ORIGINAL ARTICLE

Comparative Functional Outcome Study for Ultrasound Guided Sacroiliac Joint Injection Methylprednisolone versus Prolotherapy for Sacroiliac Joint Pain Relief

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Abstract

Background: ***Prolotherapy is a novel and economical therapeutic approach for chronic musculoskeletal pain disorders, including osteoarthritis of the knee. Corticosteroids have been fundamental in the management of sacroiliac joint (SIJ) arthropathy due to their anti-inflammatory and immunosuppressive properties.***

Aim of this work: ***To assess the efficiency and long-term effectiveness of periarticular prolotherapy in alleviating SIJ pain, contrasted with periarticular steroid injections.***

Patients and Methods: ***This prospective, randomised, single blind and controlled work was conducted on 80 patients aged > 21 years old, both sexes, with SIJ pain. Subjects had been assigned into two groups equally: group S received ultrasound-guided periarticular steroid injection (40 mg methyl prednisolone added to 6 ml Bupivacaine 0.5% and 9 ml isotonic saline 0.9 %), group P received ultrasound-guided periarticular dextrose 15% in 15 ml (6 ml Bupivacaine 0.5% and 9 ml dextrose 25%).***

Results: ***Numerical rating scale and Kurosawa scoring system were insignificantly different between pretreatments and weeks after treatment between the two groups and were significantly reduced at 3weeks and 5weeks after treatment in group P than group S (P<0.05). Heart rate and mean arterial blood pressure were insignificantly different between the two groups. Patient satisfaction was insignificantly different between the two groups.***

Conclusions: ***Sacroiliac joint pain is responsible for more than 50 % of low back pain, found mainly in females with high BMI. In patients with SIJ pain, periarticular injection of prolotherapy was more effective in pain relief than periarticular steroid injection, especially in long-term effectiveness, financial cost and fewer side effects.***

Keywords: Ultrasound; Sacroiliac Joint; Methylprednisolone; Prolotherapy

1. Introduction

Low back pain (LBP) is one of the most prevalent health issues, with a global point prevalence of 9.4%, an annual prevalence of 38%, and representing fifty percent of years lived with disability attributable to musculoskeletal disorders globally. Chronic LBP (CLBP) is a multifaceted biopsychosocial disorder characterized by recurring backache, with or without identifiable pathology, resulting in persistent pain, physical impairment, social withdrawal, and/or alterations in mood .[1]

Pain in the sacroiliac joint (SIJ) is often incorrectly diagnosed due to the prevalence of functional conditions (SIJ syndrome or dysfunction) associated with it, leading to insufficient specific imaging. Regarding the criteria established by the International Association for the Study of Pain (IASP), SIJ pain is characterized by discomfort in the SIJ region, which must be reproducible through particular pain provocation tests and entirely alleviated by intra-articular SIJ injections of local anaesthetics .[2]

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SIJ is a substantial, irregularly shaped, serpentine structure delineated both posteriorly and anteriorly by the sacroiliac ligaments. The joint comprises about one-third synovial tissue and two-thirds fibrous or ligamentous tissue, with the synovial component extending antero-inferiorly and supported at its posterior superior region by ligaments .[3]

The SIJ complex is integral to the kinetic chain between the spine and lower limbs, potentially serving as a main or secondary source of pain according on the clinical context, and ought to be regularly assessed in the examination of back or leg issues .[4]

The aetiology of SIJ pain may be categorised into two primary types: traumatic and atraumatic. Traumatic incidents often include abrupt occurrences, including vehicular accidents, falls, and injuries resulting from lifting or twisting .[5]

Corticosteroids are fundamental in the management of SIJ arthropathy due to their anti-inflammatory and immunosuppressive properties .[6] Prolotherapy is a novel and economical therapeutic alternative for chronic musculoskeletal pain problems, such as osteoarthritis of the knee .[7]

We proposed pathways for pain alleviation, comprising the enhancement of local healing in chronically wounded extra-and intra-articular tissues, the mitigation of joint instability via strengthening of elongated or ruptured ligaments, and the promotion of cellular proliferation .[8]

The aim of this work was to assess the efficiency and long-term effectiveness of periarticular prolotherapy in alleviating SIJ pain, contrasted with periarticular steroid injections.

2. Patients and methods

This prospective, randomised single blind and controlled work had been conducted on 80 individuals aged > 21 years old, both sexes, with failed medical treatment for one-month, SIJ pain confirmed with diagnostic local anesthesia (LA) injection and at least 50% improvement after injection. The work had been conducted following approval from the Ethics Committee Al-Azhar University Hospitals, Cairo, Egypt. Each participant provided written informed consent.

Criteria of exclusion had been individuals with a history of lumbar disc herniation, infection, tumors in the pelvic, and lumbar areas, recent fractures in the lumbar spine, pelvis, ankylosing spondylitis, spinal canal stenosis, fibromyalgia, uncontrolled hypertension or diabetes, coagulation, bleeding abnormalities, drug dependence, psychiatric disorders, pre-existing lower extremity neurological abnormality and hypersensitivity to drugs used in the study.

Randomization and blindness

Participants had been assigned at random to receive peri-articular steroid or peri-articular prolotherapy injections depending on a computer-generated randomization schedule. Subjects had been assigned into two groups equally: Group S (corticosteroid group), ultrasound-guided periarticular steroid injection (40 mg methyl prednisolone) mixed with LA (Bupivacaine 0.5%) in 15 ml total volume (6 ml Bupivacaine 0.5% mixed with 9 ml isotonic saline 0.9 %) and Group P (Prolotherapy group), received ultrasound-guided periarticular dextrose (15%) mixed with LA (Bupivacaine 0.5%) in 15 ml total volume (6 ml Bupivacaine 0.5% mixed with 9 ml dextrose 25 %).

All patients were subjected to a full history taking, clinical examinations, laboratory tests [full blood picture (CBC), prothrombin time (PT) and activity] and radiological investigations [electrocardiogram (ECG)]

Patients received local infiltration, using a lidocaine 2% (Debocaine 2%) within the site of puncture, mainly subcutaneous.

Technique of sacroiliac joint periarticular injection

The patient is positioned prone with a cushion under the abdomen to reduce lumbar lordosis. A low-frequency curvilinear transducer (2-5 MHz) is frequently utilised, particularly in obese individuals, to enhance penetration. The transducer is positioned transversely across the posterior superior iliac spine and then moved medially and inferiorly until the cleavage between the ileum and the lateral sacral border is visible. The fissure seen between the medial border of the ileum and the lateral sacral margin signifies the SIJ. Following sterilisation, a 20-gauge needle is inserted at the medial end of the transducer and progressed laterally under direct visualisation in alignment with the ultrasonic beam. We spread the solution in the three zones within the periarticular region to apply it to the posterior short sacroiliac, posterior long sacroiliac and sacrotuberous ligaments. Figure 1

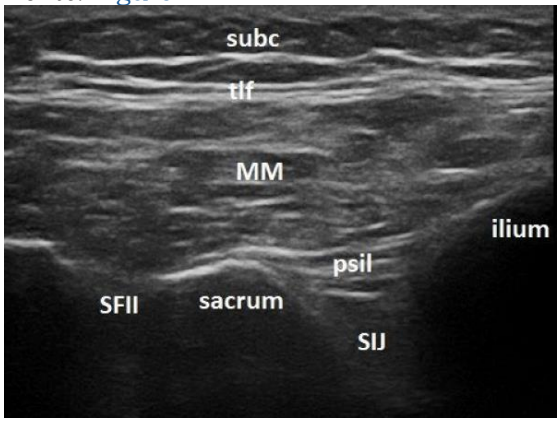

Figure 1: Short-axis sonogram showing (SIJ –

sacroiliac joint; SFII – second sacral foramen; psil – posterior sacroiliac ligament; MM -multifidus muscle; tlf -thoracolumbar fascia; subc – subcutaneous tissue) [9]

In the prolotherapy group, we administered 15 mL of a 15% dextrose solution into the SIJ biweekly, with a maximum of three injections. If the patient's manifestations increased to above 90% on the numerical rating scale (NRS) during the second or third visit, the subsequent surgery was annulled. A comparable treatment regimen was used in the steroid cohort.

The equipment utilised involved sterile towels and gauze packs, 5 mL syringes containing local anaesthetic, a 20-gauge needle, 5 mL of 2% lidocaine, gel, sterile gloves, and a marking pen, 20 ml syringe with 15 ml dextrose 15% with half volume bupivacaine 0.5%, 20 ml syringe contains bupivacaine 0.5 % with betamethasone 40 mg in total volume 15 ml (isotonic saline 0.9% and bupivacaine 0.5%), ultrasonic machine (Sonoscape® SSI-6000) and a 2-5 MHz curvilinear type probe.

Measured parameters

Pain score: using a numerical verbal pain score pre and post injection, starting from zero (no pain) to ten (maximum intensity of pain), measured after 15 min with a diagnostic test and in the next visit (every other week) with the prolotherapy or steroid injection. Kurosawa Scoring System: One-finger test: Ask the patients to indicate the main side of pain by utilising their index finger. When the patient points to the posterior superior iliac spine (PSIS) or within 2 cm of it as the main site of pain =3 Points. Groin pain is any radiating pain into the groin region before and still or absent after injection =2 points. Pain-increasing position: sitting on a chair without a backrest can provoke or increase the intensity of SIJ pain =1 point. Provocation test (shear test): The SIJ shear test is the most effective provocation test. It involves the patient lying in a prone position on an examination table. The examiner positions his palm over the patient's posterior iliac wing and exerts an inferior thrust to generate a shearing force across the sacroiliac joint (SIJ). A positive result is indicated if the patient reports pain similar to that previously experienced, earning 1 point. Posterior superior iliac spine tenderness: By examination, there is tenderness located at the PSIS =1point. Sacrotuberous ligament tenderness: there's pain and tenderness located at the site and course of the sacrotuberous ligament =1 point. These scores were recorded pre- and post-injection (every single injection) into a schedule and used for assessment of the success rate of injection and patient satisfaction.

Assessment of success rate of injection and patient satisfaction, one finger test (score 3), pain in groin (score 2), pain while sitting on a chair, SIJ shear test, PSIS and STL tenderness (everyone had score 1) and total score was 9.

The primary outcome was effectiveness of prolotherapy compared with steroid in reliving SIJ pain (within every other week time interval up to 5 weeks using NAS score and Kurosawa SIL pain score). The secondary outcomes were disability of SIJ and side effects of steroids.

Statistical analysis

Statistical analysis was performed using SPSS v26 (IBM Inc., Chicago, IL, USA). The Shapiro-Wilks test and histograms were utilised to assess the normality of data distribution. Quantitative parametric variables had been displayed as mean and standard deviation (SD) and contrasted between the two groups using the unpaired Student's T-test. Quantitative non-parametric data were displayed as median and interquartile range (IQR) and analyzed using the Mann-Whitney test. Qualitative parameters were displayed as frequencies and percentages (%) and analysed using the Chi-square test. A two-tailed P value < 0.05 was considered statistically significant.

3. Results

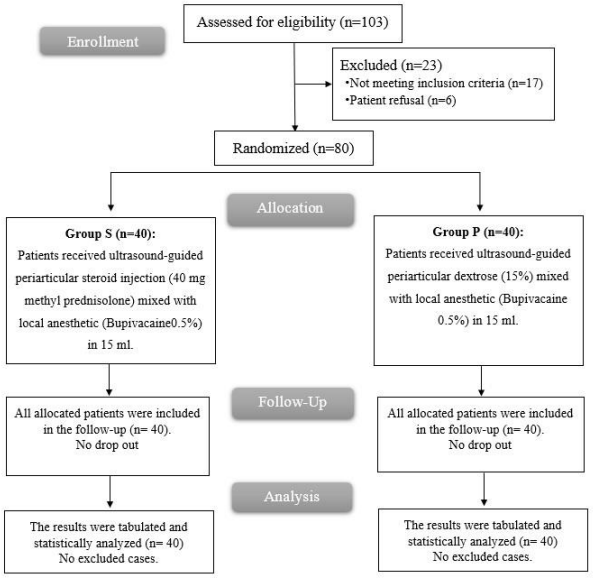

Figure 2. CONSORT flowchart of the enrolled patients

One hundred and three individuals had been assessed for eligibility, 17 individuals didn't fulfill the criteria, and 6 individuals refused to take apart in the study. The remaining individuals were assigned at random to two equal groups, each consisting of 40 participants. All participants were then monitored and subjected to statistical analysis. Figure 2

Table 1. Demographic data of patients with LBP

	N=200
SIJD AS THE PRIMARY CAUSE	103(51.5%)
SIJD WITH ANOTHER CAUSE OF LBP	64(32.0%)
OTHER CAUSES OF LBP	33(16.5%)

Data is presented as frequency (%). SIJD: sacroiliac joint dysfunction, LBP: low back pain.

Demographic data of patients with LBP were enumerated in Table 1.

Table 2. Demographic data, HR and MAP of the studied groups

		GROUP S (N=40)	GROUP P (N=40)	P
AGE (YEARS)		56.13±13.38	51.63±14.64	0.155
SEX	Male	7(17.5%)	9(22.5%)	0.576
	Female	33(82.5%)	31(77.5%)	
WEIGHT (KG)		85.13±8.77	83.53±9.32	0.431
HEIGHT (CM)		169.25±6.59	171.55±5.21	0.087
BMI (KG/M^2)		29.85±3.8	28.46±3.59	0.096
HR (BEATS/MIN)		56.13±13.38	51.63±14.64	0.155
MAP (MMHG)		97.3±10.7	92.93±11.9	0.088

Data are presented as mean ± SD or frequency (%). BMI: body mass index, HR: heart rate, MAP: mean arterial blood pressure.

Demographic data, HR and MAP were insignificantly varied among the two groups. Table 2

Table 3. NRS and Kurosawa scoring system of the studied groups

		GROUP S (N=40)	GROUP P (N=40)	P
NRS	Pretreatment	6(5-8)	6.5(5.75-7)	0.743
	1w	3(2-3)	3.5(2-4)	0.096
	3w	2(2-2)	2(1-2)	0.019*
	5w	1.5(1-2)	1(1-1.25)	0.019*
KUROSAWA SCORING SYSTEM	Pretreatment	6(5-7)	6(5.75-7)	0.909
	1w	4(3-5)	5(4-5)	0.110
	3w	3(2-3.25)	2(1-3)	0.018*
	5w	2(2-2.25)	1(0-2)	<0.001*

Data is presented as median (IQR). * Significant P value <0.05. NRS: numerical rating scale.

NRS and Kurosawa scoring system were insignificantly different pretreatment and 1w after treatment between the two groups and were significantly reduced at 3w and 5w after treatment in group P than group S (P<0.05). Table 3

Table 4. Patient satisfaction of the studied groups

		GROUP S (N=40)	GROUP P (N=40)	P
PATIENT SATISFACTION	Satisfied	14(35.0%)	19(47.5%)	0.178
	Neutral	21(52.5%)	20(50.0%)	
	Unsatisfied	5(12.5%)	1(2.5%)	

Data is presented as frequency (%).

Patient satisfaction was insignificantly different between both groups. Table 4

4. Discussion

SIJ can be responsible for 10–38% of LBP .[4] Women possess a 3–4 times greater likelihood of experiencing SIJ discomfort compared to males.[10] The results of this work reported that most patients complaining of LBP attending to our clinic were females and SIJ dysfunction was responsible for more than 50% of that pain.

SIJ pain sometimes manifests as discomfort below the belt line, radiating to the groin and lower extremities, with uncommon propagation below the knee following the L5-S1 dermatomal pattern .[11] Falowski et al.,[12] found that SIJ pain usually presents as pain or discomfort in the lumbar region and over the hips. The pain is often characterised by an aching nature, devoid of burning sensations, numbness, or tingling .[13]

In the current study, NRS was insignificantly different pretreatment and first week after treatment between both groups and was significantly lower at third and fifth week after treatment in group P than group S. Kurosawa scoring system was insignificantly different pretreatment and first week after treatment between both groups and was significantly lower at third and fifth week after treatment in group P than group S. The same findings had been stated by Woong Mo Kim et al.,[14] demonstrated that the pain and disability ratings shown considerable improvement from baseline in both groups at the two-week follow-up, with no notable variance among the groups. At 15 weeks, pain relief in the prolotherapy group was 58.7%, while it was 10.2% in the steroid group. The authors proved that prolotherapy offered substantial alleviation of SIJ discomfort and had a longer duration of effect compared to steroid injections. Hoffman et al.[15] demonstrated that 66% of patients see clinically significant functional improvements following prolotherapy treatment by a decline in the Oswestry disability index (ODI) post-injection. The authors reported that patients who are not likely to improve with prolotherapy are generally identified by a lack of improvement following the initial prolotherapy injection. Hoffman followed up with patients for 117 days (about 4 months).

As SIJ dysfunction is mainly due to injury and laxity of ligaments, healing of ligaments goes through three phases: inflammation, proliferation and remodelling. Depending upon the grade of ligament injury, the repairing process might span months to years, and the damaged ligament never completely regains its former mechanical qualities.[16] For these reasons, judgment upon the final effect of prolotherapy injection according to the result obtained by the first single injection & with follow-up for a short time, as ligament healing can take longer and requires booster doses of prolotherapy for more proliferation and remodelling. Cusi et al.[17] demonstrated that

favorable clinical outcomes were seen in 76% of those who participated in the 3-month follow-up visit (76% at 12 months and 32% at 24 months). Comparable outcomes were seen in the Quebec Back Pain Disability Scale, Roland-Morris 24, and Roland-Morris 24 Multiform questionnaires at 3, 12, and 24 months. The extended efficacy of prolotherapy (up to 2 years) may be ascribed to the elevated concentration used in this trial, while the decreased percentage at 24 months might be a consequence of the reduced patient cohort at follow-up. Mitchell B et al.,[18] evaluated 26 individuals who had periarticular prolotherapy for SIJ dysfunction. The procedure included the administration of 1.5 ml of Narapin 0.75% and 10 ml of 50% glucose at various locations. The operation was conducted three times, with six-week intervals between each occurrence. Outcome measures were evaluated by questionnaires and records of pain alleviation, strength in the back/hip/pelvis, analgesic usage, disability as per the ODI, and patient satisfaction. Fourteen patients completed the questionnaire, with an average follow-up duration of 7 months. Prolotherapy alleviated pain in fifty percent of the evaluated patients, while the other participants exhibited no alteration in their condition. Patients saw an average pain decrease of 64% after pain alleviation treatment. Sixty-four percent of patients indicated excellent outcomes in back, hip, and pelvic strengthening post-treatment, with an average strength enhancement of 63%. More than one-third of the patients exhibited a decrease in analgesic consumption. These data indicate that prolotherapy may effectively alleviate pain and enhance strength in people with sacroiliac discomfort. Raissi et al.,[19] illustrated that pain scores were insignificantly different between steroid and dextrose prolotherapy groups. This difference between our results and Rassini's results could be attributed to the difference in the number of injections and the volume of prolotherapy.

In the current study, we found that SIJ dysfunction is responsible for more than 50% of LBP. It is multifactorial, related to body weight and the nature of daily activity. Treatment cannot depend only on injection. Reduction of body weight, changing lifestyle to lessen the stress on the joint and physiotherapy to strength muscles of back. The sum of all these can be an effective method to much more prolonged and effective pain relieve than joint injection alone.

Limitations of this study were being single center, short follow up periods and multifactorial affection of pathology such as body weight and socioeconomic status.

4. Conclusion

In patients with SIJ pain, periarticular injection of prolotherapy was more effective in pain relief than periarticular steroid injection, especially in long-term relief.

Disclosure

The authors have no financial interest to declare in relation to the content of this article.

Authorship

All authors have a substantial contribution to the article

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Conflicts of interest

There are no conflicts of interest.

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