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Effectiveness of Ultrasound Guided Platelet-Rich Plasma Injections in Relieving Sacroiliac Joint Dysfunction

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Effectiveness of Ultrasound Guided Platelet-Rich Plasma Injections in Relieving Sacroiliac Joint Dysfunction

Objective: Investigate the efficacy of ultrasound guided platelet-rich plasma in reducing sacroiliac joint disability and pain.

Design: Prospective non-randomized interventional study analyzing 50 patients with low back pain secondary to sacroiliac joint dysfunction**.** Platelet-rich plasma was injected into the sacroiliac joint under ultrasound guidance. Oswestry Disability Index (ODI) and Numeric Rating Scale (NRS) were measured at baseline, 2 weeks, 4 weeks, 3 months, and 6 months post-injection.

Results: Mean reduction in Oswestry Disability Index and Numeric Rating Scale scores were significantly reduced at 6 months post-injection compared to baseline values (M -9.79%; [95% CI: -6.06, -13.52]) and (M -1.94; [95% CI -1.14, -2.78], respectively. All time frames showed significant mean reduction compared to baseline, but overall improvement tapers off after 4 weeks with no statistically significant reduction from 4 weeks to 3 months or 3 months to 6 months.

Conclusions: Ultrasound guided platelet-rich plasma injections in the sacroiliac joint are effective at reducing disability and pain with the majority of improvement seen within 4 weeks post-injection and with sustained reduction at 6 months.

Key Words: platelet-rich plasma, sacroiliac joint, injection, ultrasound guided

What is Known/What is New:

- What is Known: Corticosteroid injections are currently one of the most effective therapies for sacroiliac joint pain and dysfunction; however, relief is often only temporary. Platelet-rich plasma injections have shown promising results regarding long-term pain reduction and increased functionality in several other joints.
- What is New: This is the second prospective clinical trial analyzing platelet-rich plasma injections in the sacroiliac joint for treatment of low back pain. It shows a statistically significant reduction of pain and disability in patients with sacroiliitis and demonstrated sustainable effects up to 6 months post-injection.

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INTRODUCTION

Low back pain is one of the most common reasons for adult patients to see a physician in both an outpatient and emergency setting.[1] In approximately 15-30% of low back pain presentations, sacroiliac joint (SIJ) dysfunction is found to be the underlying etiology.[2,3] Some current therapies for chronic low back pain originating from the SIJ include non-steroidal anti-inflammatory drugs (NSAIDs), ice, physical therapy, glucocorticoid steroid injections, radiofrequency ablation, and surgical fusion.[4,5] Glucocorticoid steroid injections are the most common therapy for low back pain, however, effects are often short term.[6]

PRP is currently used for shoulder joint, knee joint, sacroiliac joint, facet joints, intervertebral discs, rotator cuff, and hamstring intervention.[5,-13] While some of these are still being investigated, the efficacy and sustainability of PRP in the shoulder and knee joint has been well established and is a common practice among physicians.[8,10-12] Previous studies have shown that utilizing PRP provides superior pain management when compared to corticosteroids, often only requiring one or two injections of PRP and having significantly measurable decreases in pain thereafter.[5,9,13] It has been extensively researched for osteoarthritis,[12] tendon,[4,7,14] and ligament injury,[14] but little research is documented on short or long-term effects on the SIJ.

Klauser et al. discussed the advantages of ultrasound guidance including convenience, widespread availability, lack of radiation exposure, and lower cost.[15] Soneji et al. and Jee et al. both compared ultrasound guidance to fluoroscopic guidance and showed no difference between modalities in terms of accuracy, efficacy, pain reduction, or patient satisfaction with SIJ

injections.[16,17] As such, ultrasound guidance was the real-time modality of choice for this study.

The objective of this study is to investigate the effectiveness and sustainability of PRP in decreasing disability and low back pain originating from the SIJ. This study evaluates disability and pain relief up to 6 months post-injection, which is the longest duration of follow up to date in the literature. The only other prospective trial evaluating PRP injections for SIJ related low back pain by Singla et al. was carried out to 3 months post-injection, which limited the data gathered on injection sustainability.

METHODS

Study Design

Sample size for this study was calculated using G*power statistical analysis. Articles in this field were found to have effect sizes ranging from 0.15 to upwards of 5.59. As such, a smaller effect size was chosen for this study in order to demonstrate significance or lack thereof. This study uses an effect size of 0.6. A two tailed *t*-test with statistical significance of $p \leq .05$ was used. 95% confidence intervals were calculated for all data points. Power analysis indicated 39 patients would be needed to achieve a β of 0.80. The goal enrollment was 40 participants.

Setting

Fifty-one patients were recruited for this study which took place between March 2018 and March 2019 in a private practice sports medicine clinic. Patients for the study were recruited from the active patient population within the clinic. One patient was dropped from the study for not meeting eligibility criteria upon further review. A total of 50 patients participated in the study

and were followed to a completion time of 6 months post-injection. Four patients missed follow up appointments and did not have data recorded on those dates. In order to maintain a power of 0.95, a minimum of 39 patients were required at each time frame.

Participants and Eligibility Criteria

After Institutional Review Board approval and clinical trial registration (NCT03122119), 50 participants between the ages of 18 and 80 years old with chronic low back pain lasting longer than 12 months and a diagnosis of sacroiliitis were enrolled for this single center clinical trial. Clinical trial registration was approved in April 2017 and patients were enrolled starting in March 2018. Additional participant selection included identifiable joint anatomy under ultrasound visualization and a minimum of one previous steroid injection in the SIJ to coincide with current therapeutic regimen progression. Exclusion criteria included corticosteroid injection in the SIJ within the last three months, suspected additional etiologies causing the patients pain (ie. lumbar or intervertebral pathology, radiculopathy, and spondylolisthesis/spondylosis), confounding or complicating comorbidities including trauma etiology, autoimmune conditions, and immunocompromised. All patients had previously attempted and failed NSAIDs and conservative management including physical therapy or home exercises. Patients were allowed to continue the above interventions if desired. Patients currently taking opioid medications for low back pain were not excluded, however, dosing was not adjusted during the trial.

Study Population

The final study included 50 patients, 15 men and 35 women, with average age of 60.2 years old (SD 17.7). The mean BMI of the study population was 28.7. Additional comorbidities of the

study population included obesity, hypertension, and diabetes. A summary of the patient demographics can be seen in Table 1. Patients with varying demographics were recruited to help decrease selection bias and improve generalizability for this single center study.

Institutional Review Board approval was obtained prior to any intervention or data collection. This study adhered to all STROBE guidelines (see Supplemental Checklist, Supplemental Digital Content 1, http://links.lww.com/PHM/A947) and reported all information accordingly. Recruited patients were then informed about the risks, benefits, and alternatives to treatment and signed informed consent documentation. At the initial encounter, the diagnosis of SIJ dysfunction was established by history, physical exam, imaging, and three positive provocative tests. Provocative tests included Fortin Finger Test, also known as a point of maximal tenderness, FABER, PSIS Distraction, Gaenslen's Test, pain mapping, and Thigh Thrust Test.[6,18] All patients had imaging performed, ranging from x-rays to CT and MRI, which assisted in diagnosing the SIJ as the underlying etiology and helped exclude other confounding pathologies.

Objective Measures

The primary outcome measured was the Oswestry Disability Index (ODI) which uses a questionnaire to assess pain levels and the impact pain has on a patient's daily life. The questionnaire was then converted to a percentage for objective comparison. The secondary outcome measure was the Numeric Rating Scale for Pain (NRS). This rating scale provided another objective tool based purely on pain severity for comparison of changes in pain levels pre- and post-injection.

Preparation of PRP

Autologous PRP was prepared using the Harvest Technology SmartPReP 2 Platelet Concentrate system utilizing the manufacturer's instructions. PRP was obtained and prepared in sterile conditions for all steps. Approximately 50mL of venous blood was withdrawn from the patient and mixed with 8mL of anticoagulant citrate dextrose solution-A (ACD-A). The anticoagulated blood was then separated by centrifugation for 15 minutes at 3200 RPM, allowing PRP to separate from whole blood. This resulted in approximately 10mL of PRP with platelet concentrates ranging from five to ten times greater than the baseline level of platelets in the average patients' systemic circulation.

PRP Injection

The patient was instructed to lie prone and a sterile field was created. Using a previously established technique which includes a combination of the Fortin Finger Test and ultrasound, the curved probe was placed over the SIJ to identify anatomical landmarks. The Fortin Finger Test was then used to identify the point of maximal tenderness to better determine the insertion site of the needle. The point of maximal tenderness, as opposed to a prespecified anatomic landmark, was chosen as the treatment location to specifically target individualized areas for each patient. Overlying skin was anesthetized with 1% lidocaine using a 22-gauge needle. Once adequate anesthesia was obtained, a 22-gauge spinal needle was introduced in a medial to lateral approach into the SIJ under real-time ultrasound guidance (Supplemental Image 1, Supplemental Digital Content 2, http://links.lww.com/PHM/A948). The needle was visualized in plane with the probe and the needle tip was used to stimulate the point of maximal tenderness within the joint space to ensure adequate placement. Upon identification of the point of maximal tenderness, 3mL of PRP

was injected into the area of maximal tenderness of the SIJ as well as the posterior ligaments during withdrawal of the needle to infiltrate the entire joint space and surrounding structures. Post-injection, patients remained prone for 15 minutes and were monitored for adverse events.

Statistical Analysis

Statistical analysis was performed using SPSS 25, XLStat 2019.1.2, and R3.5.2. Variables were assessed for normality of distribution by using the Shapiro-Wilk test and Jarque-Bera test. ODI and NRS scores were compared from baseline to 2 weeks, 4 weeks, 3 months, and 6 months using ANOVA and paired *t*-test. Discrete variables were summarized as means and standard deviations.

RESULTS

Data was recorded for 50 patients in the baseline group, 48 patients in the 2 week group, 49 patients in the 4 week group, 46 patients in the 3 month group, and 42 patients in the 6 month group based on follow-up appointment attendance. A statistically significant improvement was seen in ODI from baseline pre-injection disability levels to 6 months post-injection with a mean change of -9.79%; 95% CI [-6.06, -13.52]. Additionally, the pattern of improvement shows statistically significant reduction at 2 weeks (M -4.72%; 95% CI [-2.27, -7.17]), 4 weeks (M -7.14%; 95% CI [-4.49, -9.78]), and 3 months (M -8.78%; 95% CI [-4.62, -12.93]) (Figure 1). Results were further broken down to evaluate for disability reduction at the specified intervals throughout the 6 month period. A significant decrease in ODI scores was seen from 2 weeks to 4 weeks (M -2.90%; 95% CI [-0.92, -4.88]). However, a statistically significant reduction was not

observed in ODI from 4 weeks to 3 months (M -1.16%; 95% CI [-3.19, 5.51]) and 3 months to 6 months (M -0.04%; 95% CI [-3.87, 3.94%]) as seen in Table 2.

A statistically significant improvement was also seen in NRS pain scores when comparing baseline pre-injection pain and 6 month post-injection pain (M -1.94; 95% CI [-1.14, -2.78]). Similar to the ODI results, a statistically significant change was also seen in NRS pain scores at 2 weeks (M -1.08; 95% CI [-0.45, -1.72]), 4 weeks (M -1.58; 95% CI [-1.02, -2.14]), and 3 months (M -1.69; 95% CI [-1.02, -2.37] (Figure 2). The intervals studied were further broken down the same as with ODI and also showed a significant reduction from 2 weeks to 4 weeks (M -0.57; 95% CI [-0.22, -0.92]). There was no statistically significant reduction in NRS from 4 weeks to 3 months (M -0.07; 95% CI [-0.65, 0.52]) or from 3 months to 6 months (M -0.01; 95% CI [-0.57, 0.60]) (Table 3).

DISCUSSION

The results of this study showed improvement in pain and disability up to 6 months post-injection, demonstrating PRP injections are an effective and sustainable treatment modality for SIJ dysfunction. While the majority of the effect occurred within the first four weeks post-injection, patients continued to have a decrease in both pain and disability, with overall improvement in symptoms compared to baseline. Patients continuing standard of care treatments such as physical therapy, home exercises, NSAIDs, and opioids were not broken out into categories. Although the investigators saw reduction in opioid and non-opioid medications, that was not the scope of this study; the main focus was to evaluate for change in function.

Hyperalgesia effects were considered as a potential occurrence, especially in the setting of patients utilizing opioids. However, patients were not required to discontinue any of the above interventions prior to enrollment in order to maintain an accurate depiction of day to day clinical scenarios.

There were no major complications observed during this study. The most common complication experienced by patients was temporary injection site pain immediately after administration. Both Singla et al. and Ko et al. studies demonstrated a transient increase in post-injection pain, which did not appear to be a finding exclusive of PRP.[5,6]

This study is consistent with previous investigations of PRP in patients with chronic pain. For example, Singla et al. showed both steroid and PRP injections in the SIJ are successful in mitigating pain and functional disability; however, PRP demonstrated more efficacy and sustainability compared to steroids. Their study contained a total of 40 patients, 20 were treated with corticosteroid injections and 20 with PRP injections. Pain relief was measured with a Visual Analog Scale (VAS) [0 to 10] and a Modified Oswestry Disability Questionnaire (MODQ) [0 to 50] at two weeks, four weeks, six weeks, and three months. At three-month follow-up, 90% of patients receiving PRP injections had at least a 50% reduction in their VAS compared to a 25% reduction in the steroid group, when compared to baseline scores. Singla et al. also found the majority of the effect taking place within 2 to 4 weeks of treatment for both interventions. Similar effects were demonstrated with this current study which showed the largest reduction of symptoms at four weeks when compared to baseline. In addition to validating the Singla et al. study, the results of this study examined a more extensive follow-up period and demonstrated

sustainable results for patients receiving PRP injections for SIJ dysfunction.

The main limitation of this study is the absence of a control group or placebo. Additionally, the study was not blinded, and patients were not randomized since there was only one arm. The number of patients at follow-up varied at each timeframe due to missed appointments, affecting the periodic sample size and potentially leading to attrition bias. However, the number of active patients at each objective timeframe was consistently greater than what was required to maintain power. Another bias encountered was convenience bias due to the patient population being recruited from a single private practice sports medicine clinic. The presence of convenience bias limits the generalizability of this study; however, benefits of treatment were still demonstrated in patients with a wide variety of demographics as seen in Table 1. Lastly, this study documented ODI and NRS up to 6 months post-injection, however, longer-term follow up should be carried out to determine sustainability of the PRP injections.

CONCLUSION

Ultrasound guided PRP injections into the SIJ are a safe and effective modality for reducing functional disability as well as decreasing low back pain. The majority of the effects of PRP in the SIJ may be seen in the first 2 to 4 weeks, with sustained functional improvement and pain relief at 6 months. Further large-scale prospective studies are required to better analyze PRP effectiveness in relation to other modalities.

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FIGURE LEGEND

Figure 1: Trends in Oswestry Disability Index (ODI) scores

Figure 2: Trends in Numeric Rating Scale (NRS) scores

Figure 1

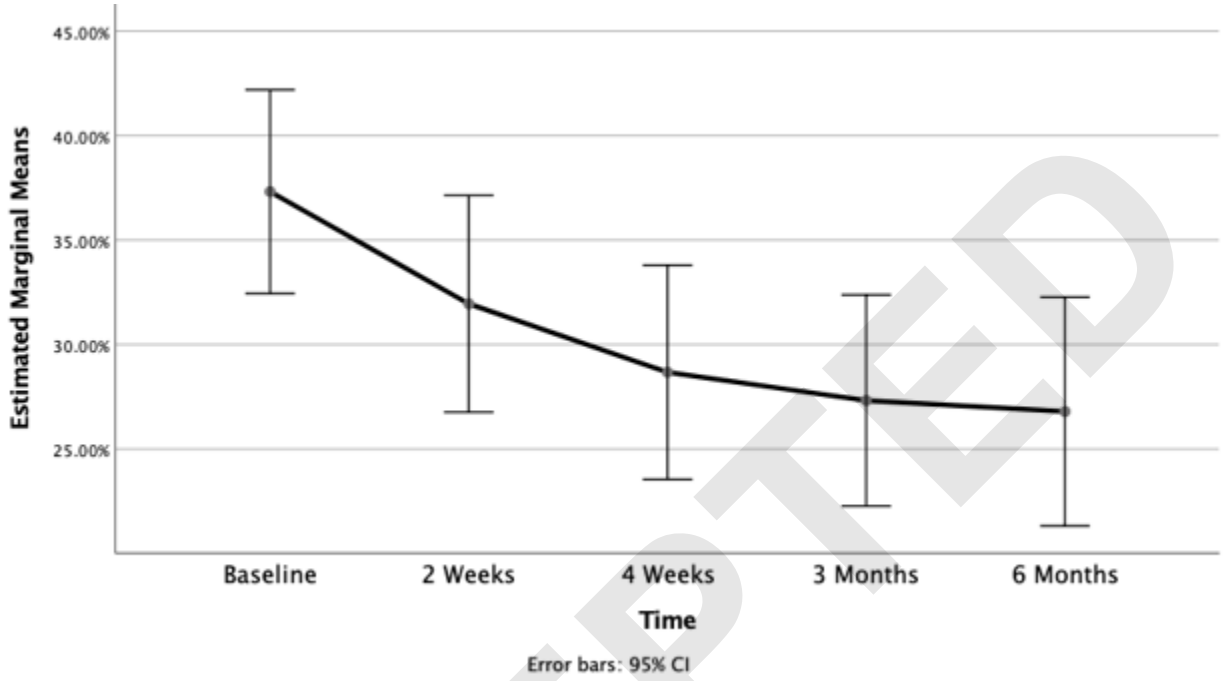

Figure 2

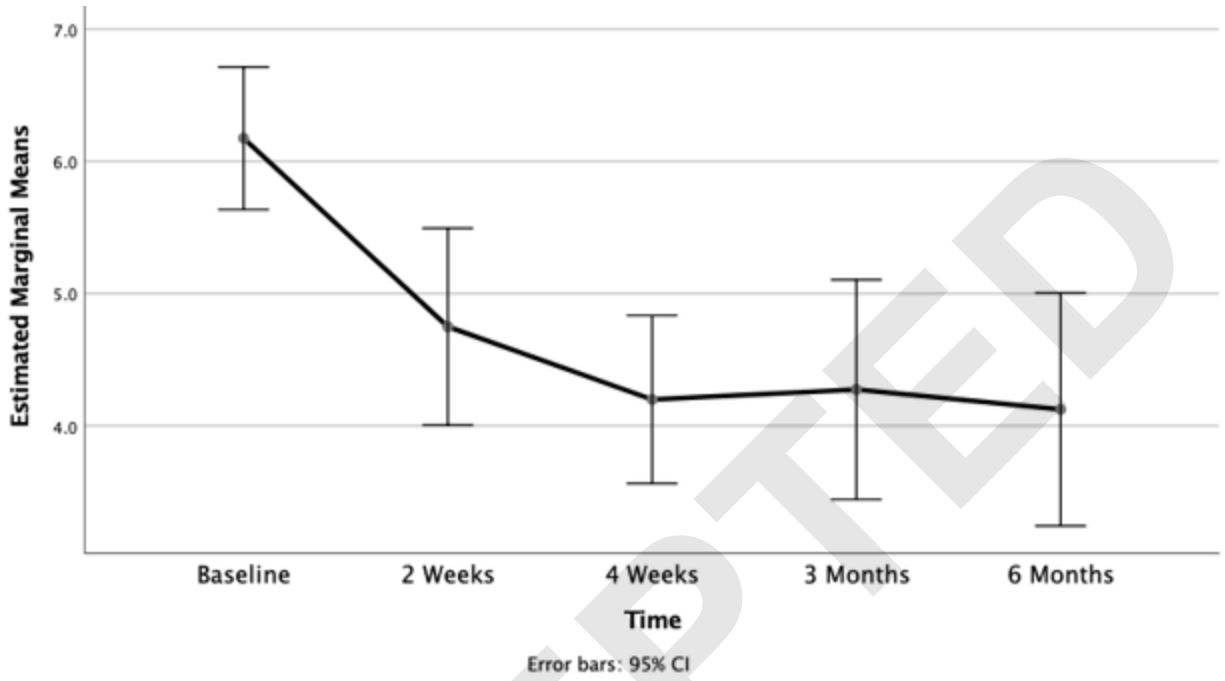

Table 1. Patient Demographics

	n = 50
Age (years)	60.2 (SD 17.7)
Male/Female	15 Males, 35 Females
BMI	28.7 (SD 5.74)
Preprocedure NRS score	5.6 (SD 2.08)
Preprocedure ODI score (%)	37.9% (SD 0.15%)
SIJ Side Distribution (R/L/Bilateral)	12 Right, 5 Left, 35 Bilateral

Table 2: Oswestry Disability Index (ODI) Scores Summarized

Mean Timeframe 1	Mean Timeframe 2	Mean Reduction	95% CI for Mean Reduction	Number of Injections (N)
Baseline	**2wk**			
38.48	33.75	-4.72	-2.27, -7.17	48
Baseline	**4wk**			
38.26	31.12	-7.14	-4.49, -9.78	49
Baseline	**3mo**			
37.84	29.07	-8.78	-4.62, -12.93	46
Baseline	**6mo**			
36.64	26.85	-9.79	-6.06, -13.52	42
2wk	**4wk**			
33.75	30.86	-2.90	-0.92, -4.88	48
4wk	**3mo**			
30.6	29.44	-1.16	-3.19, 5.51	46
3mo	**6mo**			
26.88	26.84	-0.04	-3.87, 3.94	42

CI = Confidence Interval, mo = months, wk = weeks

Table 3: Numeric Rating Scale (NRS) Scores Summarized

Mean Timeframe 1	Mean Timeframe 2	Mean Reduction	95% CI for Mean Reduction	Number of Injections (N)
Baseline	**2wk**			
6.07	4.99	-1.08	-0.45, -1.72	48
Baseline	**4wk**			
6.11	4.53	-1.58	-1.02, -2.14	49
Baseline	**3mo**			
6.11	4.41	-1.70	-1.02, -2.37	46
Baseline	**6mo**			
6.14	4.20	-1.94	-1.14, -2.74	42
2wk	**4wk**			
4.99	4.41	-0.57	-0.22, -0.92	48
4wk	**3mo**			
4.42	4.49	+0.07	-0.65, 0.52	46
3mo	**6mo**			
4.21	4.19	-0.01	-0.57, 0.60	42

CI = Confidence Interval, mo = months, wk = weeks