

Comparison of the Efficacy of Sacroiliac Joint Injection Using Fluoroscopy-Confirmed Ultrasound Guidance Versus Fluoroscopy Guidance: A Prospective, Randomized, Controlled Study

Sakroiliyak Eklem Enjeksiyonunda Floroskopi ile Doğrulanmış Ultrason ve Floroskopi Rehberliğiyle Etkinliğin Karşılaştırılması: Prospektif, Randomize, Kontrollü Çalışma

¹Selin GÜVEN KÖSE^a, ²Halil Cihan KÖSE^a, ³Feyza ÇELİKEL^b, ⁴Ömer Taylan AKKAYA^c

^aDepartment of Pain Medicine, Health Science University Derince Training and Research Hospital, Kocaeli, Türkiye

^bClinic of Physical Therapy and Rehabilitation, Sakarya Training and Research Hospital, Sakarya, Türkiye

^cDepartment of Pain Medicine, Health Science University Dışkapı Yıldırım Beyazıt Training and Research Hospital, Ankara, Türkiye

3,ABSTRACT Objective: The aim of this study is to compare the accuracy and effectiveness of ultrasound-(US) and fluoroscopy (FL)-guided sacroiliac joint (SIJ) injections in patients with non-inflammatory SIJ pain. **Material and Methods:** In this prospective randomized controlled study, 60 patients with non-inflammatory SIJ related pain were randomized into 2 groups. Patients received intra-articular SIJ injection under US or FL guidance. Primary outcomes included visual analogue scale (VAS) scores at 12 weeks after the intervention. Secondary outcomes were VAS scores at 1 week and 1 month, Oswestry Disability Index scores at months 1 and 3, Quantitative Analgesic Questionnaire and patient satisfaction at 3 months, procedure time, accuracy of needle replacement at the first attempt and number of attempts. **Results:** Both techniques provided significant pain reduction and functional improvement up to 3 months post-intervention compared with baseline ($p<0.001$), with no statistical significances between groups at any follow up point. There was no significant difference in pain medication consumption ($p=0.392$) and patient satisfaction scores ($p=0.469$) between the groups. The FL guidance for SIJ technique exhibited greater accuracy for needle replacement (93.3%) than the US (80%) at the first attempt, with no significant difference ($p=0.254$). **Conclusion:** US-guided SIJ injection with fluoroscopic confirmation is a feasible alternative to FL guidance for therapeutic SIJ injections. Patients in both groups experienced similar treatment benefits regarding pain intensity, functionality, and patient satisfaction. However, the diagnostic performance of SIJ injection alone with US guidance may be limited due to the lower accuracy rate (80%).

ÖZET Amaç: Bu çalışmanın amacı, inflamatuvar olmayan sakroiliyak eklem (SIE) ağrısı olan hastalarda ultrason (US) ve floroskopi (FL) kılavuzluğunda SIE enjeksiyonlarının doğruluk ve etkinliğini karşılaştırmaktır. **Gereç ve Yöntemler:** Bu prospektif randomize kontrollü çalışmada, SIE artritine sekonder bel ağrısı olan 60 hasta randomize olarak 2 gruba ayrıldı. Hastalara US veya FL rehberliğinde eklem içi SIE enjeksiyonu yapıldı. Birincil sonuçlar; müdahaleden 12 hafta sonra vizüel analog skala (VAS) skorlarını içeriyordu. İkincil sonuçlar; 1. hafta ve 1. ayda VAS skorları, 1 ve 3. ayda Oswestry Özürlülük İndeksi skorları, 3. ayda Kantitatif Analjezik Anketi ve hasta memnuniyeti, işlem süresi, ilk denemede iğne yerleştirme doğruluğu ve deneme sayısıydı. **Bulgular:** Her iki teknik de herhangi bir takip noktasında gruplar arasında istatistiksel anlamlılık olmaksızın, başlangıça kıyasla işlem sonrası 3 aya kadar anlamlı ağrı azalması ve fonksiyonel iyileşme sağladı ($p<0.01$). Gruplar arasında analjezik ilaç tüketimi ($p=0,392$) ve hasta memnuniyet skorları ($p=0,469$) açısından anlamlı fark yoktu. SIE tekniğinde ilk denemede, iğne yerleşimi için gruplar arasında anlamlı bir fark olmaksızın, FL (%93,3), US'den (%80) daha yüksek doğruluk gösterdi ($p=0,254$). **Sonuç:** Terapötik SIE enjeksiyonları için floroskopik doğrulama ile US kılavuzluğunda SIE enjeksiyonu, FL rehberliğine uygun bir alternatiftir. Her iki gruptaki hastalar ağrı yoğunluğu, işlevsellik ve hasta memnuniyeti açısından benzer fayda gördüler. Bununla birlikte, US rehberliğinde tek başına SIE enjeksiyonunun tanısal performansı, daha düşük doğruluk oranı (%80) nedeniyle sınırlı olabilir.

Keywords: Ultrasound; sacroiliac joint; intraarticular injection; fluoroscopy, randomized controlled trial, pain, back pain

Anahtar Kelimeler: Ultrason; sakroiliyak eklem; eklem içi enjeksiyon; floroskopi, randomize kontrollü çalışma, ağrı, sırt ağrısı

Correspondence: Selin GÜVEN KÖSE

Department of Pain Medicine, Health Science University Derince Training and Research Hospital, Kocaeli, Türkiye

E-mail: selinguven89@gmail.com

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Sacroiliac joint (SIJ) disorder is a common cause of chronic non-radicular low back pain, with an estimated prevalence between 15 and 25% of patients with chronic low back pain.¹ The potential value of the distribution pattern of SIJ based pain, conventional radiography, and physical examination is somewhat limited for the diagnosis of SIJ originated pain.^{2,3} The initial treatment approaches include oral medication, exercises, and physical therapy.⁴ Injection of the SIJ with image guidance is considered to be a plausible method for accurate diagnosis, and is also often performed for cases that do not respond efficiently to conservative treatment approaches for short- to medium-term therapeutic effect.^{3,5,6}

Given the complex anatomy and heterogeneity of the joint, image guidance for SIJ injection is essential and crucial to improve the success rate of the procedure. Fluoroscopy (FL)-guidance is usually used, and more recently, computed tomography, and magnetic resonance imaging are also performed for SIJ injection.⁷⁻⁹ With the increasing use of ultrasound (US) technology in chronic pain medicine, the important role that US guidance plays across a spectrum of spinal interventions is clear and well documented. US has many superiorities over FL, including avoidance of radiation exposure, real-time guidance, direct and dynamic visualization of surrounding structures and spread of injectate.^{10,11}

Previous research has shown that the sonoanatomy of the SIJ and the applicability of US for SIJ injections with accuracy rates of intra-articular needle replacement ranging from 40-87%.¹²⁻¹⁴ In those studies comparing US and FL guidance for SIJ injection, although the target of SIJ injection was intra-articular, if intra-articular injection failed, peri-articular spread of injection was accepted. Furthermore, they demonstrated similar treatment benefits regarding pain and functional outcomes, which could be explained by the diversity of pain source in SIJ pain. Since nociceptors are located not only in the joint capsule but also in extra-articular sources, these findings may offer promising alternatives for SIJ pain.¹⁵ However, accurate intra-articular needle placement is essential for diagnostic SIJ injections to differentiate between intra-articular and extra-articular pathologies and to consider radiofrequency pro-

cedures in the future. Therefore, we decided to deem the SIJ injection procedure successful, only if the needle was placed into the joint, which was confirmed by an arthrogram.

The first aim of this prospective, randomized parallel group trial was to evaluate the effectiveness of US and FL guidance for therapeutic intra-articular SIJ injection in patients with non-inflammatory SIJ originated pain on pain scores. Secondary aims were to compare the changes in functional improvement, pain medication consumption, patient satisfaction, and technique-related outcomes including the number of attempts and procedure time.

MATERIAL AND METHODS

PATIENTS AND RANDOMIZATION

This study was approved by the Clinical Research Ethics Committee of the University of Health Sciences, Dışkapı Yıldırım Beyazıt Training and Research Hospital (date: December 13, 2021, no: 126/05). The study was registered at ClinicalTrials.gov (NCT05235295). Patients gave written informed consent after explanation of the potential benefits and risks and were enrolled in the study between April 2022 and June 2022. Our study was designed and conducted in accordance with the ethical principles specified in the Helsinki Declaration. The study involved 60 patients aged 18 and older with moderate to severe pain [visual analogue scale (VAS) pain score $\geq 3/10$] located laterally over the SIJ line and refractory to oral anti-inflammatory and/or opioid analgesics and exercise therapy for at least 3 months, no signs of lumbar radiculopathy, at least 3 positive SIJ provocation tests (Gaenslen's test, Gillett's test, Newton's test, Patrick's test, Yeoman's test, Shear test), and pain reduction $>75\%$ after diagnostic SIJ injection.³ Patients exclusions included; body mass index (BMI) over than 30 kg/m², uncontrolled diabetes or hypertension, inflammatory and rheumatoid arthritis, bilateral SIJ involvement, psychiatric and neurologic disorders, infection, coagulation disorders, previous block within 3 months, allergy to contrast medium, steroids or local anesthetics, and pregnancy.

Patients were randomly assigned to receive SIJ treatment in the US group or the FL group using a

concealed computer-generated randomization protocol with an allocation ratio of 1:1. All procedures were conducted by an interventionist who was not involved in the evaluation process. Patients were

blinded to treatment allocation. One author, blinded to group allocation and not involved in treatments, performed outcome measurements. Figure 1 presents a schematic representation of the patient flow.

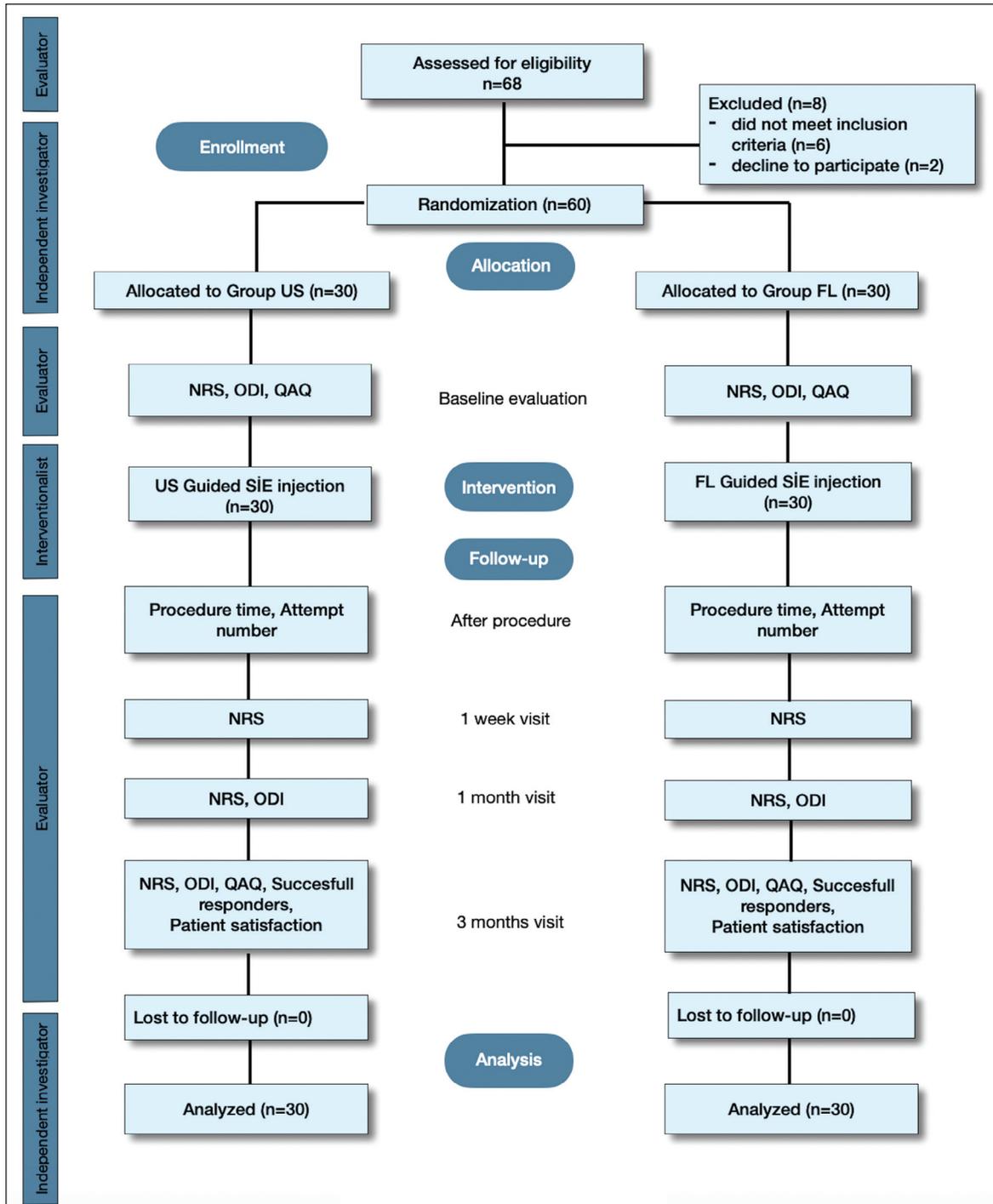


FIGURE 1: Flow diagram of patients.

US: Ultrasound; ODI: Oswestry Disability Index; QAQ: Quantitative Analgesic Questionnaire; SIJ: Sacroiliac joint; FL: Fluoroscopy.

INTERVENTIONS

FL Group

After positioning the patient in the prone position, the Carm was utilized at contralateral oblique and cranio-caudal tilt to identify the distal third of the posterior aspect of the joint. After skin infiltration with 1% lidocaine, a 22G spinal needle was gently inserted into the joint with intermittent FL guidance. Then 0.5 mL of contrast medium was injected to confirm that the needle tip was within the joint.

US Group

A 2-5 MHz curved US probe (GE Healthcare, Wauwatosa, WI, USA) was placed over the distal sacrum in the midline, in the transverse plane to scan the sacral cornu and hiatus. Subsequently, the probe was slid laterally and cephalad until the inferior part of the posterior SIJ, the cleft between the medial border of the iliac bone and the lateral edge of the sacrum, was identified (Figure 2A, 2B). The 22G spinal needle was then advanced from medial to lateral direction with an in-plane technique, after skin infiltration with 1% lidocaine. Color Doppler was activated to determine the presence of vascular structures and when the needle tip passed the posterior sacroiliac ligament and entered the joint to monitor the flow of the injected solution.

We slowly injected 0.5 mL of contrast medium and confirmed the location and ruled out intravascular uptake, through FL for both techniques (Figure 3). If the placement was not intra-articular, a new at-

tempt was made. Then, a 2 mL solution (6 mg of betamethasone and bupivacaine 0.25%) was injected.

Outcome Measurements

Descriptive data, including age, gender, BMI, side of the procedure, duration of pain, were collected at baseline. The 100 mm VAS score was calculated on a scale from 0 (no pain) to 100 (worst imaginable pain) at baseline, and week 1, month 1 and 3 after the procedure.¹⁶ While the primary outcome was the pain score at 12 weeks after the procedure compared with baseline, secondary outcomes were the rate of positive responders (reduction in VAS score by at least 50% at 12 weeks), mean changes in functional disability and pain scores, pain medication consumption and patient satisfaction scores during the follow-up period, and procedure-related variables including time taken to perform the procedure, and the number of attempts. The Oswestry Disability Index (ODI) is a self-administered questionnaire consisting of 10 items of functional ability, each with 6 options ranging from 0 to 5. The percentage of disability, the total ODI score, is obtained using the equation: Total score/50×100. 0% represents no pain or disability, while 100% represents the most severe pain and disability.¹⁷ The ODI was evaluated at baseline, and months 1 and 3 after the procedure. Participants' overall satisfaction was assessed at 3 months using a 5-point Likert scale (1, very dissatisfied; 2, dissatisfied; 3, neutral; 4, satisfied; 5, very satisfied).¹⁸ The mean change in analgesic consumption is assessed at 3 months using the QAAQ, a tool designed to record

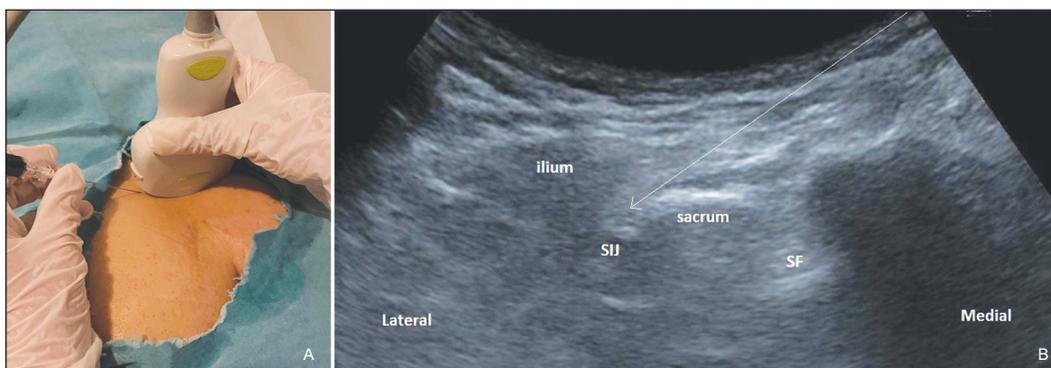


FIGURE 2: Transducer placement (A) and sonoanatomy view of SIJ IA injection (B).

SIJ: Sacroiliac joint.

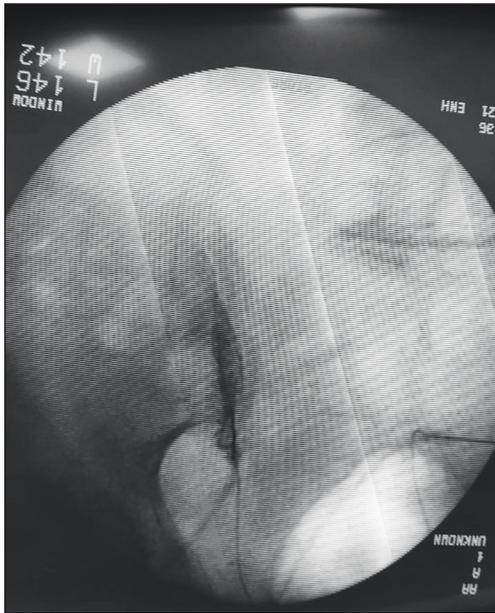


FIGURE 3: Arthrography for SIJ injection.

SIJ: Sacroiliac joint.

patient-reported pain medication use, create scores to quantify and compare it, and track changes in analgesic drug use over time. A higher score indicates higher pain medication use.¹⁹ Procedure time (T_p) was measured using a stopwatch. It was defined as the time from the start of the procedure, the initial image obtained or the first probe placement, until the end of the procedure, defined as; intra-articular needle placement was seen clearly when 0.5 mL of contrast medium was injected and the investigator stated to be satisfied with the image findings.

STATISTICAL ANALYSIS

Statistical analyses were performed using the SPSS version 16.0 (IBM) Corp., Armonk, NY statistical analysis program. The Shapiro-Wilk test was used to test the assumption of normality. Continuous variables, normally distributed, were presented as mean and standard deviation, and continuous variables without normal distribution, median (interquartile range). Either the independent sample t-test or the Mann-Whitney U test was used for comparison of continuous variables. Categorical data were presented as counts and percentages, and compared with Pearson correlation and Fisher's exact tests. A value of $p < 0.05$ was considered as statistically significant. A

2-way repeated measures analysis of variance (ANOVA) with group as a between-subjects factor, and time (between baseline and follow-up assessments) as a within subjects factor was used to detect significant differences in outcome measure scores within and between both groups, with post-hoc Bonferroni tests for multiple comparisons. A value of $p < 0.05$ was considered as statistically significant.

Sample size calculation was performed using G*Power software version 3.1.9.7 (Heinrich-Heine-Universität, Düsseldorf, Germany) according to the results of a previous study.²⁰ In this study, the mean [\pm standard deviation (SD)] VAS score was 2.1 ± 0.8 for FL-guided SII treatment at 3 months. Considering the VAS score as the primary outcome at month 3, a sample size of 27 patients in each group was determined to detect a 30% between-group difference, and a level of .05, and a power of 80%. With a 10% dropout probability, we included 30 patients in each group.

RESULTS

STUDY POPULATION

A total of 60 patients who met the inclusion criteria were included in the study. The patients' baseline demographic data and clinical characteristics were similar between treatment groups. There was no significant difference between the treatment groups in terms of gender, age, BMI, pain duration, injection side, VAS, ODI, and QAQ scores ($p > 0.05$) (Table 1).

Significant between-group differences were not present in the VAS [$F(1,58) = 0.658$, $p = 0.421$] and ODI [$F(1,58) = 1.031$, $p = 0.314$] scores (Table 2). There was no significant interaction between time and group allocation for mean VAS [$F(2.39, 139.11) = 0.518$, $p = 0.630$] and ODI [$F(1.608, 93.243) = 0.411$, $p = 0.411$] scores. In both groups, a significant effect of time was found in the VAS [$F(2.39, 139.11) = 263.649$, $p < 0.001$], and ODI [$F(1.608, 93.243) = 204.627$, $p < 0.001$] scores during the follow up period. VAS and ODI scores decreased significantly from baseline in both arms at all time points ($p < 0.001$), however, the intergroup differences were not significant at all follow-up points (Table 2). The mean difference for VAS scores was most sig-

TABLE 1: Baseline characteristics of patients and clinical variables.

	US (n=30)	FL (n=30)	p value
Age, years	59.50±7.93	61.76±5.22	0.197
Sex, n (%)			0.605
Female	14 (46.7%)	17 (56.7%)	
Male	16 (53.3%)	13 (43.3%)	
BMI, kg/m ²	27.27±1.59	27.86±1.39	0.132
Duration of pain, months	9.23±4.13	8.1±2.02	0.183
Injection side, n (%)			0.193
Left	20 (33.3%)	14 (46.7%)	
Right	10 (66.7%)	16 (53.3%)	
VAS score	7.03±0.92	7.33±1.06	0.249
ODI score	44.93±9.66	48.14±12.27	0.265
QAQ	3.10±1.25	3.03±1.03	0.737

Values are expressed as the mean±standard deviation or number of patients (%); BMI: Body mass index; US: Ultrasound; FL: Fluoroscopy; VAS: Visual analogue scale; ODI: Oswestry Disability Index; QAQ: Quantitative Analgesic Questionnaire.

nificant at 4 weeks after the procedure with -4.37 (p<0.001, Cohen’s d=4.96) in the US group and -4.43

in the ACB group (p<0.001, Cohen’s d=4.25) (Table 2). The percentage of patients achieving at least 50% pain reduction was similar in both groups at 3 months [US; 66.7% (20/30) vs FL; 63.3% (19/30), p=0.781].

A significant reduction in pain medication consumption was found at 12 weeks compared to baseline in both treatment groups (p<0.001). On the 5-point Likert scale, 80% and 85% of patients were very satisfied or satisfied with the treatment in the US and FL group, respectively. However, no significant difference was observed in pain medication consumption and patient satisfaction scores between the US and FL groups at 12 weeks (p>0.05) (Table 2).

There was no significant difference regarding procedure-related outcomes, including procedure time, accuracy of the needle replacement at the first attempt and number of attempts between the treatment groups (p>0.05) (Table 2).

TABLE 2: Follow-up of study scales in both groups.

	US group			FL group			p value
	Mean score (95% CI)	Mean difference	Cohen's d	Mean score (95% CI)	Mean difference	Cohen's d	
VAS							
Baseline	7.03±0.92 (6.68-7.37)			7.33±1.06 (6.93-7.72)			0.249
I week	3.63±0.96* (3.27-3.99)	-3.40	3.61	3.53±1.30* (3.04-4.02)	-3.80	3.20	0.737
II month	2.66±0.84* (2.35-2.98)	-4.37	4.96	2.90±1.02* (2.51-3.28)	-4.43	4.25	0.341
III months	3.43±1.38* (2.91-3.94)	-3.60	3.06	3.60±1.06* (3.20-3.99)	-3.73	3.51	0.603
Positive responders	20/30 66.7%			19/30 63.3%			0.781
ODI							
Baseline	44.93±9.66 (41.32-48.54)			48.14±12.27 (43.55-57.72)			0.265
I month	21.40±8.15* (18.35-24.44)	-23.53	2.63	22.36±8.78* (19.08-25.64)	-25.78	2.41	0.660
III months	24.33±8.18* (21.27-27.39)	-20.60	2.30	25.66±7.14* (22.99-28.33)	-22.48	2.23	0.504
QAQ							
Baseline	3.10±1.25 (2.66-3.60)			3.03±1.03 (2.64-3.41)			0.737
III months	1.53±0.81* (1.22-1.89)	-1.57	1.49	1.36±0.66* (1.11-1.61)	-1.67	1.93	0.392
Patient satisfaction							
III months	4 (4-5)			4 (4-5)			0.469
Procedure related outcomes							
Procedure time, seconds	324.46±165.34			278.20±137.63			0.244
Number of attempts							0.254
I	24 (80%)	28 (93.3%)					
II	6 (20%)	2 (6.7%)					

Values are expressed as the mean ± standard deviation, median (interquartile range). *p<0.001 is considered statistically significant according to baseline. Positive responders: Reduction in VAS score by at least 50% at 12 weeks; CI: Confidence interval; VAS: Visual analogue scale; ODI: Oswestry Disability Index; QAQ: Quantitative Analgesic Questionnaire.

DISCUSSION

This study was conducted to compare the US and FL approach for treatment and technique-related outcomes of SIJ injection in patients with non-inflammatory SIJ originated pain. Our results suggest that US-guided technique is a feasible and safe alternative treatment modality. When comparing these 2 therapeutic groups, there was no significant difference in treatment outcomes, including pain and functional disability scores, patient satisfaction and pain medication consumption. Moreover, the present research shows that intra-articular needle placement for SIJ injections was achieved more often on the first attempt under FL (28/30) than under US guidance (24/30), with no significant difference.

The treatment outcomes of this study are consistent with previous studies evaluating the use of US guidance for SIJ injection.^{13,14,21} A study comparing US and FL guidance for SIJ injection found significant pain relief and functional improvement for both groups at 3 months after the procedure, without significant difference in NRS or ODI scores between the 2 arms during the follow-up period.¹⁴ Similarly, Soneji et al. reported no significant difference in pain and disability scores between the US and FL groups for SIJ injection in patients with chronic low back pain during 3-month follow up.¹³ In those studies, although the end point of SIJ injection was intra-articular, periarticular infiltration was accepted. In this study, we only included patients who experienced at least 75% pain relief after SIJ diagnostic block, the standard used in the literature; therefore, we accepted the procedure only if intra-articular contrast spread was achieved to keep the comparison groups consistent.³

With respect to procedure time, no significant difference was observed between the US- and FL-guided groups. The use of FL guidance is recommended to confirm the accurate needle location until physicians have experience with the US approach.^{13,14} Thus, the additional time needed for US-guided SIJ injection with fluoroscopic confirmation and some radiation exposure must be taken into account, particularly for more novice users. When comparing the accuracy rate of SIJ injections on the first attempt, no

significant difference was found between US (80%) and FL (93.3%). Previous studies exploring the feasibility of US- and FL-guided SIJ injections showed variability in the rates of intra-articular injections confirmed by arthrography: the US guidance accuracy ranged from 50-87.3%, while the FL accuracy ranged from 65-98.2%.¹²⁻¹⁴ The success rate for IA injections in the present study was within the broad range indicated in the literature.

The use of intra-articular SIJ injection is both diagnostic and therapeutic. Relief of symptoms, including pain elimination, enduring pain control, or improvement in functional disability, is the gold standard for assessing the success of interventional techniques. Intra-articular SIJ injections have been successfully performed in patients with non-inflammatory SIJ-related pain.^{14,22} Even if the needle is not accurately placed in the intra-articular SIJ, symptoms can be relieved by a local anesthetic and steroid injection that spreads to the intra-articular joint, posterior SIJ ligaments or periarticular area. The neural innervations and nociceptors are located not only in the joint capsule but also in the posterior ligamentous tissue, thus they are considered as additional sources of SIJ-related pain.^{23,24} Furthermore, one study showed that peri-articular injections provide greater pain relief than intra-articular injections for SIJ pain.²⁵ It is worth noting that although peri-articular injections have shown to be effective for therapeutic purposes, the application of SIJ injection should be performed with the accurate placement of the needle in the intra-articular space after a positive diagnostic SIJ intra-articular injection. The lower third of the SIJ is the synovial component of the joint where a space should allow the least resistance upon needle passage, and the upper portion of the SIJ is fibrous and strongly attached to the surrounding stabilizing ligaments, which form wide margins of fibrocartilage, and does not constitute the true joint.^{26,27} Because of its synovial component, the lower third of the SIJ is the part of the entire SIJ in which the intra-articular SIJ injection should be performed.²⁸ Herein, we performed SIJ injections for therapeutic effect and also investigated the accuracy of needle tip placement in the intra-articular space by confirming the spread of radiocontrast agent. Considering the results of the

study, we suggest that confirmation of radiographic localization of the SIJ injection with arthrography is essential to avoid misplacement of the needle.

Recently, US has emerged as an alternative imaging method to guide spinal interventional techniques. US guidance provides compelling evidence supporting its use in caudal epidural and facet joint injections and medial branch nerve blocks.^{10,29} When performing SIJ injections, US enables the clinician to measure the depth of the posterior sacroiliac ligament and the distance from the skin to the SIJ. Additionally, there are some distinct advantages of US when used alone, more affordable, available, and free of radiation hazards compared to FL. However, one should keep in mind that the US guidance may still have limitations for diagnostic specificity of injection compared to FL as far as the accuracy of the procedure is concerned. In clinical practice, we prefer hybrid US/FL guidance for SIJ injections, which reveals neurovascular structures, reduces the need for radiation exposure, and confirms the accuracy of the procedure.

Our study has a few limitations. First, the study was not conducted as a double-blinded study; it is challenging to set up a double-blinded study with imaging techniques such as US or FL. Further studies comparing FL and US guidance for procedural treatments could optimize blinding by scanning all patients with a mock US. Second, one interventionist with experience in these techniques performed all procedures in this study, which may limit the gener-

alizability of the results, since US-guided SIJ injection is considered an intervention requiring an intermediate-to-advanced skill level. Third, only patients with a BMI < 30 kg/m² were included in this trial. It is technically challenging to apply US guidance for spinal procedures in individuals with higher BMI, and future research is required to determine the role of US for SIJ injection in this population. Finally, we followed patients for 3 months, but trials may target longer-term effects. Outcomes of short-term effects should be used to evaluate long-term consequences in the future.

CONCLUSION

In conclusion, US-guided SIJ injection with fluoroscopic confirmation is a feasible alternative to FL guidance for therapeutic SIJ injections. Patients in the US-guided group experienced similar treatment benefits regarding pain intensity, functionality, and patient satisfaction as those in the FL group, with reduced risk of radiation exposure. We suggest that intra-articular SIJ injection performed meticulously under hybrid US/FL guidance with reduced radiation hazard can be used as a valuable technique in both diagnostic and therapeutic procedures.

Conflict of Interest

No conflicts of interest between the authors and / or family members of the scientific and medical committee members or members of the potential conflicts of interest, counseling, expertise, working conditions, share holding and similar situations in any firm.

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