %)	14 (29.2)	85 (47.8)	0.032

Reported Pain-free Time



Changes on BPI



A total of 178 patients (72.3%) had a reduction of 50% or more in at least one BPI item, and 100 patients (40.6%) had a reduction of 50% or more in all BPI items. Overall, subjects were free of pain for a median of six months [IQR 2.0, 10.0].

However, significant differences in time were observed between the groups of ≥50% reduction in BPI (Figure 4). Twenty-four patients within the <50% pain group reported no pain-free time (zero months), while only three patients in the opposite group reported no pain-free periods. Using chiropractor or osteopath services is common in SI joint dysfunction. We did not find any difference in success rate in regard to use of those services.

Table 3. Mean BPI Before and After Intervention, Mean Difference and P-value Obtained from Paired Test

Item	Before	After	Mean Difference	Mean % decrease	P-value
Pain	7.81 (1.73)	3.37 (2.66)	-4.41 (2.73)	-62.50 [-80.00,-37.50]	<0.001
General Activity	7.42 (2.14)	3.05 (2.50)	-4.39 (2.82)	-62.50[-80.83,-36.46]	<0.001
Mood	7.02 (2.39)	2.91 (2.67)	-4.12 (2.80)	-66.67 [-86.16,-30.00]	<0.001
Walking ability	6.67 (2.88)	2.74 (2.56)	-3.93 (3.09)	-58.57 [-87.50,-22.22]	<0.001
Working	7.38 (2.24)	2.87 (2.63)	-4.54 (2.96)	-70.00 [-87.50,-37.50]	<0.001
Relationships	6.27 (2.86)	2.65 (2.63)	-3.60 (3.05)	-66.67 [-89.44,-22.22]	<0.001
Sleep	6.88 (2.58)	2.72 (2.7)	-4.11 (3.03)	-62.50 [-95.00, -33.33]	<0.001
Life enjoyment	7.80 (2.10)	2.87 (2.89)	-4.94 (3.06)	-71.43 [-100.0,-40.0]	<0.001

Conclusion

Our study showed a statistically and clinically significant improvement in mood and enjoyment of life, walking ability, performing daily work, and general activity. We documented a meaningful decrease of opioid consumption, as well as other analgesic medication. We believe performing the procedure bilaterally and using fluoroscopic guidance for all the procedures played an important role to improve the results while avoiding complications.

Another interesting finding was regarding the prevalence of SI joint pain. We discovered that SI joint pain is more prevalent in women before the age of 60, and this is consistent with the current literature. Most of our female patients had a history of difficult and complicated vaginal delivery, direct trauma to the lower back or pelvis, Ehlers-Danlos syndrome, or hypermobile joints syndrome along with a history of being hyper flexible during their teenage years. Our findings are compatible with the assumption that ligaments are the most likely cause of extra-articular, SI joint pain.

References

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