A comparison of ultrasound guided PRP injection and prolotherapy for mechanical dysfunction of the sacroiliac joint

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ABSTRACT

Objective: *The sacroiliac joint (SIJ) can become dysfunctional through trauma and/ or pregnancy. The mechanism involves direct or repetitive microtrauma to the buttocks/ lower back. Treatment with specialised physiotherapy alleviates the problems in ~ 80% of cases. The remainder may respond to prolotherapy (hypertonic glucose injections into the dorsal intra-osseous ligament (DIOL) after multiple injections. We hypothesised that the response may be more rapid with injection of platelet enriched plasma (PRP) into the DIOL under ultrasound guidance.*

Design: *Following Ethics approval, a study was undertaken to compare the efficacy of PRP injections Vs Standard prolotherapy.*

Setting: *A group of 45 patients (35F, 10M, Age range:18-70 yrs) was studied and the results compared to the control group who had received hypertonic glucose injections following tertiary referral from specialized sports medicine physicians.*

Main outcome measures: *All patients were assessed clinically at baseline, 3 and 12 months. Outcome measures included VAS, Roland-Morris questionnaire and Quebec Back Pain inventory, as well as clinical tests of SIJ incompetence.*

Results: *The outcome measures of change in pain scores, improvement in function between the groups was superior for the PRP group, All PRP patients experiencing significant improvement in pain score and function. The number of injections required was less for the PRP group (mean of 1.6) than the controls (mean 3.0).*

Conclusion: *PRP is a viable alternative to hypertonic dextrose injections into the DIOL in patients who have failed physiotherapy for SIJ incompetence. It is better tolerated as less injections are required and avoids radiation exposure in a relatively young group of patients.*

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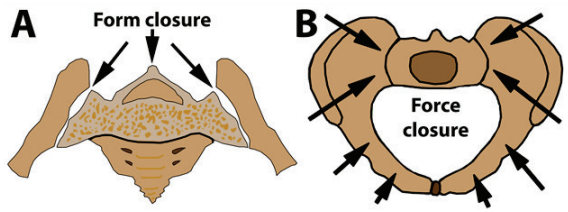
KEYWORDS: sacroiliac joint, PRP, platelet enriched, prolotherapy, dorsal interosseous ligament, ultrasound.

Introduction

Lateralising lower back pain is an epidemic that began in the 20th century and has progressed unabated into the 21st century. It has both a high social and economic cost to the community and its diagnosis and therapy have raised more questions than it has answered.[1] The role of surgery has come under significant scrutiny due to the absence of significant evidence to its utility.[2] While there are a number of papers that advocate intervertebral disc prolapse as a major cause of pathology[3], a meta-analysis indicates that it is responsible for approximately 15% of low back pain, with 85% being defined as non-specific lower back pain (NSLBP).[4]

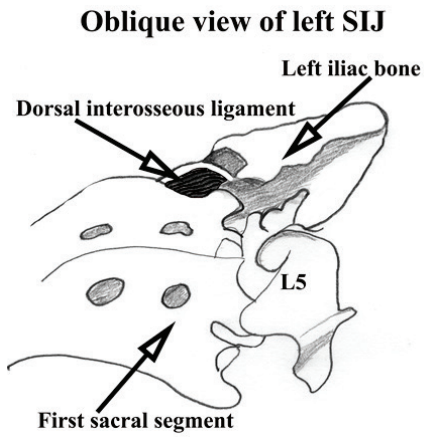
The northern European literature is replete with numerous publications that report the sacroiliac joint (SIJ) as a major cause of lateralising lower back pain, particularly in the postpartum period (pelvic girdle pain syndrome).[5-16] These studies indicate that dysfunction of the sacroiliac joint may account for up to 20% of low back pain in the peri-partum population. Others have reported a significant incidence of traumatic dysfunction of the sacroiliac joint and coined the term sacroiliac joint incompetence to include both trauma and the postpartum variant.[17] The evidential basis for the diagnosis are the European guidelines for the diagnosis and treatment of pelvic girdle pain.[18] The basis for the treatment is the integrated model of form and force closure of the sacroiliac joint.[19] Two aspects characterise the model. (*See Figure 1.*) Form closure of the sacroiliac joint is due

Figure 1. Form and Force closure of the sacroiliac joint. **Panel A.** Form closure is due to the fit of the irregular surfaces of the sacrum and iliac bones physically locking the sacrum into the pelvic ring (arrows) between the two iliac bones. The posterior integrity of the joint is maintained by the dorsal interosseous ligament. **Panel B.** Force closure is the compressive effect exerted on the pelvic ring by the co-ordinated contraction of the abdominopelvic muscles which shut the sacrum between the iliac bones and stops it rotating outward.



to the interlocking surfaces between the sacrum and the adjacent iliac bones and the stabilising influence of the dorsal interosseous sacroiliac ligaments (DIOL). (*See Figure 2.*) Force closure is due to the sequential contraction of the abdominal core muscles which lock the sacrum into the pelvic ring. Loss of the sequential contractility is a response to abnormal mechanics, where the sacrum counter-nutates or rotates out of the pelvic ring when the DIOL is damaged, triggering disadvantageous muscle activity (spasm) with resultant loss of force closure.

Figure 2. Dorsal interosseous ligament (DIOL). The deep and superficial parts of the DIOL fill in and stabilise the posterior aspect of the sacroiliac joint to form the syndesmotic part of the joint. The fibres cross the joint in a variety of orientations to maximise stability. It is considered the strongest ligament in the body, as it has to bear the weight of the thorax, neck, upper limbs and head.



While directed physiotherapy can improve pain, disability and function by re-sequencing the contractility to restore force closure, it is predicated on residual integrity of the damaged DIOL. If the damage to the ligaments is extensive, therapy fails in approximately 20% of cases[20] requiring measures such as prolotherapy (hypertonic dextrose)[20] or in extreme cases, surgical fusion of the SIJ[21] to restore function. There is evidence that platelet rich plasma (PRP) which is rich in factors such as platelet-derived growth factor (PDGF) and insulin-like growth factor 1(IGF-1) plays a significant role in wound healing.[22]

We hypothesised that ultrasound-guided PRP injection into the DIOL could restore function in this group of patients by improving the integrity of the ligaments. This was studied prospectively in an open-label group of patients who had failed targeted physiotherapy at 3 months after initiation of therapy. Results were compared with historical controls undergoing prolotherapy in a previously published trial.[20]

Material and Methods

PATIENTS

Inclusion criteria included patients who presented with pain in the lumbo-sacral region who demonstrated 3 of 4 positive validated clinical signs[18] and who had failed best practice physiotherapy for a minimum of 3 months. The group included several elite athletes from snow sports (2), football (1), hockey (1), tri-athletics (1), judo (1), surf boat rowing (1), Police SWAT team (2) and pole dancing (1). There was a clear history of discrete trauma to the lower back or buttocks or repetitive trauma such as landing on the same leg after jumping.

Exclusion Criteria: age less than 18, and patients who had a history of the following: prior pelvic fractures, pregnancy, platelet deficiency, inflammatory conditions, and neoplastic disease.

All patients gave informed written consent following ethics approval from the University of Notre Dame in Sydney (Ethics PP : 015002S) and the study was registered as a clinical trial with the Australian and New Zealand Trial Registry (ANZ TR 368092).

PREPARATION OF PLATELET RICH PLASMA

A commercially available system of PRP preparation (Regen System (RegenLab Le Mont-sur Lausanne, Switzerland) was utilised as it requires only 9 mL of blood and centrifugation (E8 Centrifuge, LW Scientific, Georgia, USA) for 5 minutes at 3500 RPM. The process takes approximately 10 minutes to complete. This system concentrates platelets by a factor of 1.6 times baseline and allows recovery of over 80% of platelets with removal of over 95% of granulocytes and 99% of red blood cells.[23]

INJECTION TECHNIQUE

The ultrasound injection technique was adapted from the work of Hartung et al.[24] Our group however targeted the injection into and around the dorsal interosseous ligament (DIOL) rather than the synovial portion of the sacroiliac joint. This technique has been described in detail previously.[25] A Sonosite Edge ultrasound machine (Fujifilm Sonosite, Washington, USA) was utilised with a 5-16 MHz linear probe.

The patients were positioned in the prone position with a pillow under the pelvis. Feet were in internal rotation and inversion to provide better access to the sacroiliac joints.[24]

The posterior superior iliac crests (PSIS) and sacral cornua were palpated and marked on the skin. (*See Figure 3.*) The ultrasound transducer was placed in a transverse orientation to the sacrum and the probe moved to the lateral edge. Moving the probe in a cephalad direction allowed identification of the contour of the ilium. The cleft between the two bony contours is the location of the sacroiliac joint. (*See Figure 4.*) The component of the joint injected in this procedure is the dorsal interosseous ligament. (*See Figures 2 & 4.*) This is found at the S1/S2 level. The S1 and S2 spinous processes were identified and marked. The transducer was placed in a lateral orientation between these two points. Therapeutic injection was undertaken at this level. As the angle of the SIJ changes in individuals, the angulation of the needle was adapted, but generally found to lie between 45 and 65 degrees.[25]

An initial skin injection along the track of the eventual injection was performed using Lignocaine 1% without entry into the DIOL. This initial track was then followed when performing the therapeutic injection of the PRP solution into the DIOL of the SIJ.

Figure 3. Establishment of the landmarks for injection of the DIOL. This is defined by the triangulation between the posterior superior iliac crests and the sacral cornua (arrows). The spines of the sacral segments are then palpated and marked and the ultrasound transducer is placed in a transverse orientation at approximately the S2 segment.

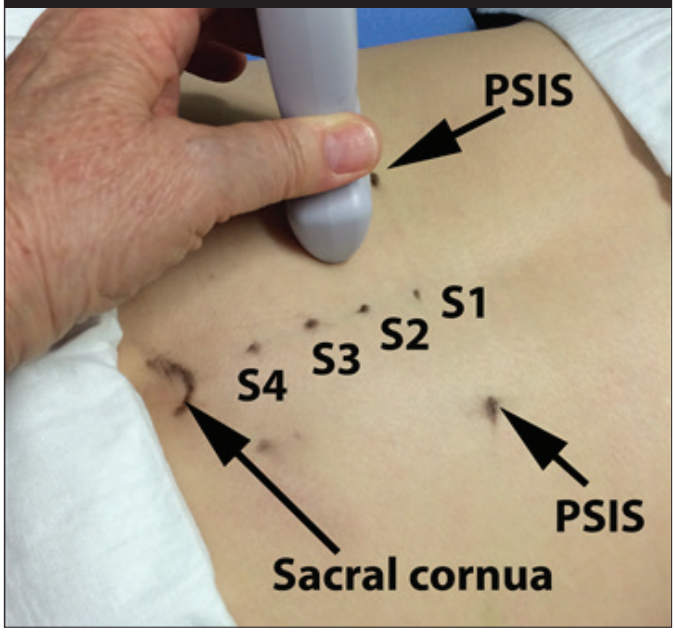
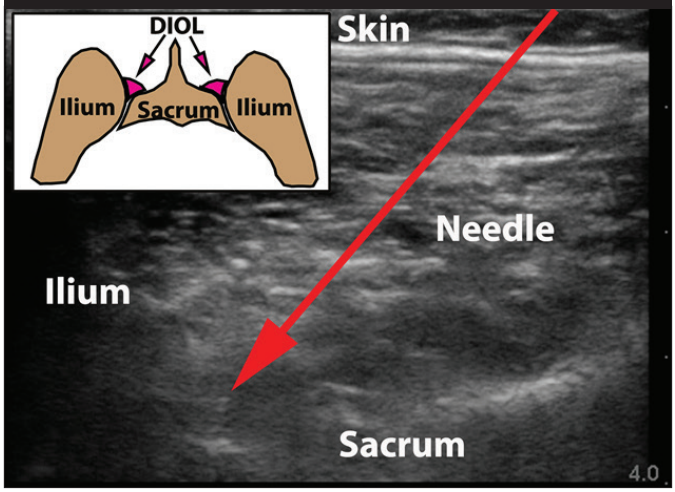


Figure 4. The ultrasound probe positioning technique in *Figure 3* yields images of the iliac bone and sacrum at the S2 segmental level at the lateral edge of the sacrum. The needle path is angulated at approximately 45 degrees to the vertical towards the gap between the iliac bone and the sacrum to reach the dorsal interosseous ligament as shown in the inset anatomical drawing (arrows) in a transverse orientation.



At the time of injection of the PRP solution into and around the DIOL, the needle was introduced into the ligament and the typical pain reproduced. The patient was asked to remember the pain distribution. They were

asked to shade in the pain distribution on a pain map immediately after the procedure ended. (*See Figure 5.*)

Injections were performed as a single injection per visit with the second injection being 6 weeks to 3 months later depending on the clinical follow-up.

CLINICAL FOLLOW-UP

All patients were assessed clinically at baseline, 3 and 12 months. Clinical scores were derived from the battery of evidence-based tests detailed in the European guidelines for SIJ mechanical dysfunction.[18] Briefly, the tests were the standing flexion test, Stork stance and hip flexion phases, active straight leg raise, pain to palpation of the DIOL, the P4 and Faber test as well as the SIJ glide with and without muscle activation. Outcome measures included the Visual analogue pain scale (VAS), Roland-Morris questionnaire and Quebec back pain inventory as well as clinical tests of SIJ incompetence.[18]

These results were compared to a group of patients treated with prolotherapy (hypertonic glucose) with equivalent follow-up and reported elsewhere.[20] Briefly, patients were treated with a single injection per visit with the remainder being administered as single injections approximately 3 months apart depending on the response at follow-up visits. All injections were administered into the DIOL under CT guidance.

Results

CLINICAL GROUP

A total of 48 patients were recruited into the study but 3 patients dropped out after the first injection, leaving 45 patients with complete follow-up. This was comprised of 35 females (Mean age: 38.7 years) and 10 males (Mean age: 33.4) with an overall age range of 18-70 years. Patients identified the peri-partum period, trauma to the buttocks/lower back or repetitive injury as the main associations with the onset of lateralising lower back pain and indicated the distribution of their pain on a baseline pain map. (*See Figure 5.*) The average length of symptoms was 46 months with a median of 57 months. Clinical findings met criteria defined in the European guidelines[18] and confirmed by the fused single photon emission computed tomography (SPECT) and low-dose x-ray computed tomography (CT) in all patients.[17] Sample images are illustrated in *Figure 6*, showing uptake of tracer in the damaged target ligament (DIOL).

Figure 5. Pain maps. The summed pain maps shows the typical distribution of pain in the group of patients studied, with localisation of pain to the lower back, buttock, lateral thigh and into the ipsilateral inguinal region. The pain maps following introduction of the needle into the DIOL at the time of PRP injection were identical to the maps produced at the time of the initial clinical examination. The distribution validates the term "pseudo-sciatica".

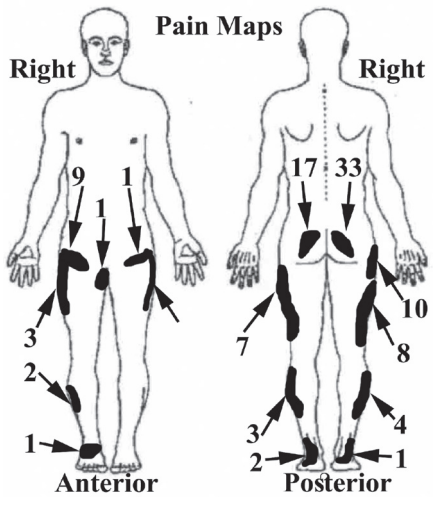
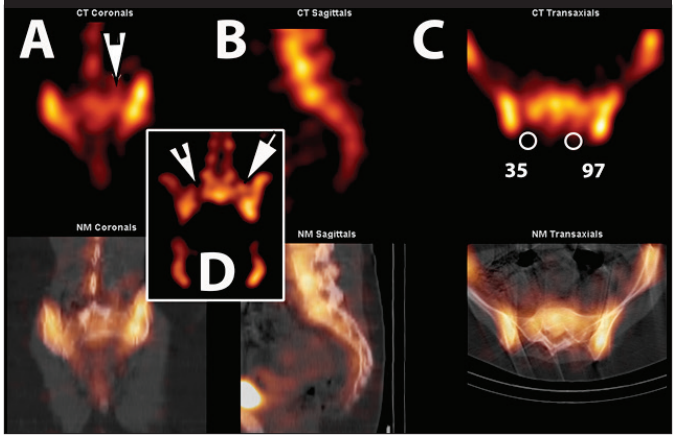


Figure 6. SPECT/ CT image of the pelvis. The nuclear medicine bone scan SPECT image shows increased soft-tissue uptake of the isotope in the damaged left DIOL(arrowhead) and left SIJ in panel A. The region of interest over the ligament soft-tissue uptake in panel C shows a relatively higher count profile (97 counts) in the circular region of interest than on the normal right side (35). Fused images in the lower panel confirm the location of the scintigraphic abnormalities in the CT study. The inset image (panel D) shows that the dorsal space of the SIJ where the DIOL is located, accumulates the isotope in the damaged ligament (arrow) on the left, and the undamaged ligament shows no evidence of uptake, with a channel of absent counts (arrowhead).



The patients that dropped out of the study (n=3) were due to breast cancer requiring surgery, chemotherapy and radiation. The second developed a painful ovarian condition with pelvic pain that made assessment of the SIJ condition impossible and the third moved overseas.

When compared to the 25 patients who historically underwent prolotherapy[20] there was no significant difference in the clinical scores 7.2 versus 7.7, mean age (40.4 versus 38.7) or length of history (48 versus 46 months).

INJECTION

The baseline pain maps were not significantly different to the pain reproduced at the time of PRP injection and are shown in *Figure 5*. Pain extended from the ipsilateral buttock and wound around the lateral upper thigh and into the ipsilateral inguinal region. An average of 1.6 injections was administered to each patient (Median 2.0 and range 1-3). There were no complications during or after the PRP injections.

FOLLOW-UP

Baseline score for the clinical examination was 7.7, RM24 93.4, RM 9.2, Quebec 31.8 and VAS 63.1. All patients experienced good pain control and functional improvement at 3 months after the PRP injections were completed. The changes in scores after injection for the variables are shown in *Table 1*. Significant improvement in clinical and pain scores and performance indicators occurred at 3 months after the injections without further improvement between 3 and 12 month across all scoring systems.

Table 1.

Comparison	Mean	95% C Interval	t	p
Clin Score 0-3 months	5.5	4.9-6.1	17.3	0.00
Clin Score 0-12 months	5.9	5.4-6.4	22.8	0.00
Clin Score 3-12 months	0.86	-0.10-1.8	1.9	0.076
RM24 0-3 months	65.6	7.4-123.7	2.6	0.032
RM24 0-12 months	83.4	59.8-107.1	7.3	0.00
RM24 3-12 months	14.0	-5.5-33.5	1.8	0.13
RM 0-3 months	5.5	2.2-8.9	3.6	0.005
RM 0-12 months	7.4	4.7-10.1	5.7	0.00
RM 3-12 months	1.7	-1.7-5.0	1.3	0.26
Quebec 0-3 months	20.9	4.9-36.9	3.0	0.017
Quebec 0-12 months	25.8	16.9-24.8	5.9	0.00
Quebec 3-12 months	3.7	-1.3-8.7	1.9	0.12
VAS 0-3 months	41.4	25.7-57.2	5.6	0.00
VAS 0-12 months	59.3	52.6-65.9	18.2	0.00
VAS 3-12 months	5.3	-6.3-16.8	1.1	0.32

Discussion

One of the unfortunate elements of SIJ mechanical dysfunction is that the pain profile and distribution is identical to "sciatica" which is traditionally ascribed to intervertebral disc prolapse in the lower lumbar spine. Thus the confusion that results when an MRI study shows no evidence of neural compromise from disc prolapse and no other culprit lesion is evident in such patients.[26,27] There is a failure to appreciate that the peri-articular tissues have the same nerve supply as the intervertebral discs[28], giving rise to the term "pseudosciatica". This study demonstrates a good response to PRP injection into the DIOL with improvement in pain and function in patients who fail to respond to appropriate physiotherapy. The principal purpose of the physiotherapy is to re-establish a co-ordinated sequence of abdominopelvic muscle contraction that leads to force closure of the pelvic ring and allows the sacrum to be held within the pelvic ring rather than rotating out of the ring.[19] This can only occur if there is adequate integrity of the DIOL that stabilises the sacroiliac joint posteriorly, as happens in 80% of patients that respond to physiotherapy.[20]

There are fundamentally two methods for achieving stability of the sacroiliac joint. Surgical fusion is the extreme solution[29] which is rarely required. Other less invasive techniques include prolotherapy or the current method of PRP injection. The injection of hypertonic glucose frequently referred to as prolotherapy promotes an inflammatory response in the tissues. This attracts platelets and growth factors and promotes the activity of fibroblasts. The healing process has three overlapping phases, commencing with an inflammatory phase that lasts approximately 2-3 days followed by a repair phase that may last up to 6 weeks with subsequent remodelling that may take a further 2 to 3 months.[30,31] PRP has the advantage of delivering more platelets to the region and therefore more growth factors to promote the healing response.[32] The original method of preparing PRP is by

taking 6.0 mls of blood into a plain blood collecting tube with an anticoagulant. The tube is spun for 20 minutes and the "buffy coat" removed. This has a large margin for error when removing the buffy coat and some of the red blood cells, granulocytes and cells other than platelets can be harvested. There are many commercial preparation systems available and these have varying cell counts and can concentrate platelets in differing amounts.[23,31] Current research indicates that differing cell-counts are required for different purposes.[31] For example joint injections require 4-5 times the platelets than ligament injections for a response.[33] The Regen preparation has no red blood cells, which can be deleterious to the repair and also captures the granulocytes which can be catabolic. More importantly, newer research again is showing that the harvest of growth factors is higher in the Regen system than some of the systems that capture 4-5 x baseline platelet counts.[34] The singular problem is that systems which currently capture 4-5 x baseline platelet counts also capture significantly more red cells. Regen System (RegenLab Le Mont-sur-Lausanne, Switzerland) was chosen for its cell profile count, small amount of blood required (9ml) and centrifugation at 3500 rpm for only 5 minutes.

The current study shows a significant improvement in the clinical and functional status of patients treated with PRP over the prolotherapy group. This may also reflect the significantly higher baseline functional impairment in the prolotherapy group, although the clinical scores were not significantly different (7.2 for the prolotherapy group versus 7.7 for the PRP group). This data is presented in *Table 2*. The other advantage of PRP was the use of a mean of 1.6 injections versus 3.0 for the prolotherapy injections. Furthermore, there was no radiation exposure to the patients as opposed to the prolotherapy injection which was done under CT guidance.

Two other groups have reported good clinical and functional outcomes in patients with mechanical dysfunction of the sacroiliac joint with the use of PRP injections.[35,36] A salient difference between these reports and the current study is that we specifically targeted the injection into the DIOL and not the sacroiliac joint as was undertaken in the two previous reports. Furthermore, one study had only 4 patients, although follow-up was for 48 months.[35] The other study[36] randomised 40 patients for injection with PRP or methylprednisolone into the SIJ under ultrasound guidance. They found

Table 2. Comparison of Prolotherapy and PRP at 12 months.

Scoring system	Prolo	PRP	t value	p value
Patient number	19	39		
Mean Clin Score - Base	7.2	7.7		
Mean Clin Score 12 month	2.2	1.3	-4.4	p<0.05
Mean RM Base	13.0	9.2		
Mean RM 12 month	10.5	1.4	-22.7	p<0.05
Mean RM24 Base	146.5	93.4		
Mean RM24 12 months	108.6	19.4	-20.7	p<0.05
QUEBEC Base	57.7	31.8		
QUEBEC 12 month	39.5	7.9	-17.4	p<0.05

a 90% improvement at 3 months in the PRP group compared to 25% improvement in the steroid arm of the study after 3 months follow-up. The site of injection is crucially important to the clinical outcome. Murakami et al.[37] undertook a study in 50 patients with mechanical dysfunction of the SIJ established by pain provocation manoeuvres. There were 25 patients in each arm of the study who had either intra-articular or peri-articular injection of lignocaine 2%. Peri-articular injections resulted in abolition of pain in all 25 patients, but the intra-articular injections resulted in abolition of pain in only 9 of 25 patients. Cross-over of the remaining 16 to peri-articular injection resulted in complete abolition of pain in all patients. It confirms that the principal site of pain-generation is not the joint, but the surrounding ligamentous tissue, as confirmed by the pain-maps generated by entry of the needle into the DIOL in the current study. Furthermore SPECT/ CT of the bone scan also shows significantly higher uptake of the bone scanning agent in the DIOL of the symptomatic SIJ[17], suggesting chronic injury to the ligament with a calcific response, as the ligament is a relatively avascular structure, not associated with the synovial portion of the sacroiliac joint.[35] It may also explain the failure to visualise the ligament injury by MRI as there is no oedematous (ie. water) response.

The vast body of critical literature on both prolotherapy[34] and PRP injection to treat various sources of musculoskeletal pain syndromes shows minimal clear-cut evidence of utility. A recent review of PRP in treatment of soft-tissue injury found that the Cochrane review of 2014 that contained 19 randomised trials and a further 10 trials since then showed insufficient evidence to support its utility.[30] A major issue raised in review of these trials was that the PRP content and quality varied

widely and probably affected effectiveness. This was one of the reasons for our choice of a commercially available system from Regen. One of the most disturbing aspects of PRP injection is its routine clinical use and cost in the absence of evidence to its utility and the failure to apply it in properly constructed research trials. Even worse is the failure to define a specific target for the intervention with a measurable outcome related to that target with appropriate long-term follow-up. We found it difficult to randomise the procedure due to the level of intervention involved with drawing blood samples, spinning the samples down and discarding the buffy coat prior to injection. This involved insurmountable objections from the Institutional Ethics Committee and led to the abandonment of the blinding process and adoption of the open label trial with a historical comparator. While not being an ideal circumstance from the trial point of view, we felt it was a valuable addition to the literature as there was a common and troubling disease, a specific target (dorsal interosseous ligament of the sacroiliac joint), reproduction of the patient's typical pain maps and adequate longitudinal clinical and functional follow-up to minimise the placebo effect.

The utility of the technique in the athletic population has two major advantages. Firstly, it offers a diagnostic portal with reproduction of typical symptoms when the needle is introduced into the DIOL. Secondly PRP speeds up the healing process with early stabilisation of the SIJ and has the potential for early deployment in the therapeutic algorithm, as time is a critical issue for elite athletes.

Conclusion

Mechanical dysfunction of the sacroiliac joint is a common and poorly recognised condition that may be more prevalent than disc prolapse as a source of lateralising lower back pain. Diagnosis was previously based on a complex series of physical examination tests but has in recent years been confirmed by SPECT/ CT imaging. While 80% of patients improve clinically and functionally with targeted physiotherapy, a significant proportion will require injection therapy with either PRP or prolotherapy to increase the integrity of the dorsal interosseous ligament of the sacroiliac joint. PRP injection under ultrasound guidance can improve function and reduce chronic pain in a high proportion of these patients with little risk or complication. ■

CONFLICT OF INTEREST

The authors involved in this study have no conflict of interest.

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