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# Ultrasound-Guided Injection of Low Molecular Weight Hyaluronic Acid *versus* Steroid for Inflammatory and Degenerative Sacroiliitis: a Single-Blinded Randomized Controlled Trial

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## SUMMARY

**Background.** Sacroiliitis may be degenerative (DSI) or inflammatory (ISI) and the latter is a clinical manifestation of spondyloarthropathies.

**Objective.** To determine the effect of hyaluronic acid *versus* corticosteroid injection for chronic sacroiliac joint arthropathy.

**Methods.** Forty patients with sacroiliitis either degenerative (DSI: 20 patients) or inflammatory (ISI: 20 patients) based on the New York criteria. Each group was allocated into 2 subgroups; 10 patients received 2 ml betamethasone dipropionate plus 2 ml lidocaine 2% (A) and 10 patients received 2 ml hyaluronic acid plus 2 ml lidocaine 2% (B). All sacroiliac joint injections were done under ultrasonographic guidance using a 22-gauge needle. Visual analogue scale (VAS) was used for pain assessment at base line, 1-, 2- and 4-week post injection.

**Results.** No significant difference was observed between main groups (ISI and DSI) regarding VAS score before injection, 1-, 2- and 4-weeks post injection while a significant difference observed between subgroups A and B in ISI group at 2 and 4 weeks ($p = 0.012$ and 0.008, respectively). Also, there was a significant difference between subgroups A and B in DSI group at 1-, 2- and 4-weeks post injection ($p = 0.04$, 0.006 and 0.005, respectively). High significant difference before and after injection in the main groups and all subgroups was recorded. However, there was no significant difference between the subgroups of ISI and DSI.

**Conclusions.** Both steroid and hyaluronic acid were effective in relieving pain in treatment of inflammatory and degenerative sacroiliitis, but steroid was more efficacious than the hyaluronic acid.

**Study registration.** The trial registration number is PACTR202111473947054 (www.pactr.org).

## KEY WORDS

*Sacroiliitis; steroid injection; hyaluronic acid injection; ultrasound; back pain.*

## INTRODUCTION

The sacroiliac joint (SIJ) is a diarthrodial joint that's been linked to discomfort in 10% to 25% of persons suffering from low back or leg pain (1).

The SIJ provides support, stability, and a mechanism for elasticity to the pelvis (2). SIJ dysfunction can be caused by capsular or synovial distortion, ligamentous tension, abnormal joint motion and stress, microfracture, or myofascial kinetic chain interruption. Pathology can be classified as intra- or extra-articular. Infection, inflammation, and degenerative or inflammatory arthritis are all frequent types of intra-articular pathologies (3).

SIJ pain is reported in at least 2-3% of patients with failed back surgery (4). However, this type of pain may have been present before surgery but passed underestimated (5).

SIJ inflammation is a hall mark for the diagnosis of axial spondyloarthritis (AxSpA) either non-radiographic AxSpA when the inflammation is only detected by magnetic resonance

imaging (MRI) or radiographic when the structural changes could be depicted by conventional radiography (non-radiographic AxSpA previously known as ankylosing spondylitis) (6, 7). Whatever the cause of sacroiliitis, the patient describes severe, excruciating pain in the buttocks and/or pelvis, as well as posterolateral on the thighs, that may spread along one or both limbs. The ache is usually unilateral, in the inferior to posterior superior iliac spine and above the knee, with numbness, tingling, and weakening. The severity of the ache worsens with standing, sitting, and ascending steps or slopes. The patients usually have bad sleeping habits (8).

Individual pain provocation tests such as the Flexion abduction external rotation (FABER) test, Thigh thrust test, Gaenslen test, Mennell's test, Sacral thrust test, compression test, and distraction test appear to have adequate diagnostic value. Using of more than one test provide a high level of reliability in distinguishing sacroiliitis from low back pain (9).

Interventional treatment of SIJ dysfunction has long been previously reported with proven yet short term efficacy of long-acting steroids (10).

It was established that using sonographic guidance to perform SIJ injections might be a useful option. When compared to fluoroscopy, ultrasonography (US) offers several advantages. In addition to the safety of US, processes may be performed at outpatient with more easiness and lower cost (11, 12).

Although intra-articular steroid injection has long been previously reported, its usage may be contraindicated for many patients. The objective of this study was to compare the efficacy of low molecular weight hyaluronic acid (HA) versus steroid injection for treatment of AxSpA-related and degenerative sacroiliac joint arthropathy.

## PATIENTS AND METHODS

It this randomized controlled trial, forty patients were diagnosed as having sacroiliitis either inflammatory (AxSpA-related) based on the modified New York (NY) criteria (13) or degenerative (radiographic diagnosis) that attending the outpatient clinic of Rheumatology and Rehabilitation Department, Al-Aazhar University Hospital, Assuit from 1 January 2020 to 1 October 2021.

After explanation of the study procedure, each participant provided an informed permission.

According to the cause of sacroiliitis, patients were then classified into two main groups; Group I (20 patients with inflammatory sacroiliitis - ISI) and Group II (20 patients with degenerative sacroiliitis - DSI).

Based on a computerized randomization table, both groups were allocated into 2 subgroups:

(A) 10 patients received 2 ml of betamethasone dipropionate plus 2 ml of 2% lidocaine intra-articular US-guided injection.

(B) 10 patients received 2 ml of hyaluronic acid plus 2 ml of 2% lidocaine intra-articular US-guided injection.

This study was approved by the local Ethical Committee of our institution on January 21, 2021, and it conforms with the declaration of Helsinki for human experimentations.

All patients were subjected to general examination, spine, neurological, sacroiliac joint examination provocative tests, laboratory investigation (included complete blood count (CBC), rheumatoid factor (RF), erythrocyte sedimentation rate (ESR: mm/hr) and C reactive protein (CRP: mg/dl)) and imaging (included Plain X ray on sacroiliac joint and lumbosacral spine).

### Interventional procedure

Under aseptic conditions, sacroiliac joint injection was performed with ultrasound guidance (TOSHIBA xario 200, Tokyo, Japan). The transducer was placed in a transverse orientation at the region of the sacral hiatus while the subject was prone, and the sacral cornuate were detected. Then, by sliding the transducer laterally, the lateral border of the sacrum was recognized, and a second bony contour, the ileum, was found by following this bony margin in a cephalic manner. As previously stated, the SIJ was seen as a hypoechoic cleft region between the two echogenic lines of the sacrum and iliac bone (11).

Tilting the transducer in a caudal position indicated the posterior caudate SIJ, the region of the joint into which the injection was conducted. Following the injection of lidocaine local anaesthetic, a 22-gauge cutting-edge spinal needle was inserted into the joint. When the needle tip was inserted into the joint area, a combination of lidocaine and betamethasone dipropionate or hyaluronic acid and lidocaine was injected as shown in **figure 1**.

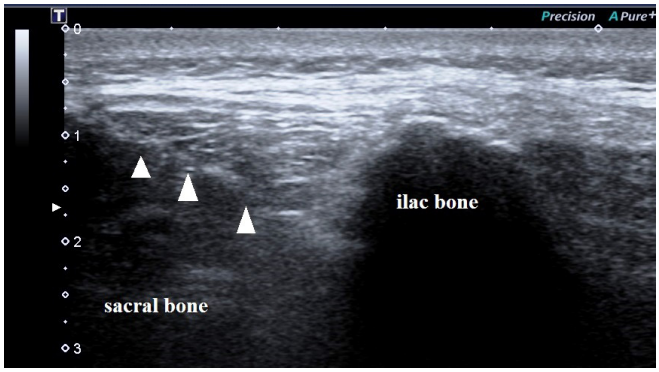


**Figure 1.** Ultrasonogrpahic guided local injection into the sacroiliac joint in a male patient with inflammatory sacroiliitis on top of radiographic axial spondyloarthritis.
Arrow heads refer to the needle.

The severity of pain was assessed using a Visual Analogue Scale (VAS) at 0 (before injection), 1, 2, and 4 weeks following the injection (Score range = 0 to 10; 4 for mild, 4-6 for moderate, and more than 6 for severe pain).

### Statistical analysis

The collected data organized, tabulated and statistically analyzed using statistical package for social sciences (SPSS) version 22 (SPSS Inc, Chicago, USA). For qualitative data, frequency and percent distributions were calculated. For quantitative data, mean, standard Error (SE), minimum and maximum were calculated. Statistical significance was defined as P-value < 0.05. The following tests were used: chi-square test, Student t-test, ANOVA and Man-Whitney test whenever appropriate.

## RESULTS

A total of forty patients with sacroiliitis who divided into two groups and two subgroups were enrolled in this study. Mean of age in group I was 45.3 ± 7.72 and ranged from 32 to 57 years and in group II was 56.5 ± 8.25 and ranged from 43 to 68 years. The majority of patients were males in both groups 80% and 85%, respectively. Non-significant difference was observed between the studied groups as regard demographic data. Regarding history in group 1 and 2, mean duration of the disease was 5.45 ± 3.41 and 7.95 ± 3.85 years without significant difference. However, there was a significant difference between the studied groups as regard the current treatment ($p < 0.001$) (**table I**).

Considering VAS score, there was no significant difference between main groups I and II regarding VAS score before injection, 1-, 2- and 4-weeks post injection while a significant difference between subgroups A and B in group I was recorded regarding VAS score at 2 and 4 weeks after injection. Also, there was a significant difference between subgroups A and B in group II regarding VAS score at 1, 2 and 4 weeks after injection. There was a high significant difference before and after injection in the main groups and all subgroups. However, there was no significant difference between subgroups I (A) and II (A) and I (B) and II (B) (**table II**).

## DISCUSSION

Whatever the cause of SIJ dysfunction, the resulting sacroiliitis is mostly treated conservatively with nonsteroidal anti-inflammatory medications and physiotherapy as manipulation techniques (14, 15). However, in severe cases local injection of various substances into the joints leads to rapid relieve of pain and dysfunction (16).

As many other regional pain syndromes, local therapy of the SI joints with intra-articular corticosteroid injection, offers significant therapeutic benefit. Various studies have been conducted to explore the indications, therapeutic response, and outcomes of intraarticular and soft tissue injection (9, 17-19).

However, long-acting steroid is contraindicated in many medical comorbid conditions and in such instances, low molecular weight HA resembles a good alternative that has been stated to exert pain relieving effects through its anti-inflammatory properties in many soft tissue and degenerative conditions (20-24).

To the best of our knowledge, this is the first study to compare the effect of HA and long-acting steroid in both inflammatory and degenerative sacroiliitis.

In our results, a non-significant difference was observed between the main groups I and II as regards VAS score. However, a high significant difference between VAS score before and after injection was recorded.

Also, we found a significant difference between subgroups A and B in group I regarding VAS score at 2- and 4-weeks post injection. Also, there was significant difference between subgroups A and B in group II regarding VAS score at 1-, 2- and 4-weeks post injection. High significant difference before and after injection in all subgroups was recorded. However, there was no significant difference between subgroups I (A) and II (A) and I (B) and II (B).

In consistence with our results, Srejic *et al.* (22) reported that pain was found to be 40-67% better at twelve to sixteen weeks following the injections as evaluated on a visual analogue scale. The longevity of HA positive impact on arthralgia and joint function was not identified. However, their study was a pilot one included only four cases.

Scale *et al.* (20) in their study on the knee osteoarthritis, demonstrated that when HA injection groups were compared to control groups, the two-injection and three-injection HA treated group both showed statistically significant better results for pain outcome as well as overall treatment assessment at the twelve-weeks assessment. At the twelve-weeks assessment, the three-injection group improved statistically considerably more than the two-injection group on all outcomes. At the six-month follow-up, both HA therapy groups outperformed the control group in terms of lowering weight-bearing discomfort and nocturnal pain and recovering joint function.

Many other studies compared the effect of other interventional treatments with local steroid for treatment of sacroiliitis. Dutta *et al.* (25) reported that percutaneous radio-frequency ablation is more effective than intraarticular methylprednisolone injection for SIJ Pain in selected patients with similar demographics.

**Table I.** Comparison between the studied groups regarding the demographic, laboratory data and medical treatment.

| | Group I (n = 20) | | Group II (n = 20) | | Test | p |
|---|---|---|---|---|---|---|
| **Age (years)** | | | | | | |
| Range | 32-57 | | 43-68 | | t = 4.433 | < 0.001* |
| Mean ± SD | 45.3 ± 7.72 | | 56.5 ± 8.25 | | | |
| **Sex** | | | | | | |
| Male | 16 (80.0%) | | 17 (85.0%) | | $\chi^2$ = 0.173 | 0.677 |
| Female | 4 (20.0%) | | 3 (15.0%) | | | |
| **Duration of disease (years)** | | | | | | |
| Range | 1-14 | | 3-15 | | t = 0.712 | 0.481 |
| Mean ± SD | 5.45 ± 3.41 | | 7.95 ± 3.85 | | | |
| **ESR before injection** | | | | | | |
| Range | 31-55 | | 5-22 | | 15.245 | < 0.001* |
| Mean ± SD | 45.85 ± 7.55 | | 14.05 ± 5.48 | | | |
| **ESR 4 weeks after** | | | | | | |
| Range | 27-55 | | 2-20 | | 13.845 | < 0.001* |
| Mean ± SD | 41.9 ± 8.35 | | 11.05 ± 5.43 | | | |
| t1 (p1) | 6.440 (< 0.001*) | | 16.882 (< 0.001*) | | | |
| **CRP before injection** | | | | | | |
| Range | 0-23 | | 0-9 | | 163.5 | 0.327 |
| Median (IQR) | 4 (0.75-17.25) | | 3.5 (0.5-6) | | | |
| **CRP 4 weeks after** | | | | | | |
| Range | 0-23 | | 0-7 | | 167.0 | 0.383 |
| Median (IQR) | 3 (0-16.25) | | 3 (0.5-4.75) | | | |
| z (p1) | 2.807 (0.005) | | 1.334 (0.182) | | | |
| **Current treatment** | **o.** | **%** | **o.** | **%** | | |
| NSAIDs | 6 | 30.0 | 20 | 100.0 | $\chi^2$ = 21.538 | < 0.001* |
| DMARDs | 0 | 50.0 | 0 | 0.0 | | |
| Combinations | 4 | 20.0 | 0 | 0.0 | | |

t: Student t-test; $\chi^2$: chi square test; U: Mann-Whitney test; z: Wilcoxon-test; NSAIDs: Non-Steroidal Anti-Inflammatory Drugs; DMARDs: Disease Modifying Anti-Rheumatic Drugs; p: P-value for comparing between different categories; $p_1$: P-value for comparing between different periods; *statistically significant at $p \leq 0.05$.

**Table II.** Comparison between main groups and subgroups as regard VAS score at baseline and follow up points.

| VAS score | Group I | | p | Group II | | $p_1$ | $p_2$ | $p_3$ | $p_4$ |
|---|---|---|---|---|---|---|---|---|---|
| | Group A (n = 10) | Group B (n = 10) | | Group A (n = 10) | Group B (n = 10) | | | | |
| **Before injection** | | | | | | | | | |
| Range | 3-10 | 6-10 | 0.088 | 3-10 | 3-9 | 0.804 | 0.114 | 0.624 | 0.038 |
| Mean ± SD | 7.3 ± 2.16 | 8.7 ± 1.16 | | 6.7 ± 3.13 | 7 ± 2.11 | | | | |
| **1 week after** | | | | | | | | | |
| Range | 2-9 | 5-10 | 0.054 | 2-10 | 5-9 | 0.044* | 0.553 | 0.533 | 0.862 |
| Mean ± SD | 6.4 ± 2.27 | 8.1 ± 1.29 | | 5.6 ± 3.27 | 8 ± 1.25 | | | | |

| VAS score | Group I | | p | Group II | | $p_1$ | $p_2$ | $p_3$ | $p_4$ |
|---|---|---|---|---|---|---|---|---|---|
| | Group A (n = 10) | Group B (n = 10) | | Group A (n = 10) | Group B (n = 10) | | | | |
| **2 weeks after** | | | | | | | | | |
| Range | 0-9 | 5-10 | 0.012* | 0-8 | 5-9 | 0.006* | 0.428 | 0.481 | 0.478 |
| Mean ± SD | 5.3 ± 2.63 | 7.9 ± 1.29 | | 4.4 ± 2.95 | 7.5 ± 1.18 | | | | |
| **4 weeks after** | | | | | | | | | |
| Range | 0-7 | 3-8 | 0.008* | 0-6 | 3-8 | 0.005* | 0.233 | 0.317 | 0.286 |
| Mean ± SD | 4.4 ± 2.07 | 6.8 ± 1.48 | | 3.4 ± 2.27 | 6.1 ± 1.37 | | | | |
| ($p_1$) | 15.968 (< 0.001*) | 12.572 (< 0.001*) | | 15.347 (< 0.001*) | 29.477 (< 0.001*) | | | | |

F: repeated measures ANOVA; VAS: visual analogue scale; p: P-value for comparing between subgroups A and B; $p_1$: P-value for comparing between different periods; $p_2$: P-value for comparing between main group 1 and 2; p3: P-value for comparing between subgroup A and A; p4: P-value for comparing between subgroup B and B; *statistically significant at $p \leq 0.05$.

Soliman *et al.* (26) compared the effect of steroid and platelet rich plasma (PRP) and found that both were effective in relieving pain and improving function and disability in treatment of sacroiliitis by ultrasound guided injection, but PRP was more efficacious than the steroid with longer lasting effect. On the other hand, Kim *et al.* (27) compared intra-articular concentrated dextrose prolotherapy to intra-articular corticosteroid for sacroiliac joint dysfunction and found that dextrose injections led to prominent analgesic effect compared to corticosteroid.

Although this study provided preliminary evidence on the effectiveness of HA for treatment of both inflammatory and degenerative sacroiliitis, it has some limitations; first the small sample size especially with subgrouping of our patients leads to decreasing the power and raise the possibility of the type II error. Given the rarity of the sacroiliac joint dysfunction and inflammation, this limitation could be overcome through a multicentric approach. Second, the gender difference couldn't be evaluated due to the small proportion of female patients in both groups. Third, the quality of life (QoL) improvement was not evaluated. Although there is no specific questionnaire for evaluation of QoL in patients with sacroiliitis, the brief pain inventory (BPI) and "the Euro QoL 5-D" have been previously applicated (28, 29). Forth, in some instances the low back pain caused by sacroiliac joint dysfunction can be caused by spinal radiculopathy resulting from lumbo-sacral spondylosis which may bias our selection of patients especially in the group with degenerative sacroiliitis. Lastly, the short term follow up is another limitation and more large-scale studies with longer follow up periods are needed to support our results.

## CONCLUSIONS

Low molecular weight hyaluronic acid is a good alternative for steroid for treatment of inflammatory and degenerative sacroiliitis. Hyaluronic acid was more efficacious in degenerative than inflammatory sacroiliitis while steroid is equal in efficacy in both conditions.

## FUNDINGS

None.

## DATA AVAILABILITY

Data are available under reasonable request to the corresponding author.

## CONTRIBUTIONS

MA, AM: conceptualization, methodology. KH: data curation, visualization, investigation, draft writing. All authors: revision and validation.

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## CONFLICT OF INTERESTS

The authors declare that they have no conflict of interests.

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