Randomized Trial

# A Prospective Randomized Noninferiority Trial Comparing Upper and Lower One-Third Joint Approaches for Sacroiliac Joint Injections

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Disclaimer: There was no external funding in the preparation of this manuscript. Conflict of interest: Each author certifies that he or she, or a member of his or her immediate family, has no commercial association (i.e., consultancies, stock ownership, equity interest, patent/licensing arrangements, etc.) that might pose a conflict of interest in connection with the submitted manuscript.

Manuscript received: 05-10-2017
Revised manuscript received: 09-09-2017
Accepted for publication: 11-17-2017

Free full manuscript: www.painphysicianjournal.com

**Background:** Sacroiliac intraarticular injection using the upper one-third joint technique is recommended for injections that are difficult with the lower one-third joint technique.

**Objective:** To evaluate the success rate of intraarticular sacroiliac joint (SIJ) injections using the upper and lower one-third joint techniques.

**Study Design:** Prospective randomized noninferiority study.

**Setting:** An interventional pain-management practice in a university hospital.

**Methods:** In this single-blind, noninferiority trial, 181 patients were randomly assigned to either the upper (group U, 90 patients) or lower (group L, 91 patients) one-third joint techniques. The primary end point was the rate of successful intraarticular injections (%), with a noninferiority margin of 10 percentage points. The secondary end points included numeric rating scale (NRS) pain scores before, during and after the procedure, procedure time, degree of contrast spread, and occurrence of intravascular uptake or complications.

**Results:** The intraarticular injection rate was 93.3% (84 of 90 patients) in group U and 95.6% (87 of 91 patients) in group L (difference, 2.6 percentage points; 95% confidence interval, –8.9 to 4.4). This study found no significant between-group differences in the degree of contrast spread throughout the joint (88.1% with group U and 87.4% with group L, $P = 0.883$), intravascular incidence (11.1% and 9.9%, respectively; $P = 0.789$), rate of complications (1.1% and 1.1%, respectively; $P = 1.000$), inadvertent spread beyond the joint (12.2% and 19.8%, respectively; $P = 0.201$), or mean post-procedural NRS score for pain (2.24 ± 1.87 and 2.52 ± 1.97, respectively; $P = 0.342$). However, the mean procedure time (111.2 ± 72.7 and 77.8 ± 60.4 s, respectively; $P = 0.001$), and mean NRS score for pain during the procedure differed significantly between the groups (2.28 ± 1.45 and 1.77 ± 0.99, respectively; $P = 0.006$).

**Limitations:** This study was designed as a noninferiority study of successful intraarticular injection rates and did not evaluate long-term outcomes.

**Conclusions:** The upper one-third joint technique for performing SIJ injections was not inferior to the lower one-third joint technique in terms of the intraarticular injection success rate.

**Key words:** Fluoroscopy, low back pain, lower one-third joint technique, sacroiliac joint, sacroiliac joint injection, upper one-third joint technique

**Pain Physician 2018; 21:251-257**

Sacroiliac joint (SIJ) dysfunction is a common source of low back and buttock pain with or without referred pain, with a prevalence rate ranging from 10 to 26.6% after diagnostic block (1-8). Owing to the inability to diagnose SIJ pain using noninvasive tests, SIJ injection is regarded as the

assessment of choice for diagnosis (6,9). Based on a recent systematic review, local anesthetic blocks provide good evidence for the diagnosis of SIJ pain, while provocative tests provide fair evidence, and imaging provides limited evidence (6).

Several studies have shown that sacroiliac periarticular injections are as effective as sacroiliac intraarticular injections for neural blockade around the joint (10-15). However, there is limited evidence of the effectiveness of sacroiliac periarticular injection with local anesthetic and steroid or botulinum toxin (16). Sacroiliac intraarticular injection remains indispensable for an accurate diagnosis.

Osteophytes around the joint, or an extremely narrow joint space, sometimes make sacroiliac intraarticular access difficult (17-20). To overcome this, an alternative approach using the upper one-third joint technique was introduced (21). The purpose of this investigation was to examine the noninferiority of the upper one-third joint technique relative to the lower one-third joint technique for sacroiliac intraarticular injection, by comparing the rate of successful intraarticular injection between the 2 techniques.

## Methods

### Patients

The study protocol was reviewed and approved by the Institutional Review Board of Seoul St. Mary's Hospital, Catholic University (IRB No. KC13OISI0670). All of the patients enrolled in this study gave informed consent and were allocated to one of 2 groups. The study included patients older than 20 years who had at least 3 signs on provocative tests (gapping, thigh thrust, Gaenslen, compression, sacral thrust, or Patrick's test). Patients were excluded if they had lumbosacral transitional vertebrae, screw fixation in the sacrum, local infection, or a coagulopathy.

### Study Design and Intervention

The study was a prospective, randomized, noninferiority trial. The methods of trial design are reported in accordance with the instructions of the revised Consolidated Standards of Reporting Trials (CONSORT) 2010 statement for randomized trials (22). Using simple randomization by a computer-generated random sequence, each patient was allocated to one of 2 groups. Before the enrollment of patients, envelopes containing a sheet with the allocated treatment were numbered sequentially and sealed. The sealed envelopes were opened by an investigator irrelevant to the patients' assessment. Each patient had only one SIJ injection: in one group injections were done with the upper one-third joint technique (group U, n = 90) and in the other with the lower one-third joint technique (group L, n = 91) (Fig. 1). All of the procedures were performed by a physician (Y.H.K.) with more than 10 years' experience with SIJ injections. The practitioner conducting the procedures and the evaluator assessing outcomes could not avoid recognizing the group to which the patients belonged due to the location of the block needle. However, the patients were unaware of the group to which they were allocated.

### Upper One-third Joint Technique

This technique was proposed by Park et al (21). The patient was placed in a prone position with a pillow under the abdomen on a fluoroscopy table. The procedure area was disinfected with povidone-iodine and draped in the usual sterile manner. Before inserting the needle, the skin and subcutaneous tissue were infiltrated with 1% lidocaine in the midline of the L5–S1 interspinous space. A 10 cm long, 22-gauge curved-tip spinal needle (Neurotic Nerve Block Needle, Hakko, Tokyo, Japan) was inserted and directed towards the upper one-third of the joint at an angle of about 45°. When the curved-tip needle contacts hard tissue on the silhouette of the iliac crest in the anteroposterior fluoroscopic view, we can differentiate the iliac crest from the sacrum by rotating the needle. The needle was advanced beyond the line of the iliac crest until it reached the joint and caused a popping sensation. The intraarticular position was confirmed after injecting 0.2–0.5 mL contrast material (IOBRIX, 300 mgI/mL; Taejoon Pharm, Seoul, Korea). The injected contrast material dispersed throughout the SIJ in a cephalocaudal fashion. After the contrast material outlined the SIJ without intravascular uptake on both anteroposterior and lateral fluoroscopic views, a solution of steroid and local anesthetic (5 mg triamcinolone with 2 mL 0.8% lidocaine) was injected. If vascular runoff was detected, the process was repeated after changing the needle direction.

### Lower One-third Joint Technique

The patients were prepared in the manner described above. After local anesthesia to the skin and subcutaneous tissue with 1% lidocaine, a 10 cm long, 22-gauge curved-tip spinal needle was positioned at the lower one-third of the SIJ recess under fluoroscopic guidance. Correct needle insertion was ensured using

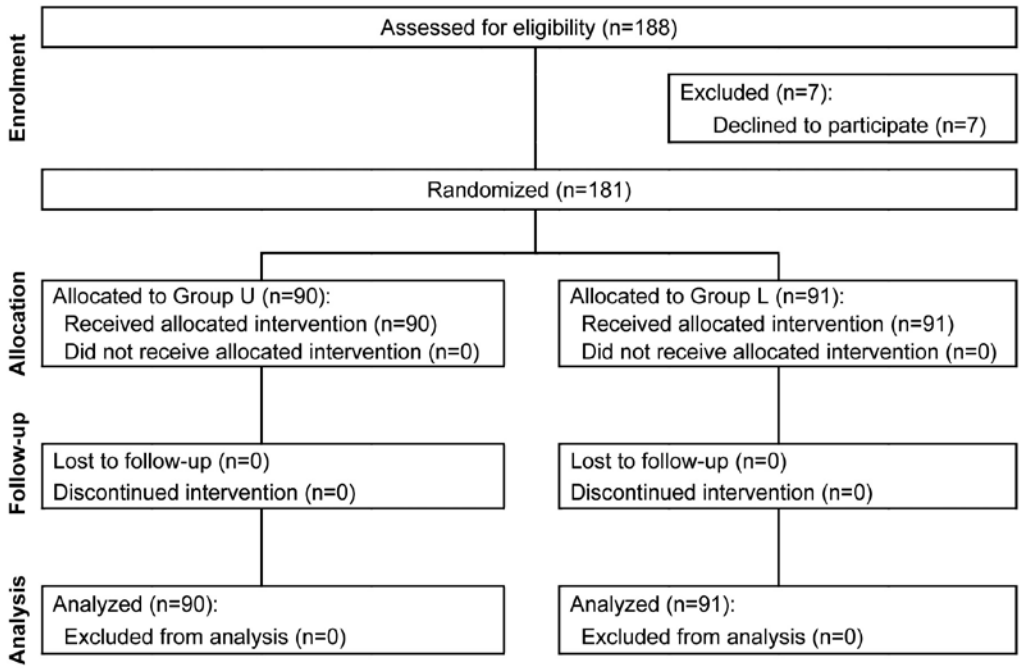


Fig. 1. *Flow diagram of the progress.*

both anteroposterior and lateral fluoroscopic images, following negative aspiration and injection of 0.2–0.5 mL contrast material for an arthrogram. Then, the same steroid solution as in group U was injected.

## Block Assessment

The procedure time was defined as the interval between needle insertion and confirmation of a correct arthrogram. In the previous study, all successfully performed SIJ injections took less than 300 seconds, and failures took more than 300 seconds (21). Therefore, a failed procedure was defined as one that took longer than 300 seconds without intraarticular injection. If the procedure failed, the procedure time was recorded as 300 seconds. In group U, contrast spread was graded as follows: 1, stayed in the upper one-third of the joint; 2, reached the middle one-third of the joint; and 3, reached the lower one-third of the joint (on lateral fluoroscopic images). In group L, contrast spread was graded as follows: 1, stayed in the lower one-third of the joint; 2, reached the middle one-third of the joint; and 3, reached the upper one-third of the joint in lateral fluoroscopic images.

## Data Collection

The following patient data were collected by an independent assessor: age, gender, height, weight, side of injection, numeric rating scale (NRS) pain intensity scores before, during, and 30 minutes after the procedure (range: 0 [no pain] to 100 [worst pain imaginable]), procedure time, degree of contrast spread, occurrence of intravascular uptake or complications, success or failure of the intraarticular injection, and inadvertent spread beyond the joint.

The primary end point was the rate of intraarticular injection. The secondary end points included the NRS score for pain before, during, and after the procedure, procedure time, degree of contrast spread, occurrence of intravascular uptake or complications, and incidence of inadvertent spread beyond the joint.

## Statistical Analysis

Assuming a sacroiliac intraarticular injection success rate of 95% using the lower one-third joint technique (19,20), and a noninferiority margin of 10%, a sample size of 180 patients was needed to demonstrate the noninferiority of the upper one-third joint technique

Table 1. *Patient demographics and characteristics of the blocks.*

| | Group U (n = 90) | Group L (n = 91) |
|---|---|---|
| Age, years[a] | 59.1 ± 13.2 | 56.8 ± 13.3 |
| Male/female, n | 26/64 | 26/65 |
| Side right/left, n | 52/38 | 44/47 |
| BMI, kg/m$^2$ [a] | 23.7 ± 3.2 | 23.4 ± 3.1 |
| NRS score for pain before procedure[a] | 6.97 ± 1.41 | 6.59 ± 1.37 |

n = number; BMI = body mass index; NRS = numeric rating scale.
[a]Values are mean ± SD.
Differences between groups were not significant ($P > 0.05$).

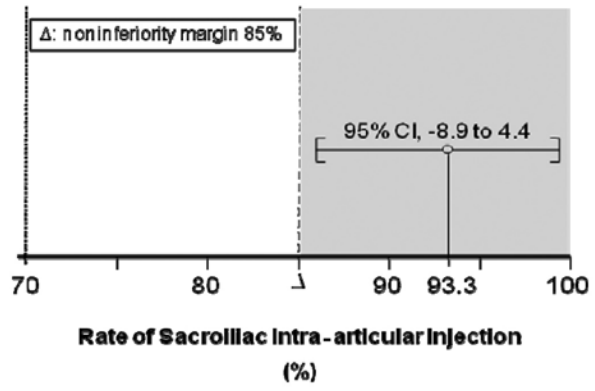


Fig. 2. *Difference of sacroiliac intraarticular injection between groups. The dashed line at 85% indicates the noninferiority margin of 10%. The gray zone indicates the zone of noninferiority. The confidence interval excludes the limit of noninferioity, and noninferiority is demonstrated. CI = confidence interval.*

in comparison with the lower one-third joint technique with 90% statistical power and a 2 sided alpha value of 0.05. The study was continued until at least 90 patients were enrolled in each group. The margin of noninferiority was determined by experts at our institution. A difference of less than 10% in the intraarticular injection rate was considered clinically acceptable.

For the primary outcome, the noninferiority of the upper one-third joint technique was considered if the upper boundary of the 2 sided 95% confidence interval (CI) lay below the noninferiority margin of 10% (23). Pearson's chi-square test or Fisher's exact test and the Student's t-test were used to analyze secondary outcomes. A *P*-value < 0.05 was considered statistically significant. The statistical analyses were performed with SPSS software (ver. 18.0; SPSS Inc., Chicago, IL, USA).

## Results

Of the 188 patients screened from December 2013 through November 2016, 181 were randomly assigned to group U (n = 90) or L (n = 91) (Fig. 1). The patient demographics of the two groups were comparable (Table 1). The intraarticular injection rate was 93.3% (84 of 90 patients) in group U versus 95.6% (87 of 91 patients) in group L, for an absolute difference of 10% (95% CI, –8.9 to 4.4) (Table 2). Because the upper boundary of the 2 sided 95% CI lay below the noninferiority margin of 10%, the noninferiority of the upper one-third joint technique to the lower one-third technique was established (Fig. 2).

This study found no significant difference between groups in terms of the degree of contrast spread throughout the joint (88.1% for group U and 87.4% for group L, $P = 0.883$), intravascular incidence (11.1% and 9.9%, respectively; $P = 0.789$), complication rate (1.1% and 1.1%, respectively; $P = 1.000$), inadvertent spread beyond the joint (12.2% and 19.8%, respectively; $P = 0.201$), or mean post-procedural NRS pain score (2.24 ± 1.87 and 2.52 ± 1.97, respectively; $P = 0.342$). However, the mean procedure time (111.2 ± 72.7 and 77.8 ± 60.4 seconds, respectively; $P = 0.001$) and the mean NRS pain score during the procedure differed significantly between the groups (2.28 ± 1.45 and 1.77 ± 0.99, respectively; $P = 0.006$) (Table 2). There were significant group differences in the mean pre- and post-procedural NRS pain scores (6.97 ± 1.41 vs. 2.24 ± 1.87 for group U and 6.59 ± 1.37 vs. 2.52 ± 1.97 for group L, $P < 0.001$) (Table 3). All participants tolerated the procedures, including 2 patients who developed motor weakness and recovered within 30 minutes of the procedure.

## Discussion

Based on a predicted 10% margin of noninferiority, this study demonstrated the noninferiority of the upper

Table 2. *Comparison of outcomes and characteristics of the blocks.*

| Outcome | Group U (n = 90) | Group L (n = 91) | *P* value | Difference (95% CI) |
|---|---|---|---|---|
| | | | | *percentage points* |
| Success incidence, n (%) | 84 (93.3) | 87 (95.6) | 0.536[a] | 2.3 (-8.9 to 4.4) |
| Procedure time, s[b] | 111.2 ± 72.7 | 77.8 ± 60.4 | 0.001[c]* | |
| Degree of contrast spread, n (%) | | | 0.883[d] | |
| grade 1 & 2 | 10 (11.9) | 11 (12.6) | | |
| grade 3 | 74 (88.1) | 76 (87.4) | | |
| Intravascular incidence, n (%) | 10 (11.1) | 9 (9.9) | 0.789[d] | |
| NRS score for pain during procedure[b] | 2.28 ± 1.45 | 1.77 ± 0.99 | 0.006[c]* | |
| NRS score for pain after procedure[b] | 2.24 ± 1.87 | 2.52 ± 1.97 | 0.342[c] | |
| Complication, n (%) | 1 (1.1) | 1 (1.1) | 1.000[a] | |
| Inadvertent spread, n (%) | | | 0.201[d] | |
| only intraarticular joint | 79 (87.8) | 73 (80.2) | | |
| L5 or S1 or S2 | 9 (10.0) | 11 (12.1) | | |
| S3 or piriformis | 2 (2.2) | 7 (7.7) | | |

n = number. NRS = numeric rating scale. CI = confidence interval.
[a]Fisher's exact test.
[b]Values are mean ± SD
[c]Student's t-test.
[d]Pearson's chi-square test.

Table 3. *Comparison of NRS score for pain.*

| | Before procedure[a] | After procedure[a] | *P* value |
|---|---|---|---|
| Group U (n = 90) | 6.97 ± 1.41 | 2.24 ± 1.87 | < 0.001* |
| Group L (n = 91) | 6.59 ± 1.37 | 2.52 ± 1.97 | < 0.001* |

NRS = numeric rating scale.
[a]Values are mean ± SD.
*Indicates significant difference.

one-third joint technique relative to the lower one-third joint technique for sacroiliac intraarticular injection. Another study demonstrated that the upper one-third joint technique was an alternative approach in 20 difficult cases (21). In that study, the upper one-third joint technique was clinically feasible, with a success rate of 90%, similar to that of our study. However, that study was not designed as a noninferiority study comparing the 2 techniques. We used a noninferiority design because no other technique seems to have a significantly greater success rate compared with the lower one-third joint technique.

The change in pain score after a procedure, and the safety profile, are both clinically important, as is the success rate (as the primary outcome). In this study, the NRS pain score before and 30 minutes after the procedure was evaluated in patients suspected of having SIJ dysfunction. We observed significant improvements after the procedure in both groups, with no difference between the groups. There was also no group difference in the degree of contrast spread, so there should also have been no difference in the NRS pain score in the short-term. If the contrast spread is only of grade 1 using the lower one-third joint technique, the upper one-third joint technique can be used for a wider spread of contrast. We presumed that the upper one-third joint technique would result in more intravascular

injections, complications, and NRS pain score during the procedure, as well as a longer procedure time, than the conventional technique, because of physician unfamiliarity with the technique and the many ligaments along the trajectory of the needle. However, no differences in the intravascular injection success rate or complications were seen between the 2 groups. Although we expected more complications such as motor weakness, particularly due to the higher degree of contrast spread to other regions in group U, we did not observe a significant difference in inadvertent spread beyond the joint in comparison with group L. Among the secondary outcomes, the procedure time and NRS pain score during the procedure were significantly greater in group U than in group L. We attributed these results to greater physician familiarity with the conventional technique and the greater distance between the skin and the target in group U. The mean differences in procedure time (about 33 seconds) and NRS pain score during the procedure (about 0.5) are clinically acceptable and can be tolerated by patients. Moreover, if patients require both right and left SIJ injections, most in group U will need just a single injection site for the local anesthetic block on the midline of the L5–S1 interspinous space versus at least two injection sites in group L (21). Therefore, the notion that the upper one-third joint technique results in less pain improvement and a poorer safety profile in comparison with the lower one-third joint technique is incorrect.

This study had several limitations. First, one physician performed all of the injections and the upper one-third joint technique may require a long learning curve due to physician unfamiliarity. Second, this study was designed to assess the noninferiority of the procedure rather than the long-term outcome. Therefore, no conclusions can be drawn regarding the long-term outcome of the upper one-third SIJ technique. High body mass index requires a longer needle, which may make it difficult to direct the needle to the target.

## Conclusion

In conclusion, we found that use of the upper one-third joint technique for performing SIJ injections was not inferior to the lower one-third joint technique in terms of the intraarticular injection rate.

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