ORIGINAL ARTICLE

Comparison of Fluoroscopy and Ultrasound Guidance for Sacroiliac Joint Injection in Patients with Chronic Low Back Pain

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■ **Abstract**

Background and Objectives: Sacroiliac joint (SIJ) arthritis is a common cause of chronic mechanical low back pain (LBP) that is often treated with injection of local anesthetic and steroids. Ultrasound (US) has emerged as a viable alternative to fluoroscopy (FL) to guide SIJ injections; however, few studies have compared these modalities. In this prospective randomized, controlled trial, we compared both accuracy and efficacy of US and FL guidance for SIJ injections.

Methods: Forty patients with chronic moderate-to-severe LBP secondary to SIJ arthritis were randomized to receive US- or FL-guided unilateral SIJ injections. Primary outcomes included pain at 1 month measured by numerical rating scale (NRS) scores. Secondary outcomes included NRS scores at 24 hours, 72 hours, 1 week, and 3 months after injection, physical functioning at 1 month after the procedure, procedure time, incidence of intra-articular and peri-articular needle placement, patient discomfort, overall patient satisfaction, and daily opioid consumption.

Results: There was no significant difference in NRS pain scores between the 2 groups at 1 month or at any other follow-up points. A significant reduction from baseline mean NRS scores was observed in both groups at 1 month after injection (US 22.7%, $P = 0.025$; FL 37.3%, $P < 0.001$). There was no significant difference in procedure-related variables, physical functioning, discomfort, opioid utilization, and patient satisfaction between the 2 groups.

Conclusions: Ultrasound-guided SIJ injection with fluoroscopic confirmation has similar accuracy and efficacy to fluoroscopy alone for SIJ injections in patients with chronic low back pain secondary to SIJ arthritis. ■

Key Words: sacroiliac joint, injection, X-ray, fluoroscopy, ultrasound, pain, back pain, randomized controlled trial

INTRODUCTION

Sacroiliac joint (SIJ) arthritis is a common and often overlooked pathology affecting 15% to 30% of individuals with chronic mechanical low back pain (LBP).[1] Injection of the SIJ with local anesthetic and steroid is often used for short- to medium-term therapeutic benefit. Injection of the SIJ by anatomic landmark

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guidance alone is associated with a low intra-articular success rate of 12%.[2] Fluoroscopic (FL) guidance is commonly used to improve accuracy of this procedure, and more recently, computed tomography (CT) and magnetic resonance imaging (MRI) have also been utilized.[2–4] However, these imaging modalities have several limitations including cost, requirement for appropriate infrastructure, and radiation exposure (FL, CT). Ultrasound (US) guidance has recently emerged as an alternative modality to guide SIJ injection.[5,6] The benefits of US-guided injection over FL are that US if used alone is more affordable, available, and it avoids radiation exposure. US also allows "real-time" visualization of needle tip and spread of injectate during injection.

Prior studies have described sonoanatomy of the SIJ and feasibility for US-guided injections,[5–8] but accuracy rates of US-guided SIJ injection (defined as incidence of intra-articular injection) have ranged from 40% to 80%.[5,6,9] Furthermore, 2 studies have suggested that the therapeutic value of peri-articular SIJ injections may be similar to that of intra-articular (IA) injection, which calls into question the clinical value of IA needle placement for SIJ injection.[9,10] Moreover, only 1 study evaluated intermediate-term (few weeks to few months) analgesic impact after injection but it excluded participants on any analgesic medication other than acetaminophen.[11] To address the lacunae in current knowledge about impact of different image-guided techniques, we conducted a prospective, randomized controlled trial comparing the impact of US and FL guidance for SIJ injections on accuracy and efficacy in patients with chronic LBP secondary to SIJ arthritis.

METHODS

Participants

The local research ethics boards at the University University Health Network and Mount Sinai Hospital in Toronto approved this trial, which was registered with clinicaltrials.gov (registration number NCT01719081). All methods and results have been reported as per CONSORT guidelines.[12] After obtaining written and informed consent, 40 patients were prospectively enrolled for US- or FL-guided SIJ injections at 2 multidisciplinary pain clinics in teaching hospitals in Toronto. Inclusion criteria were characteristics of SIJ disease on history, at least 3 positive physical examination maneuvers [FABER (flexion, abduction, and external rotation), POSH (posterior shear), REAB (resisted abduction), Fortin's finger test], moderate-to-severe pain (NRS pain score $\geq$ 3/10) refractory to oral anti-inflammatory and/or opioid analgesic therapy.[13,14] Exclusion criteria included ages less than 18 or more than 85 years, BMI above 35 kg/m^2, pain suggestive of bilateral sacroiliac joint involvement (it would have been difficult to assess pain and disability secondary to each SIJ), ongoing litigation related to the patient's pain, a diagnosis of severe anxiety or depression, allergy to local anesthetics or steroids, pregnancy, and multiple comorbidities. A research coordinator not involved in postprocedure study data collection recruited patients. Patients were randomized to either FL- or US-guided SIJ injection by the research coordinator using sequentially numbered containers. The information of the assigned group was placed in a sealed envelope.

Intervention

Patients were placed in the prone position for sacroiliac joint injection. After ensuring asepsis, a 22-G, 8-cm-long Quincke spinal needle was used for injection in both groups after local anesthesia to skin and subcutaneous tissues. The injectate included 40 mg of methylprednisolone acetate (Depo-Medrol®; Pfizer Canada Inc., Kirkland, Quebec, Canada) diluted in 3 mL of bupivacaine 0.25% with epinephrine 1:200,000 (total 4 mL injectate). Injections were performed by staff pain physicians (AB, PP, PT) experienced in using both image-guided modalities (US and FL) for SIJ injection. Needle tip location was confirmed by injecting radio-opaque contrast (0.5 mLs) followed by fluoroscopy imaging. The goal of the injection was intra-articular; however, peri-articular spread of contrast (on surface immediately outside joint) was accepted if intra-articular injection was not achieved. Images were saved for verification, and therapeutic injectate was then administered.

US-Guided Sacroiliac Joint Injection. A Sonosite M-Turbo US machine (Sonosite Fujifilm Inc, Bothell, Washington, USA) with a curvilinear transducer (5 to 2 MHz) was used for US-guided injections as per the technique previously described in the literature (Figure 1).[5] The posterior superior iliac spine, lateral border of sacrum, and ilium were identified in transverse orientation. Subsequently, the probe was moved caudally until the superior part of the posterior SIJ was identified. The SIJ was traced caudally until the distal

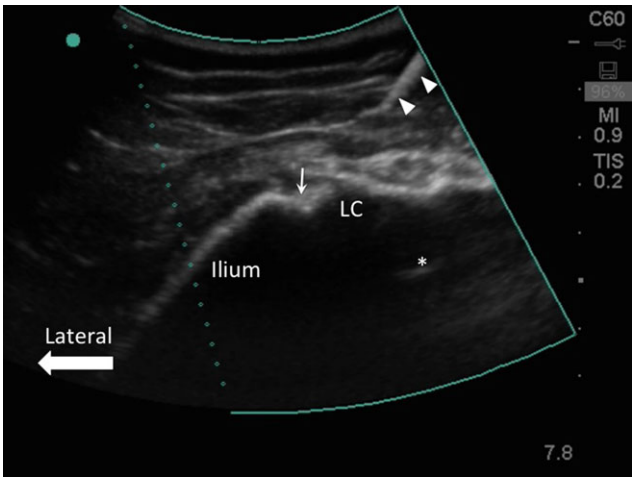

Figure 1. Ultrasound image of the lower part of sacroiliac joint. LC- lateral crest; bold arrow heads- needle; *- drop shadow of second sacral foramen; line arrow-sacrolilac joint. Reproduced with permission from Philip Peng Educational Series.

third of the SIJ was visualized as evident by the flat contour of the iliac crest and the presence of the second sacral foramen on the medial aspect of the sacrum. Color Doppler was utilized to determine the presence of vascular structures and to plan needle trajectory. The spinal needle was advanced from a medial to lateral direction using an in-plane technique or an out-of-plane technique as deemed appropriate by the physician performing the procedure.

FL-Guided Sacroiliac Joint Injection. In the FL-guided injection group, the C-arm was utilized to visualize the distal third of the posterior SIJ. Cephalo-caudad tilt and contra-lateral oblique angulation were used to optimize view of the target area. The spinal needle was then advanced using a coaxial technique toward the joint.

Outcome Measurements

Outcomes were assessed as per recommendations from the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) guidelines.[15,16] The primary outcome for this study included difference in numerical rating score (NRS) for pain at 1 month between the US and FL groups. Secondary outcomes included NRS pain scores at 24 hours, 72 hours, 1 week, and 3 months after study intervention, limitation of physical functioning as measured by the Oswestry Disability Index (ODI) at 1 month after the intervention, and procedure-related variables (time, radiation exposure, patient discomfort and incidence of intra-articular versus peri-articular needle placement). In the FL group, procedure timing was defined as time between first fluoroscopic image and completion of injection. In the US group, timing was defined as time from application of the US probe to completion of injection (including fluoroscopic confirmation of needle tip location). A research coordinator recorded all parameters of the procedure including timing and patient discomfort during the procedure but that individual was not involved in subsequent data collection. Daily opioid consumption at 1 month and overall patient satisfaction 3 months after the intervention were also assessed.[16,17] An independent observer blinded to group allocation was responsible for telephone follow-up at 24 hours, 72 hours, and 1 week as well as in-person follow-up at one and 3 months following the interventions.

Statistical Analysis

The primary hypothesis of this study was that US guidance for SIJ injections would be similar to FL guidance in reducing mean NRS pain scores at 1 month after the intervention. The margin for comparing FL- and US-guided SIJ injection was defined as a mean NRS pain score within 30% 1 month after the injection. The significance level was 0.05 for assessing difference between the 2 image guidance techniques with NRS pain score as a primary outcome. Based on an internal review of our patients who had received FL-guided SIJ injections in the past, we assumed a mean NRS pain score of 4.6 at the 1 month mark (on a 0 to 10 scale) with a 30% difference in pain scores from baseline corresponding to a difference of 1.5 between the two groups and a standard deviation of 1.6 in each group. With a two-sided significance α-level of 5% and a power of 80%, 19 patients were needed in both groups to allow detection of this difference. Allowing for a trial attrition rate of around 10%, we aimed to enroll 20 patients in each group (total of 40 patients in the study).

The data collected from the study contained continuous and categorical variables. Continuous data were examined for normality of distribution using Kolmogorov–Smirnov test. Continuous data with normal distribution were summarized as means and standard deviations, and data with non-normal distributions were summarized as medians and interquartile ranges. Categorical data were summarized as numbers and percentages. Variables with normal distribution were analyzed using t-tests, and those with non-normal

distribution were analyzed using Wilcoxon rank-sum tests. All t-tests were 2-sided and unpaired except the within groups comparison of change from pre- to 30 days postprocedure for pain NRS, ODI, and morphine use for which paired *t*-tests were used. For *P*-values of t-tests, pooled values were used when there was equality of variances and Satterthwaite values were used for unequal variances. Categorical variables were analyzed using chi-square test (or Fisher's exact test when 25% or more cells had expected counts of less than 5). A *P*-value of < 0.05 was accepted as significant. All analyses used an intention-to-treat approach, in which patients were evaluated in the group to which they were originally randomly assigned, regardless of the treatment they actually received. SAS version 9.3 (SAS Institute, Cary, NC, USA) was used for all analyses.

RESULTS

A total of 44 patients were recruited for the study between Jan 2012 and May 2013. Four patients were excluded prior to study intervention because they had pain suggestive of bilateral sacroiliac joint involvement and as a result did not meet inclusion criteria. A total of 40 patients underwent the study intervention including 20 in both the US and FL groups (Figure 2). There were no differences between the two groups in terms of baseline characteristics, preprocedure NRS pain scores, limitation of physical function as measured by ODI, daily opioid analgesic intake, or duration of pain prior to the procedure (Table 1).

Patients were followed for 3 months after the procedure. No patients were entirely lost to follow-up. However, 2 patients were unable to attend their 1-month assessment (one from each group) and 1 patient did not complete 3-month follow-up (FL group). The reason for lost follow-up in all three of these instances was inability of the patients to be available for follow-up either by phone or in person. Missing data were not imputed for statistical analysis.

Analysis of NRS pain scores 1 month postprocedure revealed a significant reduction from baseline in both the groups: 22.7% in the US group ($P = 0.03$) and 37.3% in the FL group ($P < 0.01$) (Table 2). There was no significant difference in NRS pain scores between the 2

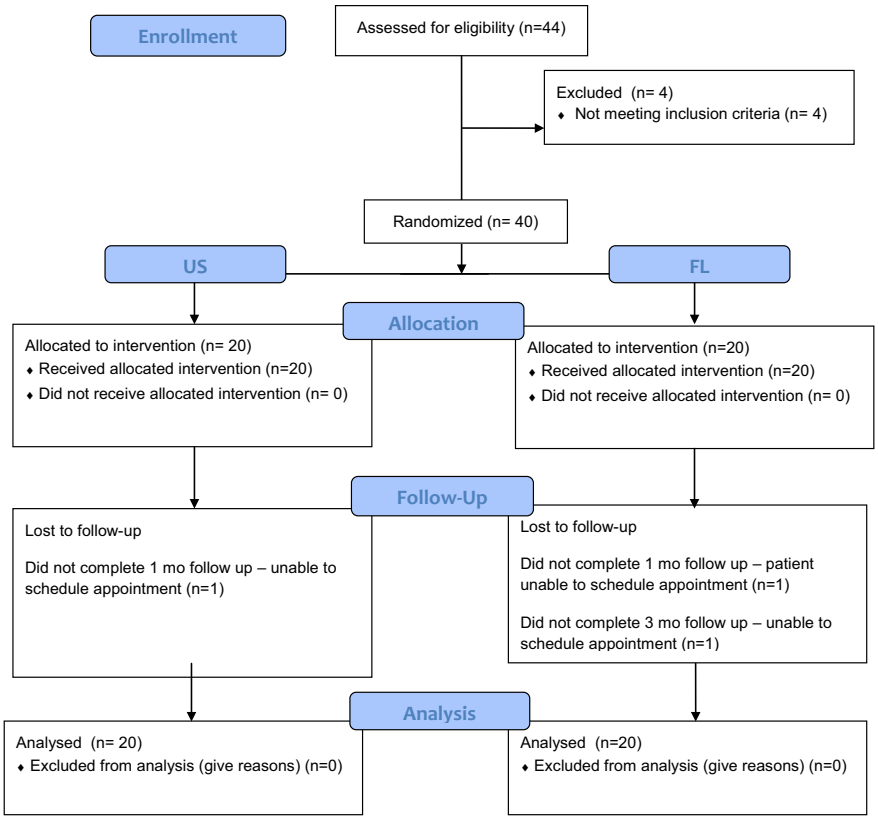

Figure 2. Participant flow diagram illustrates subject inclusion and exclusion.

Table 1. Patient Characteristics

	US (n = 20)	Fluoroscopy (n = 20)	P-value
Age (years)	50.90 (12.77)	46.85 (11.51)	0.299
Male/Female	5/15	6/14	0.723
BMI (kg/m^2)	25.26 (4.32)	26.25 (4.28)	0.471
Preprocedure			
NRS pain scores	6.6 (2.0)	6.7 (1.3)	0.820
ODI score (%)	57.20 (16.04)	59.30 (14.94)	0.671
Duration of pain (months)	49.50 ± 38.69	71.70 ± 103.00	0.882
Morphine consumption (mg)	2.25 (0 to 22.5)	30.00 (0 to 45.00)	0.245
Daily morphine consumption (≤30 mg vs. >30 mg)	16/4	14/6	0.717

Data are mean (SD), median (interquartile range), or proportions.
NRS, Numerical Rating Score; ODI, Oswestry Disability Index.

groups at 1 month or at any of the other follow-up time points after the procedure (24 hours, 72 hours, 1 week, 3 months) (Table 2). Between groups, comparison of ODI at 1 month did not reveal any difference between US and FL guidance. However, within group analysis of ODI scores at 1 month after the procedure, it was revealed that the FL group had a statistically significant improvement in ODI scores at 1 month (reduction by 11.8%, P = 0.02) (Table 2), but there was no change in ODI in the US group (reduction by 4.7%, P = 0.54).

Patient satisfaction was similar between the 2 groups, and daily oral opioid consumption (measured in terms of oral morphine equivalent dose in mg) at 1 month postprocedure was unchanged in either the FL or US groups (Table 2). However, only 21 of 40 patients in the study (55%) were on opioids and the data for opioid consumption were skewed by a smaller number of patients taking greater than 30 mg of morphine.

For procedure-related outcomes, there was no statistically significant difference in the overall rates of intra-articular versus peri-articular injection between the 2 groups (50% intra-articular in US group and 65% intra-articular in the FL group; P = 0.52) (Table 3). There was no difference in patient discomfort during the procedure between the 2 groups. Significantly less time was required to complete the procedure in the FL group compared to the US group (323.10 ± 132.32 seconds and 560.75 ± 251.82 seconds, respectively; $P < 0.01$) (Table 3). The mean radiation exposure in the FL group was 38.47 ± 37.41 mGy. There were no significant adverse effects for patients in either group.

Table 2. Comparison of Patient-related Outcomes between the Two Groups

	Ultrasound (n = 20)	Fluoroscopy (n = 20)	P-value
NRS pain scores			
Preprocedure	6.6 (2.0)	6.7 (1.3)	0.820
Postprocedure 24 hours	5.4 (2.4)	6.4 (2.6)	0.181
Postprocedure 72 hours	4.8 (2.4)	5.1 (2.5)	0.656
Postprocedure 1 week	4.8 (2.7)	4.5 (2.5)	0.785
Postprocedure 1 month	5.1 (2.7)	4.2 (2.6)	0.266
Postprocedure 3 months	5.5 (2.2)	6.2 (2.3)	0.362
ODI scores			
Preprocedure	57.20 (16.04)	59.30 (14.94)	0.671
Postprocedure 1 month	54.53 (18.07)	52.32 (19.19)	0.716
Daily morphine consumption (mg)			
Preprocedure	2.25 (0 to 22.5)	30.00 (0 to 45.00)	0.245
Postprocedure 1 month	1.13 (0 to 22.5)	30.00 (0 to 35.0)	0.285
Preprocedure (≤30 mg vs. >30 mg)	16/4	14/6	0.717
Postprocedure (≤30 mg vs. >30 mg)	16/4	14/6	0.717
Overall patient satisfaction			
Not Satisfied	9 (45%)	5 (25%)	0.375
Satisfied	7 (35%)	11 (55%)	
Most Satisfied	4 (20%)	3 (15%)	

Data are mean (SD), median (interquartile range), or numbers (percentages).
NRS, Numerical Rating Scale for pain; ODI, Oswestry Disability Index.

DISCUSSION

Ultrasound was compared to fluoroscopy for patient- and procedure-related outcomes of SIJ injections in this prospective, randomized controlled trial with blinded postprocedure assessment in patients with moderate-to-severe low back pain secondary to SIJ arthritis. This study supported our hypothesis that when comparing US and FL guidance for SIJ injection, there is less than 30% difference in NRS pain scores at 1 month. There

Table 3. Comparison of Procedure-related Outcomes between the Two Groups

	Ultrasound (n = 20)	Fluoroscopy (n = 20)	P-value
Intra-articular injection	10 (50%)	13 (65%)	0.523
Procedure time (seconds)	560.75 (251.82)	323.10 (132.32)	<0.001
Procedure discomfort (NRS)	5.3 (2.5)	6.4 (2.1)	0.142

Data are mean (SD) or numbers (percentages).
NRS, Numerical Rating Scale (0- no discomfort and 10- extreme discomfort).

was no difference in NRS pain scores between the 2 groups at any of the time points during the follow-up period of 3 months. Physical functioning and overall patient satisfaction were also similar between the 2 groups.

This is the first study to utilize both patient-related outcomes (pain scores over 3 months after the procedure, physical functioning, opioid consumption, and overall satisfaction) as well as procedure-related outcomes (accuracy, procedure time and patient discomfort) to compare US and FL guidance for SIJ injection in patients with SIJ arthritis. While our study was not fully powered for noninferiority analysis, based on our results, we propose that it is reasonable to consider the use of ultrasound guidance as an alternative to fluoroscopy for procedural guidance in this patient population.

The outcomes of this trial are comparable to other studies that involved use of US for SIJ injection. Jee et al. compared US and FL guidance for SIJ injection and they reported significant pain relief and improvement in ODI for both groups at 12 weeks after the procedure.[11] Furthermore, similar to our study, there was no difference in NRS pain scores or ODI between the 2 groups at any time point during follow-up. However, the mean duration of LBP in their study was only 6.26 months and patients were excluded if they were taking medications other than acetaminophen. Patients enrolled in our study were from a tertiary level multidisciplinary clinic with a considerably longer duration of chronic pain (60.6 months vs. 6.26 months in Jee study), and 55% of our patients were on opioids because they had failed analgesic trials of acetaminophen and nonsteroidal anti-inflammatory medications. We believe that results of our study are applicable to patients with LBP secondary to SIJ arthritis who have had chronic pain of a prolonged duration.

Of the prior studies that explored the feasibility of US-guided SIJ injections, there has been significant variability in the rates of intra-articular injection. Three prior studies have reported higher intra-articular injection rates than our trial (76.7%, 80 to 100% and 87.3%, respectively).[5,6,11] However, the first 2 studies included relatively younger patients (mean age of 26 and 25.6 years, respectively, compared to 48.9 years in our study) and only patients with inflammatory SIJ arthropathy were enrolled while patients with osteoarthritis of the SIJ were excluded. Osteoarthritic changes can make it more difficult to access the intra-articular portion of the joint compared to inflammatory pathologies (eg, rheumatoid arthritis, ankylosing spondylitis). In a study by Hartung et al., use of US for SIJ injections was associated with a 40% rate of intra-articular injections. Interestingly, the analgesic benefit was similar in patients with intra- or peri-articular injections (at the surface jut outside of the joint). Other studies have also suggested that peri-articular injection may have similar outcomes to intra-articular injection[10]. The pain outcomes in Hartung's study (25% to 33% reduction in pain scores at 1 month after the procedure) were similar to that reported in our study.[9] In summary, our intra-articular success rate is within the wide range reported in literature on use of US for SIJ injections and we believe that results differ depending on study populations. The likelihood of achieving peri-articular injection rather than intra-articular injection is more likely in older patients with degenerative SIJ pathologies (eg, osteoarthritis) compared to younger patients with inflammatory arthritis of the SIJ.

With regard to functional outcomes, our study did not identify any difference between the US and FL groups. Level of disability was measured by Oswestry Disability Index (ODI) scores that measure disability due to low back pain. Higher ODI scores reflect more disability than lower scores. There was no difference in ODI scores between the US and FL groups at one month after the study intervention. Within group analysis in our trial did reveal that patients in the FL group had a statistically significant reduction in ODI scores, whereas this improvement was not identified in the US group. Examination of results in the FL group, however, reveals that the improvement was an absolute ODI reduction of only 6.98 (on a scale of 0 to 100). A minimum clinically important difference (MCID) of at least 10 to 12 for change in ODI has been found to be clinically meaningful in patients with chronic back pain.[18,19] Our study found relatively small changes in ODI suggesting that neither FL- nor US-guided injections were associated with overall clinical improvement in function as measured by ODI. Jee et al. reported greater reduction in ODI scores after SIJ injection. However, preprocedural ODI scores were lower in their study cohort compared to ours reflecting less severe baseline disability in their patient population.[11] The lack of MCID in ODI scores in our study may be partially explained by the severity and chronicity of disease among the enrolled patients.

Our study found that greater time was required for US-guided injection compared to FL guidance (561 seconds and 323 seconds, respectively, $P < 0.01$). The additional time required in the US group is partially explained by the use of fluoroscopic confirmation to

document needle tip location in the US group. The additional time required for US-guided SIJ injection with fluoroscopic confirmation must be taken into consideration if utilizing US, particularly for more novice users. The time required for US-guided injection in this trial was similar to that reported in other trials.[5]

We acknowledge that this study has several limitations. Our study had 20 patients in each arm. While this allowed for comparison of the 2 injection techniques, a larger patient population would be required to adequately qualify for noninferiority analysis. Similarly our study was not powered to assess safety aspects and complication rates of the 2 guidance techniques (eg, intravascular injection, sciatic nerve block). A larger patient cohort will need to be enrolled to confirm our findings and compare adverse effects. Secondly, although this study had a blinded observer for data collection in the postprocedure phase, ideally patients and procedure specific assessment should also have been blinded to allocation of trial group. Future studies comparing FL and US guidance for procedural interventions can utilize a mock US in all patients for scanning purposes to optimize blinding. Furthermore, our study followed patients for a duration of 3 months but trials could focus on longer term outcomes up to 6 months to 1 year after the interventions. All US- and FL-guided injections in our trial were performed by experts with experience in both techniques. US-guided SIJ injection is considered an intermediate-to-advanced skill level intervention, and generalizability to broader pain practice, particularly for novice operators, is uncertain.[5,20] Finally, our study was limited to patients with a BMI < 35 kg/m^2. The application of US for axial procedures in patients with a higher BMI is technically challenging, and studies are required to evaluate the role of US for SIJ injection in this population.[21]

In conclusion, ultrasound guidance with fluoroscopic confirmation may be a reasonable alternative to fluoroscopic guidance for SIJ injection in patients with chronic mechanical low back pain secondary to SIJ arthritis. The results of our study did not identify a difference in accuracy, efficacy, or overall patient satisfaction between these 2 image-guided techniques for SIJ injection; however, future studies are required for confirmation.

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