# IMPACT OF STEROID AND LIDOCAINE INJECTION IN THE SACROILIAC JOINT IN AXIAL SPONDYLOARTHRITIS PATIENTS: A RANDOMIZED CONTROLLED TRIAL

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***Abstract. Background.*** *The value of steroid and lidocaine injection of the sacroiliac joint in axial spondyloarthritis patients on magnetic resonance imaging scores and clinical disease outcome measures is not yet well assessed.* ***Patient and methods.*** *Participants were randomly assigned into two groups; Group I received unilateral ultrasound-guided sacroiliac joint injection with 0.5% lidocaine hydrochloride mixed with triamcinolone. At the same time, group II received subcutaneous saline injection. All participants fulfilled the ASAS criteria for axial SpA and all had bone marrow edema of at least one sacroiliac joint at baseline. Outcomes measures were: Visual Analogue Scale (VAS) for pain, Ankylosing Spondylitis Disease Activity Score (ASDAS), spine mobility scales, Bath Ankylosing Spondylitis Functional Index (BASFI), and Spondyloarthritis Research Consortium of Canada (SPARCC) scores. Participants were assessed at baseline (before and after sacroiliac joint injection) and after three months. This clinical trial was registered on clinicaltrials.gov under the number NCT04895228.* ***Results.*** *In this study, a total of 61 participants were registered. There was a significant difference between both groups regarding pain, spine mobility, SPARCC, and ASDAS scores in favor of group I. Spine mobility showed the earliest improvement, followed by pain whilst SPARCC, and ASDAS scores showed improvement after three months. Higher disease activity, younger age, and shorter disease duration were all associated with better outcomes. Bilateral hip involvement was a predictor of poor response.* ***Conclusion.*** *Sacroiliac joint injection of lidocaine and triamcinolone in axial SpA patients is a cost-effective and practical technique for controlling pain, improving function, disease activity scores, and bone marrow edema with acceptable complications and relatively sustained effect.*

***Key words:*** *intra-articualr injection, sacroiliac joint, bone marrow edema, ultrasound*

## Introduction

Axial spondyloarthritis (Axial SpA) is the primary sort of inflammatory arthritis influencing the axial skeleton. Axial SpA represents a great burden on the social, financial, and physical aspects of patient's life. Radiographic axial SpA (r Ax-SpA) affects around 0.5% of the population worldwide. Inflammatory back pain, radiographic sacroiliitis, and a high frequency of HLA–B27 are distinguishing features. Non-radiographic axial SpA (nr Ax-SpA) could deteriorate to ankylosis of the spine and sacroiliac joint. The disease progression varies widely among patients. Extra-articular manifestations include enthesitis, dactylitis, uveitis, psoriasis, and inflammatory bowel disease. Diverse management modalities aim for improving pain and maintaining function with an overall target to stop irreversible damage [1]. Treatment of the spine in axial SpA demands a multidisciplinary approach. Patient education, physiotherapy, and exercise are available alternatives besides medical and surgical treatment. Nonsteroidal anti-inflammatory drugs (NSAIDs) can control pain and inflammation to a lesser extent. Disease-modifying anti-rheumatic drugs (DMARDs) were ineffective in treating axial SpA. Tumor necrosis factor alpha (TNF-α) inhibitors were able to slow disease evolution and spinal stiffness. Furthermore, they can control extra-articular manifestations [2]. Although TNF-α inhibitors have a faster onset of action than DMARDs with higher efficacy, they are more expensive, increase the liability of infection, injection site reaction, development of autoantibodies, and drug resistance. Moreover, relapse after drug withdrawal is a known complication [3].

Sacroiliac joint injection of different TNF-α inhibitors showed satisfactory results but with a high cost [4]. The benefit of sacroiliac joint (SIJ) injection of steroids and lidocaine in axial SpA is debatable. Some studies limit its role in pain improvement, while others postulate that it can alleviate disease activity and spine mobility. Despite the fact that SIJ injection improved disease activity measures in different studies, its effect on reducing bone marrow edema (BME) erosions, and fat was not studied thoroughly [5-8].

## Objectives

This pilot study is trying to shed light on the role of SIJ injections of steroids and lidocaine on Magnetic Resonance Imaging (MRI) scores of the SIJ along with pain, function, and disease activity measures. Secondary outcome measures included predictors of good responders.

## Material and methods

All participants registered in this study were informed about the methodology and goals in detail, and they signed a written consent. Ethics committee of Sohag faculty of medicine, Egypt, approved the study protocol. The study was also registered on clinical trials.gov site and the number was NCT04895228. Medical and personal information was kept confidential. The study was performed following the principles of the declaration of Helsinki.

## Study design and location

This is a prospective hospital-based randomized single-blinded controlled trial. Patients who fulfilled the Assessment in Ankylosing Spondylitis (ASAS) working group (ASAS criteria) for axial SpA were enrolled in the study through regular follow-up in Sohag University Hospital, rheumatology outpatient clinic.

The cases were randomly assigned into two groups; Group I (active group) received sacroiliac injections Ultrasound (US)-guided with 0.5% lidocaine hydrochloride (xylocaine, AstraZeneca) 4 ml mixed with 1 ml of triamcinolone 40 milligrams (Kenacort, Bristol Myers Squip), whereas Group II (control group) received a subcutaneous injection of 5 ml of normal saline. Both groups were matched for age and sex. Both were under treatment with anti-TNF secukinumab (Cosentyx 150 mg, Novartis) and NSAIDs with or without synthetic DMARDs (only methotrexate with a dose between 12.5 and 25 mg weekly or sulfasalazine with a dose between 1.5 to 2 g daily). Both groups were assessed at baseline before and after injection and after three months. Outcome measures Visual analogue scale (VAS) for pain, Ankylosing Spondylitis Disease Activity Score (ASDAS), and mobility, all were measured three times while Spondyloarthritis Research Consortium of Canada (SPARCC) and Bath Ankylosing Spondylitis Functional Index (BASFI) scores were measured at baseline (before injection) and after three months. Hip involvement was counted if the patient had limited range of motion, hip destruction according to MRI or radiography, or finally those who performed total hip replacement. On each visit, SIJ injection was performed at baseline by an experienced rheumatologist under US guidance. Clinical evaluations were performed by another rheumatologist.

## Eligibility criteria

### *Inclusion criteria*

All participants were ≥ 18 years old with axial SpA according to ASAS classification criteria with BME of at least one SIJ. ASDAS-CRP score ≥ 1.3 was also considered as an entry criterion [9]. All the patients had limitations of spine mobility either in flexion or extension, according to modified Schober's or fingertip-to-floor test or lateral binding, according to lateral lumbar flexion [10, 11].

Exclusion criteria: completely ankylosed spine, infection at the injection site or allergy to lidocaine, previous spine surgery, chronic painful conditions ex (fibromyalgia), and finally pregnancy.

### *Randomization and blinding*

Randomization was done using 1:1 allocation. For every two participants, the first selected a group number from one box, and the next was allocated to the other group. Randomization was guaranteed by the 1st author. The participants were blinded for the injected substance, whereas the rheumatologist was not blinded.

## Interventions

### *SIJ injection*

The US-guided injection was performed by a linear probe 7.5 to 12 MHz (Logiq e, General Electric, China). Initially, a US scan was performed in a prone position. A pillow was sited below the abdomen to flatten lumbar lordosis. The transducer was placed axial on the sacral hiatus and the sacral cornua were recognized. Then the transducer was shifted laterally to identify the lateral border of the sacrum. The transducer moved cephalic to identify the bony margin of the ilium. The Injection was performed using a sterile technique, a 22 Gauge needle was used for injection. The injection was done using an in-plane technique. It was introduced from medial to lateral after subcutaneous infiltration of 2 ml of 0.5% lidocaine. Before injection, aspiration was tried to avoid intravascular injection. The injectant was triamcinilone 40 mg (Kenacort) 2 ml + 2 ml of 0.5% lidocaine hydrochloride (Xylocaine). In the case of bilateral SIJ edema, the joint with a higher SPARCC score was selected for injection. Blood sugar was measured before the

injection and if the participant had hyperglycemia, the injection was suspended. After the procedure, participants were inspected for complications, vital signs, and for blood sugar [12, 13].

***Saline injection***

By using the same preparations in the previous step, 4 ml of saline were injected subcutaneously at the SIJ level but superficial to it and the injection was confirmed by US. This was usually inferior to the Venus dimple.

The injection of both groups was scheduled on different occasions.

***Outcome measures***

**1. VAS for pain**

The VAS was graded from 0 to 10. Grade 0 means no pain and 10 denotes the worst possible pain [14-16]. Even though VAS is a part of ASDAS, its separation from ASDAS score shows a flawless image of pain improvement

**2. ASDAS-CRP**

In these score, five sections are assessed: back pain (score from 0-10), morning stiffness duration (score from 0-10), Patient Global Assessment (score from 0-10), Peripheral Pain/Swelling (score from 0-10), and C-reactive protein (calculated in mg/l). The score was considered using ASDAS calculator. ASDAS improvement is considered when the score reduction is ≥ 1.1 [17].

**3. Spine mobility scales**

Modified Schober's test, finger-tip to floor, and lateral lumbar flexion tests were used to assess spinal mobility [10, 11].

**4. BASFI**

The BASFI comprises ten questions. Each question's score ranges from 0 (no limitation) to 10 (maximal limitation). A score of (6/10) means high functional limitation. It contains eight domains covering everyday tasks that depend on functional anatomy (bending, changing position, reaching, standing, turning, and climbing steps) and two domains measuring the patients' capability to deal with everyday life [18].

**5. SPARCC score**

This score is based totally on the assessment of increased signal on T2 with fat suppression or short tau inversion recovery (STIR) sequences denoting BME on oblique coronal scans of the SIJ. All signal changes in the ilium bone and sacrum till the sacral foramina. Six consecutive slices through the SIJ are scored. STIR signals of the sacral interforaminal were set as a reference. Each SIJ is divided into four equal quadrants. The increased STIR signal in any quadrant is documented in each of those six slices, yielding a maximum score of 48. A lesion signal (comparable in intensity to a signal from a blood vessel) or a depth ≥ 1 cm gives an additional score with a maximum of four per single slice, yielding a total score of 72 (Figure 1) [19].

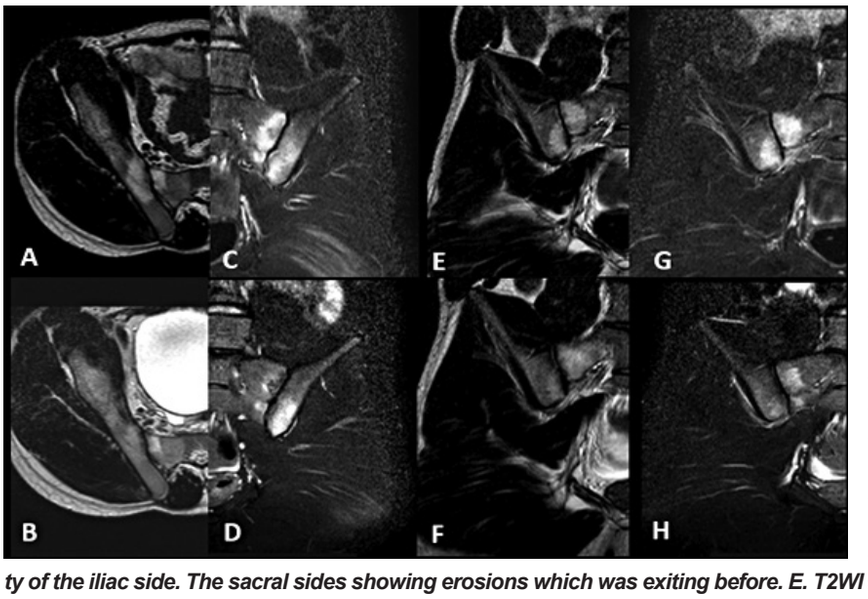



***Fig. 1. Impact of sacroiliac joint injection on MRI scores. A. T2WI semi-coronal of the right SIJ at baseline showing subchondral hyperintense signal of the ilium and sacrum at the upper 1/2 of the SIJ with more infiltration of the iliac side. B. T2WI Of the same SIJ after 3 months of injection showing resolution of the iliac side with decreased signal intensity in the sacrum but without change in its size. C. STAIR semi-coronal of the left SIJ at baseline showing extensive bone marrow oedema of sacral side and to a lesser extent at the iliac side at baseline. Sacral side showing subchondral erosion. D. STAIR semi-coronal of the left SIJ joint after 3 months of injection with near complete resolution of the sacral side and increase signal intensity of the iliac side. The sacral sides showing erosions which was exiting before. E. T2WI semi-coronal of the right SIJ at baseline showing extensive hyperintense signal involving both sacral and iliac sides of the joint. Subchondral sclerois is seen on the iliac side. F. T2WI semi-coronal of the right SIJ joint 3 months after injection showing improvement of the iliac side signal size and intensity. The signal on the iliac became more diffuse and less demarcated. Subchondral sclerosis is seen on the iliac side. G. STAIR semi-coronal of the right SIJ at baseline with extensive subchondral bone marrow oedema of the iliac and sacral sides at baseline. H. STAIR semi-coronal of the Rt SIJ 3 months after injection showing near complete resolution of the illium and decrease signal intensity and size.***

SPARCC SIJ structural score was used to assess erosions and fat metaplasia on T1W-MRI at baseline and three months. The presence or absence of lesions (erosion, fat metaplasia) in SIJ quadrants was documented. Each scored from 0 to 8 per slice for five slices (total score of 0-20) [20].

MRI-SIJ and MRI-spine were performed using a 1.5 T scanner (PHILIPS ACHIEVA Netherlands), with a phased-array surface coil, acquiring T1-weighted turbo spin echo (T1TSE; TR 583/TE 9.4) and short-tau inversion recovery (STIR; TR 2980/TE47) sequences. The coronal oblique and sagittal views of the SIJ and spine were taken, with a slice thickness of 4 mm.

Participants were assessed at baseline (before and after sacroiliac joint injection) and after three months. A double baseline assessment was performed for VAS, spine mobility cores, and BASFI. Other outcome measures were considered once before injection and another time after three months.

### *Sample size*

We planned a study of a continuous response variable from independent control and experimental subjects with one control(s) per experimental subject. Since the data within each subject group was normally distributed, we calculated that we would need to study at least 26 experimental subjects and 26 control subjects to be able to reject the null hypothesis that the population means of the experimental and control groups are equal with probability (power) of 0.95.

### *Statistical analysis*

Statistical package for social sciences (IBM-SPSS), version 25 (IBM-Corporation, Chicago, USA; August 2017) was used for statistical data analysis. Data were expressed as mean and standard deviation (SD), number, and percentage. Mean and standard deviation were used as descriptive value for quantitative data. Student's t-test was used to compare the means between two groups, and paired t-test was used to compare means of the same variable at different periods of time. Fisher Exact test was used to measure the linear association between two qualitative variables. Pearson correlation test was used to compare two quantitative variables. The value of (r) is explained in the following figures: $r < 0.2 \rightarrow$ negligible correlation, 0.2-0.4 → weak correlation, 0.4-0.7 → moderate correlation, and 0.7-1 → strong correlation. Also, positive r means positive or direct correlation, while negative r means negative or inverse correlation. For all these tests, a p-value of less than 0.05 was considered significant and < 0.001 was considered to be highly significant.

## Results

Participants' flow, losses, and exclusions

The original number of cases was 120, but because 23 cases had no bone marrow edema, 14 cases refused to be included in the study, and 22 cases were lost during follow-up and did not complete the study, so only 61 cases remained (Figure 2).

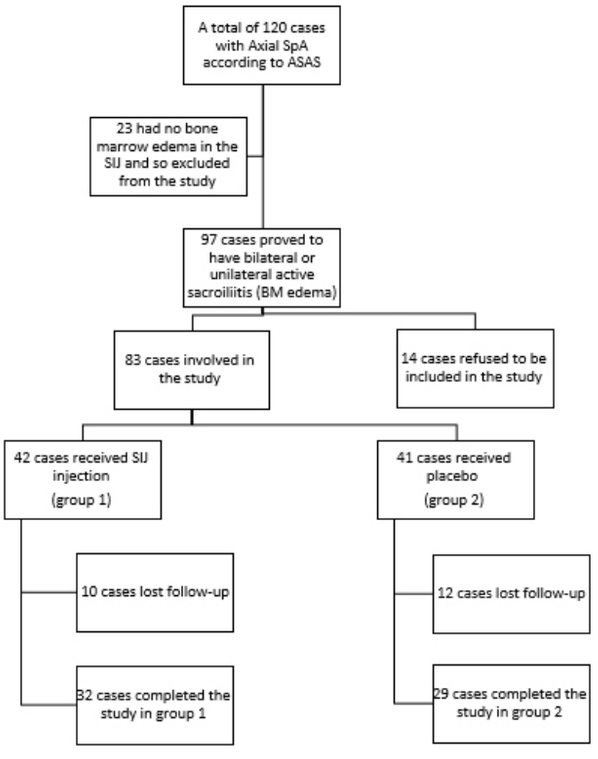



***Fig. 2. Flowchart of the included cases in the study***

### *Baseline data*

The mean age of the participants was around 36.3 years among group 1 cases and 34.1 years among group 2 cases, with no significant difference between the two groups. Radiographic axial SpA (ankylosing spondylitis) was present in 22 cases (36.1%), and the remaining 39 cases (63.9%) had non-radiographic axial SpA. Around 75% of the cases were males. However, male to female ratio was nearly 2:1 in the non-radiographic axial SpA, while in radiographic, the male to female ratio was around 4:1. The mean disease duration was around 5.8 ± 2.4 years among non-radiographic axial SPA compared to 7.5 ± 2.2 years among ankylosing spondylitis (AS) patients.

### *Outcomes and estimation*

Baseline comparison between the two groups (SIJ or active group; and control one) showed non-significant differences regarding VAS, ASDAS, BASFI, finger-to-floor test, lateral bending test, and

SPARCC. All these measures showed significant improvement after three months compared to the baseline, and all of them except for BASFI, SPARCC (fat) and SPARCC (erosions) showed significant improvement among the injection group compared to the control group (Table 1).

The percentage of improvement of all measures showed significant differences between the two groups. This improvement was most pronounced for Oswestry disability index (ODI) (55.3%), followed by VAS immediately after injection (54.6%), then SPARCC BME (53.4%), and ASDAS (46.8%) (Table 2).

Comparing the degree of improvement of VAS, ASDAS, and SPARCC with clinical and laboratory data revealed that VAS improvement was associated with younger age and female sex. However, this was only significant regarding the correlation between immediate VAS improvement and shorter disease duration. On the other hand, there was no significant difference in ASDAS improvement that was

***Table 1. Clinical data of the study groups***

| | | Group I (N = 32) | Group II (N = 29) | P value* | 95% CI | |
|---|---|---|---|---|---|---|
| | | | | | Lower | Upper |
| VAS | Before injection (0) | 7.94 ± 0.88 | 7.93 ± 0.70 | 0.975 | -0.404 | 0.417 |
| | After injection (1) | 3.66 ± 1.47 | 6.90 ± 1.01 | < 0.001 | -3.894 | -2.586 |
| | 12 weeks later (2) | 4.97 ± 1.40 | 7.17 ± 0.76 | < 0.001 | -2.790 | -1.617 |
| | P value 0 vs 1** | < 0.001 | < 0.001 | - | - | - |
| | P value 0 vs 2** | < 0.001 | < 0.001 | - | - | - |
| | P value 1 vs 2** | < 0.001 | 0.265 | - | - | - |
| ASDAS | Before injection | 2.69 ± 0.45 | 2.60 ± 0.35 | 0.372 | -0.114 | 0.299 |
| | 12 weeks later | 1.45 ± 0.42 | 2.41 ± 0.41 | < 0.001 | -1.175 | -0.748 |
| | P value ** | < 0.001 | 0.005 | - | - | - |
| BASFI | Before injection | 60.94 ± 10.16 | 63.00 ± 11.44 | 0.459 | -7.594 | 3.469 |
| | 12 weeks later | 56.69 ± 8.44 | 61.28 ± 10.33 | 0.061 | -9.403 | -0.226 |
| | P value ** | < 0.001 | 0.051 | - | - | - |
| ODI | Before injection | 38.75 ± 12.12 | 37.93 ± 11.14 | 0.785 | -5.165 | 6.802 |
| | 12 weeks later | 18.75 ± 11.85 | 31.72 ± 9.28 | < 0.001 | -18.467 | -7.481 |
| | P value ** | < 0.001 | 0.006 | - | - | - |
| SPARCC (BM edema) | Before injection | 34.34 ± 9.78 | 32.86 ± 9.18 | 0.545 | -3.393 | 6.357 |
| | 12 weeks later | 14.69 ± 6.47 | 28.97 ± 7.95 | < 0.001 | -17.976 | -10.580 |
| | P value ** | <0.001 | 0.001 | - | - | - |
| SPARCC (fat) | Before injection | 7.91 ± 2.48 | 7.52 ± 3.45 | 0.618 | -1.140 | 1.918 |
| | 12 weeks later | 7.19 ± 2.62 | 8.59 ± 3.59 | 0.091 | -2.999 | 0.201 |
| | P value ** | 0.002 | < 0.001 | - | - | - |
| SPARCC (erosions) | Before injection | 4.69 ± 2.53 | 4.59 ± 2.63 | 0.879 | -1.221 | 1.424 |
| | 12 weeks later | 4.84 ± 2.63 | 5.48 ± 2.80 | 0.362 | -2.030 | 0.752 |
| | P value ** | 0.023 | < 0.001 | - | - | - |
| SPARCC (total) | Before injection | 47.25 ± 9.07 | 44.28 ± 9.17 | 0.208 | -1.703 | 7.651 |
| | 12 weeks later | 26.72 ± 7.39 | 43.03 ± 8.38 | < 0.001 | -20.355 | -12.277 |
| | P value ** | < 0.001 | 0.281 | - | - | - |
| Finger to floor | Before injection (0) | 27.63 ± 9.11 | 25.10 ± 10.27 | 0.314 | -2.444 | 7.487 |
| | After injection (1) | 16.81 ± 6.38 | 23.52 ± 10.40 | 0.003 | -11.078 | -2.331 |
| | 12 weeks later (2) | 19.19 ± 7.16 | 24.69 ± 11.03 | 0.027 | -10.224 | -0.781 |
| | P value 0 vs 1** | < 0.001 | < 0.001 | - | - | - |
| | P value 0 vs 2** | < 0.001 | 0.517 | - | - | - |
| | P value 1 vs 2** | < 0.001 | 0.085 | - | - | - |
| Lateral bending | Before injection (0) | 20.72 ± 5.93 | 22.66 ± 4.75 | 0.167 | -4.709 | 0.836 |
| | After injection (1) | 24.38 ± 5.86 | 22.48 ± 3.40 | 0.133 | -0.595 | 4.379 |
| | 12 weeks later (2) | 23.81 ± 4.61 | 22.07 ± 2.75 | 0.082 | -0.227 | 3.714 |
| | P value 0 vs 1** | < 0.001 | 0.794 | - | - | - |
| | P value 0 vs 2** | < 0.001 | 0.429 | - | - | - |
| | P value 1 vs 2** | 0.226 | 0.301 | - | - | - |

* p values were calculated using Student t test, except for the sex, where Fisher Exact test was used.

** p values for paired data was calculated using paired t test, to compare the baseline values (0) with either immediate post-injection (1) or 12 weeks later (2) values.

associated with younger age, shorter disease duration, and the presence of BME. Regarding the total SPARCC score, it was negatively correlated with the disease duration among the SIJ injection group, which means that early cases would show greater improvement than the long-standing ones (Table 3).

Regarding the treatment given for the study population, all the cases were receiving biological DMARDs in the form of anti-IL-17, namely Secukinumab (Coentyx, NOVARTIS) (44 cases: 72.1%) or anti TNF-α including Etanercept (Enbrel, Pfizer), Adalimumab (Humira, AbbVie or Golimumab (Simponi, Janssen) in the remaining 17 cases (27.9%). There were non-significant differences between the cases regarding the outcome between those who received anti IL-17 and those who received anti TNF-α (data not shown).

Hip involvement was found in around 21% of the participants (13 cases; 5 among group I and 8 among group II). Among these cases, 5 patients showed bilateral hip involvement, and 8 showed unilateral hip involvement (5 right and 3 left). We found that poorer response was found among cases with hip involvement compared to those without, and among cases with bilateral hip compared to those with unilateral hip involvement. However, all these findings showed non-significant due to the limited number.

***Table 2. Percentage of improvement of the different scales of the study groups***

| Percentage of improvement compared to the baseline score | | Group I (N = 32) | Group II (N = 29) | P value* |
|---|---|---|---|---|
| VAS | Immediate | 54.59 ± 6.07 | 12.29 ± 15.90 | < 0.001 |
| | 12 weeks later | 37.53 ± 16.11 | 9.22 ± 9.41 | < 0.001 |
| ASDAS | 12 weeks later | 46.79 ± 9.85 | 6.71 ± 2.38 | < 0.001 |
| BASFI | 12 weeks later | 6.45 ± 7.98 | 2.28 ± 7.50 | 0.040 |
| ODI | 12 weeks later | 55.31 ± 25.95 | 10.06 ± 35.48 | < 0.001 |
| SPARCC (BM edema) | 12 weeks later | 53.38 ± 27.69 | 10.19 ± 16.54 | < 0.001 |
| SPARCC (fat) | 12 weeks later | 9.64 ± 15.78 | -18.00 ± 16.8 | < 0.001 |
| SPARCC (erosions) | 12 weeks later | -3.63 ± 9.24 | -22.03 ± 27.37 | 0.003 |
| SPARCC (total) | 12 weeks later | 41.23 ± 21.83 | 1.45 ± 4.05 | < 0.001 |
| Finger to floor | Immediate | 39.42 ± 10.79 | 6.75 ± 11.48 | < 0.001 |
| | 12 weeks later | 30.05 ± 12.15 | 1.37 ± 13.48 | < 0.001 |
| Lateral bending | Immediate | 14.15 ± 18.96 | -0.97 ± 15.79 | 0.001 |
| | 12 weeks later | 13.02 ± 18.57 | -2.69 ± 17.58 | 0.001 |

***Table 3. Correlation between the disease duration and the percentage of improvement of the different scales of the study groups***

| Percentage of improvement compared to the baseline score | | Group I (N = 32) | | Group II (N = 29) | |
|---|---|---|---|---|---|
| | | R | P | R | P |
| VAS | Immediate | -0.075 | 0.048 | 0.081 | 0.676 |
| | 12 weeks later | -0.028 | 0.880 | 0.012 | 0.950 |
| ASDAS | 12 weeks later | 0.051 | 0.781 | -0.040 | 0.839 |
| BASFI | 12 weeks later | 0.186 | 0.306 | 0.175 | 0.365 |
| ODI | 12 weeks later | 0.184 | 0.312 | 0.012 | 0.950 |
| SPARCC (BM edema) | 12 weeks later | -0.187 | 0.306 | 0.068 | 0.725 |
| SPARCC (fat) | 12 weeks later | -0.170 | 0.351 | 0.108 | 0.577 |
| SPARCC (erosions) | 12 weeks later | 0.175 | 0.356 | 0.494 | 0.090 |
| SPARCC (total) | 12 weeks later | -0.322 | 0.042 | 0.036 | 0.853 |
| Finger to floor | Immediate | 0.007 | 0.968 | 0.059 | 0.761 |
| | 12 weeks later | 0.187 | 0.305 | -0.042 | 0.829 |
| Lateral bending | Immediate | -0.086 | 0.641 | -0.188 | 0.329 |
| | 12 weeks later | -0.015 | 0.936 | -0.078 | 0.688 |

R: Pearson Correlation Coefficient, P: P value

This table shows that the immediate improvement of VAS and the improvement of SPARCC score (total score) were negatively correlated with the disease duration among the SIJ injection group, which means that early cases would show higher improvement compared to long standing ones.

### *Adverse events*

Complications of injection in the active group included injection site pain in 2 cases: headache and flushing in one case. No complications were recorded in the control group, as the injection time was shorter, and the needle advancement was for only few centimeters.

## Discussion

SIJ injection of different injectants in axial SpA patients was tried but without a thorough assessment via a well-designed randomized clinical trial. Steroid injection was considered more practical due to the cost-benefit. There was a great debate about its value, whether it can only improve pain, or whether its effect can extend to improve function, disease outcome measures, and BME.

In this randomized clinical trial, SIJ injection was able to ameliorate pain, mobility, disease activity scores, and BME with significant differences from the control group and improved fat, erosions, and BASFI scores with non-significant differences. Of note, that improvement was more in earlier disease, younger age, and shorter disease duration and in more active disease. Participants with bilateral hip arthritis showed the least improvement in all parameters. Spine mobility showed the best improvement followed by pain then ASDAS, BME, and finally BASFI score.

BASFI showed the least and non-significant improvement because it comprises cervical mobility and it is not expected to improve with SIJ injection. In a previous study, we used ODI to assess function instead of BASFI, and it showed improvement in axial SpA patients after epidural block [21]. We decided to deploy BASFI instead because parallel studies used it. Soliman et al. recorded similar results when they injected infliximab in the SIJ [22].

Lumbar spine mobility showed the earliest improvement immediately after injection and continued for three months and the difference was significant at all three follow-up points in comparison to the control group. In comparison to our results, Hanly et al. stated that improvement in spine mobility persisted for three months and declined to the baseline level after six months. Further, the difference between the control and the active group did not reach a significant level. They did not use ASAS criteria for diagnosis. Instead, they considered radiographic sacroiliitis. The mean disease duration for the participants was much longer than in our study. Finally, the number of participants in that study was much limited. All these differences might explain the variance in the results [23].

Pain showed less significant improvement immediately after injection, but the improvement was more significant after three months. In another study, long-acting steroid preparations needed 1-15 days to improve pain and reached the peak after one month and this effect persisted for six months [24].

BASMI was not used in the present study since cervical mobility was not expected to ameliorate with SIJ injection, and this would negatively affect the study results. It was replaced by Schober's, lateral bending, and fingertip-to-floor tests to yield more accurate results that display the modifications in lumbar spine mobility.

To the best of our knowledge, this is the first study to investigate the impact of steroid injection along with lidocaine on BME in axial SpA patients. Most of the previous literature tested the impact on pain and function without considering MRI scores. In our study participants in the active group achieved a significant reduction in SPARCC after three months. This improvement was inversely related to disease duration and was related to ASDAS score at baseline. This improvement was faster than infliximab which required nearly six months [22]. In another study by Yang Cui et al., the SPARCC score showed a significant reduction under anti-TNF therapy. MRI follow-up was performed within 12 months. The reduction in the score was significant after three months and persisted for 12 months. Improvement in ASDAS was related to the SPARCC score [25].

SIJ injections can be performed by variable approaches. Although CT, MRI, and Fluoroscopic-guided injection are more accurate, the cost is much higher besides the radiation exposure and the longer time of the procedure. Several literatures stated the difference between these approaches and US-guided SIJ injection is non-significant. [26-30].

### *Limitations of the study*

The number of study participants is limited. This can be attributed to the fact that some participants consider injections as an invasive maneuver and refuse to accept them, or they do not adhere to the follow-up time schedule. In addition, it would be better if the follow-up would extend to six months, but this will lead to more drop-out, and it would be unethical to hold the medication unchanged in active patients for more than three months.

## Conclusion

US-guided steroid and lidocaine injection of the SIJ injection is potent in alleviating pain, mobility, disease activity, and MRI scores in axial SpA patients. Pain achieved the best amelioration and spine mobility had the longest survival. This effect is more remarkable with early disease, shorter duration, and younger patients and with higher ASDAS scores. Further future studies are merited to determine the ideal timing

of injection and the most suitable disease pattern that can benefit best from the SIJ injection.

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