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## ORIGINAL ARTICLE

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# Steroid vs. Platelet-Rich Plasma in Ultrasound-Guided Sacroiliac Joint Injection for Chronic Low Back Pain

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### ■ Abstract

**Background:** Despite widespread use of steroids to treat sacroiliac joint (SIJ) pain, their duration of pain reduction is short. Platelet-rich plasma (PRP) can potentially enhance tissue healing and may have a longer-lasting effect on pain. **Objectives:** To assess the efficacy and safety of PRP compared with methylprednisolone in ultrasound-guided SIJ injection for low back pain.

**Study Design:** Prospective randomized open blinded end point (PROBE) study.

**Methods:** Forty patients with chronic low back pain diagnosed with SIJ pathology were randomly allocated into 2 groups. Group S received 1.5 mL of methylprednisolone (40 mg/mL) and 1.5 mL of 2% lidocaine with 0.5 mL of saline, while Group P received 3 mL of leukocyte-free PRP with 0.5 mL of calcium chloride into ultrasound-guided SIJ

injection. Visual analog scale (VAS) scores, Modified Oswestry Disability Questionnaire (MODQ) scores, Short Form (SF-12) Health Survey scores, and complications (if any) were evaluated at 2 weeks, 4 weeks, 6 weeks, and 3 months.

**Results:** Intensity of pain was significantly lower in Group P at 6 weeks (median [interquartile range (IQR)] = 1 [1 to 1] vs. 3.5 [2 to 5];  $P = 0.0004$ ) and 3 months (Median [IQR] = 1 [1 to 3] vs. 5 [3 to 5];  $P = 0.0002$ ) as compared to Group S. The efficacy of steroid injection was reduced to only 25% at 3 months in Group S, while it was 90% in Group P. A strong association was observed in patients receiving PRP and showing a reduction of VAS  $\geq 50\%$  from baseline when other factors were controlled. The MODQ and SF-12 scores were improved initially for up to 4 weeks but deteriorated further at 3 months in Group S, while both the scores improved gradually for up to 3 months in Group P.

**Conclusion:** The intra-articular PRP injection is an effective treatment modality in low back pain involving SIJ. ■

**Key Words:** low back pain, methylprednisolone, platelet-rich plasma, sacroiliac joint injection, ultrasound-guided, prospective randomized open blinded end point study

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### INTRODUCTION

The sacroiliac joint (SIJ) has been implicated as the primary source of pain in 10% to 27% of patients with

mechanical low back pain below the L5 vertebra.<sup>1</sup> The treatment of SIJ pain remains a therapeutic challenge. Besides physiotherapy and systemic therapies including nonsteroidal anti-inflammatory drugs (NSAIDs) and biological agents, intra-articular and periarticular injections of SIJ, radiofrequency neurotomy, and surgical fusion are often performed for pain relief.<sup>2-6</sup> SIJ steroid injection is a commonly used technique and has been found to be effective to treat SIJ pain. But due to its short-term effect, there is clearly a need to investigate treatments that have a longer-lasting effect and also directly address the disease process itself. Current research efforts aim at modifying the rate of joint healing using biological healing factors, which are various growth factors found abundantly in the human blood, especially in platelets.<sup>7</sup>

Platelet-rich plasma (PRP) is an autologous biological blood-derived product that can be exogenously applied to various tissues wherein it releases high concentrations of platelet-derived growth factors that enhance the body's natural healing response.<sup>8</sup> In addition, PRP possesses antimicrobial properties that may contribute to the prevention of infections.<sup>9</sup> Local injection of PRP is a new modality that has been effectively used for the treatment of various painful conditions. Use of PRP in conditions like tendinopathy,<sup>10</sup> muscle strain injury,<sup>11</sup> ligament injury,<sup>12</sup> and knee osteoarthritis<sup>13</sup> has shown promise and has been associated with significant reduction in pain, disability, and functional limitation, as well as improved structural integrity and biomechanical strength.<sup>14</sup> In a recent case series, periarticular administration of PRP for low back pain caused by SIJ laxity led to significant improvement in pain scores.<sup>6</sup> However, there is no study at present to evaluate the efficacy of intra-articular injection of PRP for the treatment of chronic SIJ pain. Considering the vast potential of PRP and its safety, this study aimed to investigate the efficacy of ultrasound-guided (USG) intra-articular SIJ injection of leukocyte-free PRP for chronic low back pain due to SIJ pathology. In the current study, we tested the hypothesis that the SIJ injection of leukocyte-free PRP may be more effective as compared with steroid injection for the treatment of SIJ pain.

## METHODS

After Institutional Ethics Committee approval, 40 American Society of Anesthesiologists (ASA) grade I and II patients of either sex between the ages of 18 and 65 years

with chronic low back pain (predominantly below the L5 vertebra) of moderate intensity (visual analog scale [VAS] score of > 3) for > 3 months were selected. Patients having unilateral SIJ pathology on X-ray, magnetic resonance imaging (MRI), or nuclear scan with 3 or more positive provocative tests (sacral thrust, iliac distraction, iliac compression, thigh thrust, Patrick's test, and Gaenslen's test) were included in the study after written informed consent was obtained. Exclusion criteria were systemic infection (fever, chills, and/or night sweats) or localized infection at the anticipated introducer entry site; spinal pathology that may impede recovery, such as spondylolisthesis at L5/S1, or scoliosis, symptomatic foraminal, or central canal stenosis; history of potentially confounding intervertebral disk disease or zygapophyseal joint pain; pregnancy; active radicular pain; immunosuppressive conditions (tuberculosis, acquired immune deficiency syndrome, cancer, diabetes, surgery < 3 months); allergy to medications used in the procedure; narcotic use (> 60 mg morphine daily or equivalent); and contraindications pertaining to the use of platelet concentrate like history of thrombocytopenia, use of anticoagulant therapy, active infection, tumor, or metastatic disease. The sensitivity and specificity for 3 or more of the 6 provocative tests for diagnosis of SIJ pain were 94% and 78%, respectively.<sup>15</sup> SIJ and zygapophyseal joint pain were differentiated based on history and physical examination findings. Patients on > 60 mg opioids were excluded because, in our experience, they do not respond adequately due to severe pain. The patients were randomly allocated into 2 groups by computer-generated random numbers, and the allocation sequence was concealed in sealed opaque envelopes. Group S received 1.5 mL of methylprednisolone (40 mg/mL)<sup>16</sup> and 1.5 mL of 2% lidocaine with 0.5 mL of saline, while Group P received 3 mL of leukocyte-free PRP with 0.5 mL of calcium chloride (total volume 3.5 mL in both groups) into USG intra-articular SIJ injection.

### Preparation of Platelet-Rich Plasma

About 100 mL of blood was drawn from the patient and collected in a blood bag with citrate phosphate dextrose and adenine (CPD-A1) on the day of scheduled intervention. PRP was separated from the whole blood by centrifugation for 15 minutes at 720 g, from which leukocytes were filtered to yield the final 3 mL of leukocyte-free PRP inside a biosafety cabinet. A leukocyte filter (Imugard III-PL; Terumo Penpol Limited,

Thiruvananthapuram, India) was used to filter off the leukocytes from the PRP. These were polyurethane filters that could filter > 99% of leukocytes from the PRP. Entrapment of leukocytes is carried out mainly by pore size distribution within the filter, with very limited cell–material interaction. Blood was obtained and handled in sterile conditions at all steps of PRP preparation.

### Interventional Procedure

SIJ injection was given under all aseptic precautions using ultrasound guidance with a low-frequency (4 to 5 MHz), curvilinear transducer as described by Harmon and O’Sullivan.<sup>17</sup> The patient was placed in the prone position. The transducer was settled in a transverse direction at the level of the sacral hiatus, and the sacral cornua were identified. Then, the lateral edge of the sacrum was identified by moving the transducer laterally, and a second bony contour, the ileum, was identified by following this bony edge in a cephalad direction. The SIJ was observed as a hypo-echoic cleft area between the 2 echogenic lines of the sacrum and iliac bone. The posterior caudate SIJ, the portion of the joint into which the injection was performed, was identified by tilting the transducer in a caudal direction. After administration of local anesthesia with 2% lidocaine, a 22-gauge cutting-edge spinal needle was advanced into the joint in a medial-to-lateral direction, in plane approach, under real-time sonographic guidance. When the needle tip was positioned precisely in the joint space, a mixture of 2% lidocaine with methylprednisolone or PRP with calcium chloride was injected (total 3.5 mL) according to the patient’s group assignment. Following injection, the patients were laid down in the supine position for 30 minutes and were monitored for heart rate, blood pressure, oxygen saturation, and any adverse events.

### Follow-up

The patients were followed up at 2 weeks, 4 weeks, 6 weeks, and 3 months for assessment of pain intensity, functional disability, and any adverse events. The pain score was assessed by VAS (score range = 0 to 10; <4, 4 to 6, and more than 6 for mild, moderate, and severe pain, respectively). The percentage change in score from baseline was calculated according to the formula:

Percentage mean VAS benefit

$$= \frac{\text{Pre-injection mean VAS} - \text{mean VAS at follow-up}}{\text{Pre-injection mean VAS}} \times 100$$

The Modified Oswestry Disability Questionnaire (MODQ) score (score range = 0 to 50, percentage range = 0% to 100%; 0% to 20% = minimal disability, 20% to 40% = moderate disability, 40% to 60% = severe disability, 60% to 80% = crippled, and 80% to 100% = bed-bound) and Short Form Health Survey (SF-12) score (score range = 0 to 100)—further divided into the Physical Health Component Score-12 (PCS-12) and Mental Health Component Score-12 (MCS-12)—were assessed at baseline, 2 weeks, 4 weeks, 6 weeks, and 3 months. The investigator performing the SIJ injections and the person collecting the data were blinded to the injectate being given at the time of procedure. All pain medications, including NSAIDs, were discontinued at the beginning of the trial; patients did not receive additional medical therapy or physiotherapy during the study. Sulfasalazine was continued in patients with ankylosing spondylitis (AS) during the study period. None of the patients were on tumor necrosis factor- $\alpha$  inhibitors. For the CONSORT 2010 flow diagram, see Figure 1.

### Statistical Analysis

Statistical analysis was performed using Statistical Package for the Social Sciences software, version 20 (IBM-SPSS, Armonk, NY, USA) and GraphPad prism software (GraphPad Software, Inc., La Jolla, CA, USA). Numerical variables were evaluated for normality of data by the Kolmogorov–Smirnov test. Continuous data like age, weight, and height were compared using independent Student’s *t*-test, whereas nonparametric data like sex ratio, pain score, and disability score were compared between the 2 groups using the chi-squared test of Mann–Whitney *U*-test. Skewed data were analyzed using Fischer’s exact test. VAS, MODQ, and SF-12 scores were compared to baseline by repeated measures analysis of variance for multiple comparisons with post hoc analysis using Bonferroni correction. Multivariate analysis was performed to calculate the adjusted odds ratio (OR) for the reduction of VAS  $\geq$  50% in both groups after controlling confounding variables by applying binary logistic regression. All tests were evaluated for 95% confidence limits. A *P* value of < 0.05 was considered statistically significant.

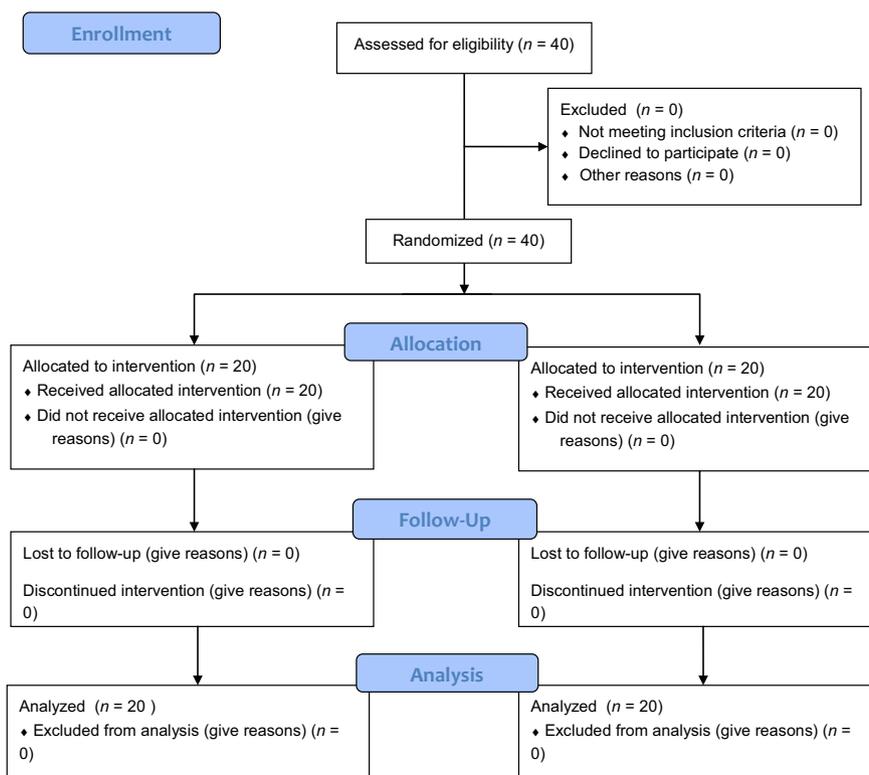


Figure 1. CONSORT 2010 flow diagram.

## RESULTS

### Baseline Parameters

There was no significant difference in the baseline parameters between the two groups (Table 1). The mean platelet content in PRP was  $2.94 \pm 1.43 (\times 10^9)$ . Group P and Group S had 4.50 (4.00 to 5.00) and 5.00 (4.00 to 5.00) of positive provocative tests, respectively. AS and traumatic SIJ dysfunction were common causes of pain in both groups.

### Outcome Measures

There was significant decrease in intensity of pain (VAS) from pre-injection to further follow-ups in both groups. VAS scores were comparable at 2 weeks, 4 weeks, 6 weeks, and 3 months in Group P, while a significant increase in VAS score was observed at 3 months as compared to 2 weeks and 4 weeks in Group S (Figure 2). There was no significant difference in VAS score between the 2 groups at pre-injection, 2 weeks, and 4 weeks, while it was significantly lower in Group P at 6 weeks and 3 months as compared to Group S (Table 2).

Table 1. Baseline Parameters

Parameters	Group P <i>n</i> = 20	Group S <i>n</i> = 20
Age (years)	35.20 ± 12.86	37.00 ± 10.89
Height (cm)	164 ± 6.00	166 ± 7.00
Weight (kg)	61.95 ± 12.22	61.1 ± 7.55
BMI	23.69 ± 2.54	22.41 ± 2.08
Sex (M:F)*	16:4	16:4
ASA grade (I:II)*	18:2	20:0
SIJ sideways distribution (R:L)*	6:14	6:14
Cause of pain <sup>†</sup>		
Ankylosing spondylitis	10 (50%)	8 (40%)
Trauma	7 (35%)	8 (40%)
Idiopathic	3 (15%)	2 (10%)
Degenerative	0	2 (10%)
Sacral tenderness <sup>‡</sup>	10 (50%)	9 (45%)

\*Expressed as ratio Rest specified as mean ± SD.

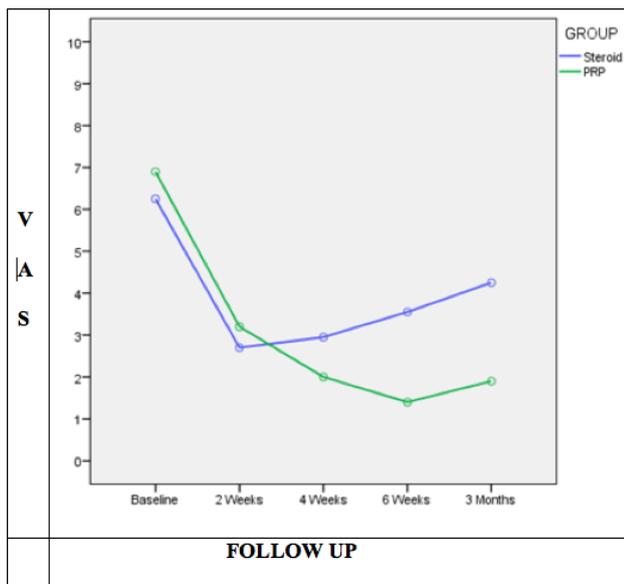
<sup>†</sup>Expressed as number of patients (%) in each group.

BMI, body mass index; ASA, American Society of Anesthesiologists; SIJ, sacroiliac joint; R, right; L, left.

There was no statistically significant difference in patients having  $\geq 50\%$  reduction in VAS score at 2 weeks and 4 weeks among groups; and at 4 weeks, about 70% to 75% of patients were pain free in both groups. The percentage of pain-free patients at 3 months was 90% in Group P but was reduced to only 25% in Group S. A significantly higher number of

patients were pain free in Group P as compared to Group S at 6 weeks and 3 months (Table 3).

In Group P, a strong association was observed in patients receiving PRP and reduction in VAS score of  $\geq 50\%$  from baseline on application of standard logistic regression analysis of primary outcome when other factors (age, sex, body mass index [BMI], LBA duration, and provocative test) were controlled. The odds of achieving reduction in VAS  $\geq 50\%$  from baseline in Group P were 10.91 times higher than in Group S at 6 weeks (adjusted OR = 10.91, 95% confidence interval [CI] 1.56 to 76.38,  $P = 0.016$ ) and 37.277 times higher at 3 months (adjusted OR = 37.277, 95% CI 4.652 to 298.694,  $P = 0.001$ ). There was no significant association between reduction in VAS score and other selected variables like age, sex, BMI, LBA duration, or provocative test.



**Figure 2.** Trends in visual analog scale (VAS) scores of both groups at baseline and subsequent follow-ups. PRP, platelet-rich plasma.

There was a significant decrease in intensity of pain (VAS) from pre-injection to 4 weeks, 6 weeks, and 3 months in Group P, and from pre-injection to 2 weeks, 4 weeks, and 6 weeks in Group S in AS patients. Decrease in intensity of pain (VAS) was evident at all follow-ups in Group P but only at 2 weeks and 4 weeks in Group S in trauma patients. There was no significant difference in VAS score between the 2 groups at pre-injection and 2 weeks, while it was significantly lower in Group P at 6 weeks and 3 months as compared to Group S in AS patients, and at 4 weeks, 6 weeks, and 3 months in trauma patients (Figure 3).

There was significant improvement in the MODQ score from pre-injection to 2 weeks, 4 weeks, 6 weeks, and 3 months in both groups. The MODQ scores were comparable among groups at pre-injection, 2 weeks, and 4 weeks after SIJ injection, while they were significantly lower in Group P at 6 weeks and 3 months as compared to Group S. At each follow-up, the percentage benefit from baseline increased in Group P, except at the last follow-up, and decreased in Group S (Figure 4).

The PCS and MCS were comparable among groups during the pre-injection period. There was significant improvement in PCS and MCS from pre-injection to 2 weeks, 4 weeks, 6 weeks, and 3 months in both groups. The PCS was comparable at 2 weeks, 4 weeks, 6 weeks, and 3 months in Group P, while there was a significant reduction in PCS at 3 months as compared to 2 weeks, 4 weeks, and 6 weeks in Group S. The MCS improved at 6 weeks and 3 months in Group P but deteriorated in Group S. PCS and MCS were significantly better in Group P at 6 weeks and 3 months as compared to Group S (Figure 5).

Postinjection complications were comparable among groups, except for a higher incidence of postinjection pain and stiffness in Group P, which subsided within 2 days (Table 4). No major complications were observed in any group of patients.

**Table 2. Median (Interquartile Range) of Visual Analog Scale Scores at Different Time Frames**

Time	Median (IQR)		Median Difference	95% CI		P
	Group P	Group S		Lower	Upper	
Pre-injection	7.5 (5 to 8)	6 (5 to 7)	1.000	0.000	2.000	0.132
2 weeks	3 (0 to 5)	3 (2 to 3)	0.000	-1.000	2.000	0.706
4 weeks	1.5 (1 to 3)	3 (2 to 4)	-1.000	-2.000	0.000	0.054
6 weeks	1 (1 to 1)	3.5 (2 to 5)	-2.000	-4.000	-1.000	0.0004
3 months	1 (1 to 3)	5 (3 to 5)	-3.000	-4.000	-1.000	0.0002

IQR, interquartile range; CI, confidence interval.

## DISCUSSION

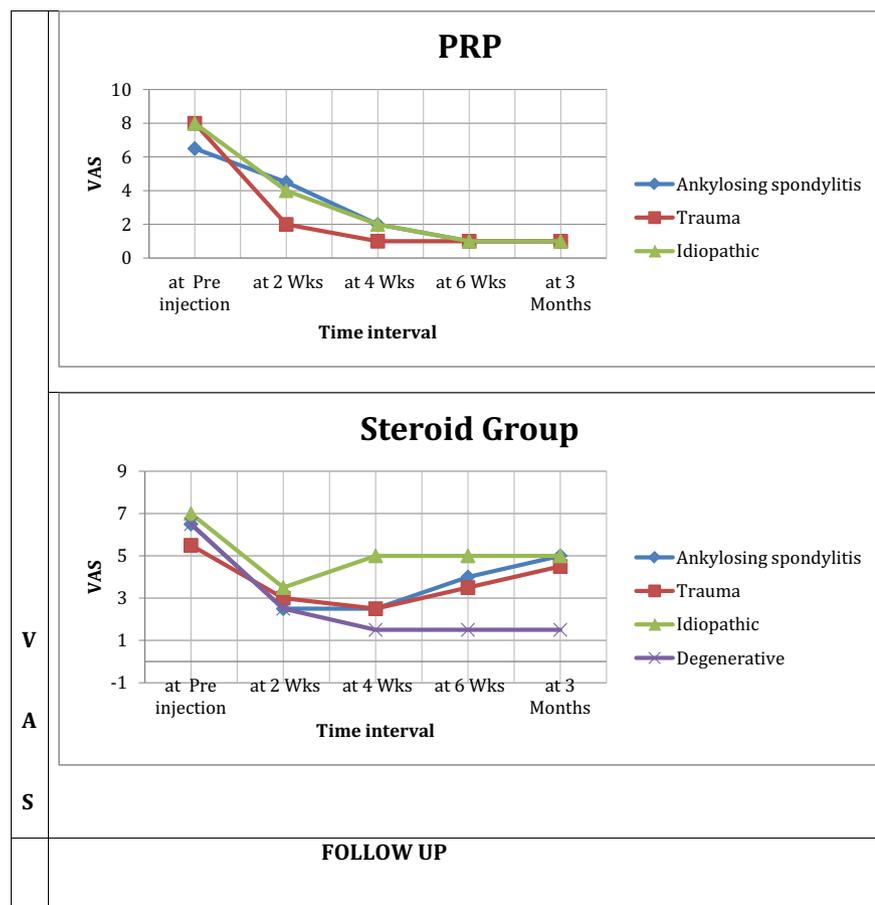
The results of the present study showed that patients receiving PRP had more and longer-lasting improvement in pain intensity and functional limitation compared to the patients receiving steroids. The effect of PRP was sustained, while patients receiving steroids had deterioration of the initially improved VAS score at 3 months. Also, more patients receiving PRP had pain relief. PRP was effective in 60% and 90% of patients, while steroids were effective in 75% and 25% of patients at 2 weeks and 3 months, respectively.

**Table 3. Patients with Reduction of Visual Analog Scale Scores  $\geq 50\%$  at Different Time Frames**

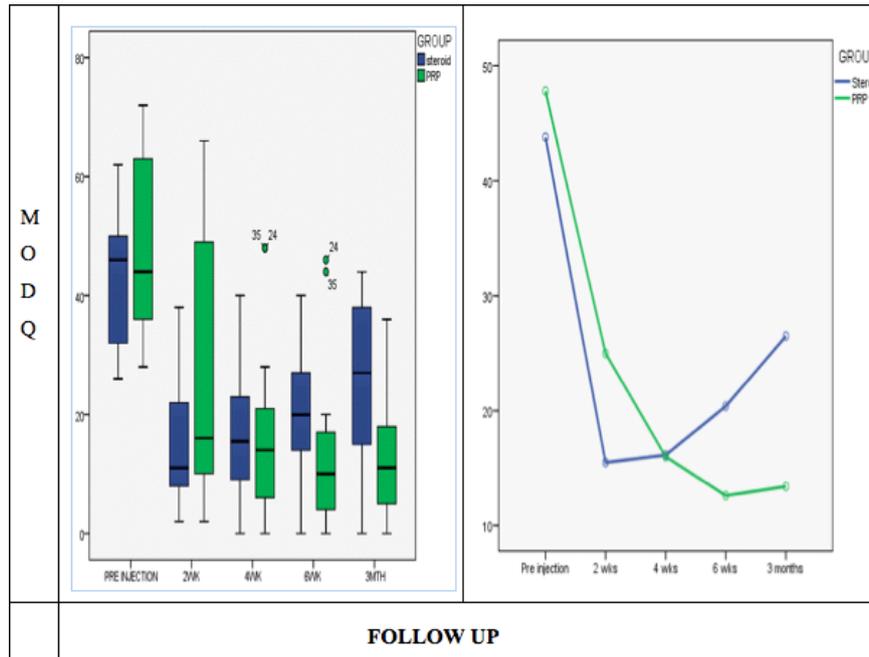
Time	Reduction of VAS $\geq 50\%$			Unadjusted OR	95% CI for Unadjusted OR	
	Group P	Group S	P			
2 weeks	12 (60%)	15 (75%)	0.311	—	—	—
4 weeks	15 (75%)	14 (70%)	0.723	—	—	—
6 weeks	18 (90%)	9 (45%)	0.002	11.0	1.99	60.57
3 months	18 (90%)	5 (25%)	0.001	27.0	4.56	159.66

CI, confidence interval; OR, odds ratio.

Previous studies also showed improvement in pain and functional disability with the use of PRP injection in various pain conditions like tennis elbow,<sup>18,19</sup> knee osteoarthritis,<sup>13</sup> Achilles tendinopathy,<sup>10</sup> and chronic patellar tendinosis.<sup>14</sup> In a randomized controlled trial, reduction of 25% in VAS score and disabilities of the arm, shoulder, and hand (DASH) scores without a re-intervention was found in both the leukocyte-enriched PRP group and steroid group after 1 year and 2 years in patients with chronic lateral epicondylitis. DASH scores of the corticosteroid group returned to baseline, while those of the PRP group significantly improved (as-treated principle).<sup>18</sup> In another study, Patel et al.<sup>13</sup> reported improved mean VAS and physical function scores at 6 weeks and 3 months in patients with bilateral early knee osteoarthritis receiving single- or double-injection PRP as compared to the control (saline) group. In a recent case series of SIJ laxity, Ko<sup>6</sup> also found a decrease in the numeric rating scale score compared to baseline in all 5 patients receiving single/multiple periarticular PRP injections into the sacroiliac ligament.



**Figure 3.** Trends in visual analog scale (VAS) scores of both groups at baseline and subsequent follow-ups based on cause of pain. PRP, platelet-rich plasma.



**Figure 4.** Median (interquartile range) of Modified Oswestry Disability Questionnaire (MODQ) scores at different time frames. Left panel shows pairwise comparison of MODQ scores at each follow-up with one another and each other. Right panel shows comparison of the 2 groups for percentage change in MODQ from baseline at all follow-ups. PRP, platelet-rich plasma.

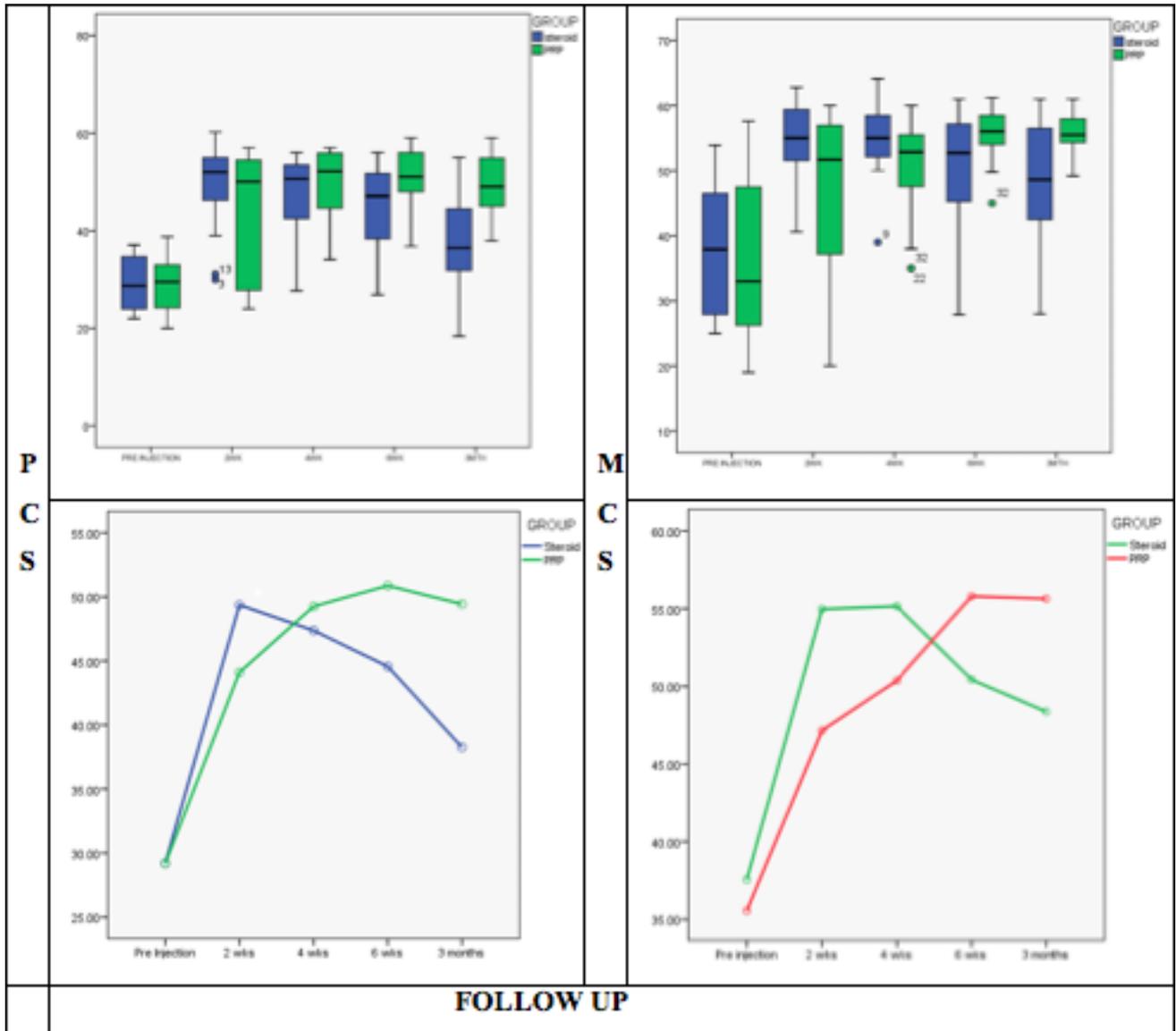
The efficacy of steroid injection was less and of shorter duration in the present study. We found that only 25% of patients receiving intra-articular steroid SIJ injections had a reduction in the VAS score of  $\geq 50\%$  at 3 months. Previous studies also demonstrated similar efficacy of pain relief after SIJ steroid injection. Borowsky et al.<sup>3</sup> reported reduction in the VAS score of  $\geq 50\%$  in 12.50% and 31.25% of patients after intra-articular and periarticular SIJ injection of steroid (40 mg methylprednisolone), respectively, at 3 months. Hawkins and Schofferman<sup>2</sup> also found that only 40 of 118 patients (33.9%) had a reduction in the VAS score of  $\geq 50\%$  with a single steroid (dexamethasone/betamethasone) SIJ injection.

Analyzing these studies, it is evident that anti-inflammatory factors alone are not enough to improve the disability and general health in patients with SIJ pain. Addition of growth factors enhances the biological environment and helps to attain tissue homeostasis. Thus, a cocktail of anti-inflammatory factors along with growth factors plays a vital role in improving disability and general health. It might be hypothesized that PRP administration affects ongoing degeneration in the joint and modifies the disease course, in addition to reducing pain, disability, and improving general health, leading to a prolonged effect on pain relief. However, this

requires further investigation with a larger sample size and longer follow-ups to support the proposed hypothesis, which might revolutionize the management of SIJ pain.

We did not find any major complications in either group. Although the incidence of pain and stiffness was higher in the PRP group, it was transient, local, and mild in nature. The study by Ko<sup>6</sup> also mentioned postinjection pain after PRP injection into SIJ ligaments in 1 patient. It might be due to the stimulation of the body's natural response to inflammatory mediators, which is the physiological effect of platelets or calcium rather than injection technique. No serious complications such as infection, marked muscle atrophy, deep vein thrombosis, fever, hematoma, tissue hypertrophy, adhesion formation, or systemic complications like dizziness, headache, nausea, gastritis, sweating, or tachycardia occurred among our study subjects. The use of autologous blood products reduces the risk of transmissible infection and allergic reaction. Laboratory studies have also suggested that PRP may have an antimicrobial effect.<sup>9</sup>

We used ultrasound guidance to perform the injection due to the complex anatomy of the SIJ, which has a high failure rate when performed blindly.<sup>17</sup> USG SIJ injections were utilized compared to commonly used fluoroscopy-guided SIJ injections because the success rate



**Figure 5.** Median (interquartile range) of Physical Health Component Score (PCS) and Mental Health Component Score (MCS) at different time frames. Left panels show trends in mean PCS, and right panels show trends in mean MCS of all groups at baseline and subsequent follow-ups. PRP, platelet-rich plasma.

for USG SIJ injection has been reported to be high in the hands of experienced operators.<sup>20</sup> Moreover, ultrasonography has various advantages over fluoroscopy, computed tomography, and MRI, being an economical, reproducible, easily available imaging method without the use of ionizing radiation and real-time guidance of needle penetration to the target area.<sup>17</sup> Our PRP preparation technique was also different from the previous technique.<sup>6</sup> We used a leukocyte filter so that our final PRP product was leukocyte-free and rich in platelets, with the number of platelets injected being an average of 2.94 billion.

### LIMITATIONS OF THE STUDY

This was a prospective randomized open blinded end point (PROBE) study that could result in bias due to the subject not being blinded for the study groups. A follow-up duration of 3 months is not enough to adequately evaluate chronic conditions like SIJ pain. We evaluated only clinical parameters using VAS, MODQ, and SF-12 scoring systems, which primarily measure pain and disability. Other laboratory parameters signifying the pathophysiological effects of treatment on the disease process were not assessed. AS disease activity scoring

**Table 4. Distribution of Complications Among Study Groups**

Complications	Group P	Group S	P
Postinjection pain and stiffness	9 (45%)	1 (5%)	0.008
Chest pain and difficulty breathing	1 (5%)	1 (5%)	1.000
Giddiness	0	1 (5%)	1.000
Contralateral pain	1 (5%)	1 (5%)	1.000
Total	11 (55%)	4 (20%)	0.048

was not performed, and immunosuppressive therapy (sulfasalazine) has been shown to inhibit arachidonic acid-induced platelet aggregation, which might have an effect on PRP activity.

## CONCLUSION

The results of this study showed that the steroid and PRP both were effective in relieving pain and functional disability, but PRP was more efficacious than the steroid. The reduction in pain intensity and improvement in functional disability were significantly greater and lasted longer in the PRP group as compared to the steroid group. The patients receiving steroids improved dramatically in the short term, with decreased efficacy later. A greater number of patients with significant relief of pain were in the PRP group. As there were no serious adverse events, it is fair to conclude that SIJ injection of PRP is a safe and effective technique for the treatment of low back pain due to SIJ arthropathy.

## FUNDING

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