Unguided sacroiliac injection: Effect on refractory buttock pain in patients with spondyloarthropathies

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Summary

Objective > This study was designed to evaluate the efficacy and safety of unguided sacroiliac injections for refractory sacroiliac pain due to spondyloarthropathies.

Method > An open-label clinical trial lasted 20 weeks for each of 29 patients, with different subtypes of spondyloarthropathies. It was conducted from September 2004 through January 2007. In patients with refractory inflammatory buttock pain (the inclusion criterion), we performed unguided injections of triamcinolone acetonide 40 mg into each sacroiliac joint on an outpatient basis. Assessments by patients and clinicians were recorded at baseline and every 4 weeks until the end of the study.

Results > At week 4, significant decreases were seen in the patients’ assessment of pain, morning stiffness, and sleep disturbance and in the clinicians’ sacroiliac examination score. Pain reduction, as scored by patient and clinician, was maintained through week 20. No significant improvement was seen on the finger-to-floor or Schober tests. Magnetic resonance imaging (MRI) results showed a significant decrease in inflammatory scores after the sacroiliac injections. The patients’ pain score and sleep disturbance were both clearly associated with the MRI inflammation index. The injection was well tolerated by all patients and no serious adverse event was seen.

Conclusion > This technique for sacroiliac injection was effective, and the final results showed a significant improvement in pain, similar to

Résumé

Des infiltrations non guidées des sacro-iliaques chez des sujets atteints de spondyloarthropathies souffrant de douleurs réfractaires

Objectif > Cette étude a évalué l’efficacité et la tolérance d’infiltrations non guidées des sacro-iliaques chez des sujets atteints de spondyloarthropathies souffrant de douleurs fessières réfractaires.

Méthode > Vingt-neuf patients ayant une spondyloarthropathie de causes diverses et souffrant de douleurs fessières inflammatoires réfractaires (critère d’inclusion) ont été inclus dans cette étude clinique ouverte d’une durée de 20 semaines conduite entre septembre 2004 et janvier 2007. Le traitement a consisté en l’injection de 40 mg d’acétonide de triamcinolone dans chaque articulation sacro-iliaque, pratiquée en ambulatoire sans guidage. Une évaluation par le patient et l’investigateur était réalisée à l’inclusion puis toutes les 4 semaines jusqu’à la fin de l’étude.

Résultats > À 4 semaines, l’auto-évaluation montrait une diminution significative de la douleur, de la raideur matinale et des troubles du sommeil. L’examéné clinique était significativement amélioré. La réduction de la douleur (auto-évaluation et évaluation clinique) était maintenue jusqu’en semaine 20. La distance doigt-sol et le test de Schober n’étaient pas significativement améliorés. Une diminution significative du score inflammatoire était observée.
The spondyloarthropathies include ankylosing spondylitis, reactive arthritis, some forms of psoriatic arthritis, arthritis/spondylitis associated with inflammatory bowel disease, and undifferentiated spondyloarthropathy. The most common subgroup is ankylosing spondylitis, and its disease course is the most severe [1]. A diagnosis of spondyloarthropathy may lead to years of medical care. The chronic progressive course of this disease calls for various types of treatment, including systemic medication, physical therapy, and occasionally surgery.

Inflammation of one or both sacroiliac joints is considered to be an early and important problem in spondyloarthropathies [2]. Anti-tumor necrosis factor (anti-TNF) antibodies [3] and methylprednisolone pulse therapy [4–6] have been used occasionally in severe refractory disease, but their cost and potential complications discourage their use. Some investigators have found imaging-guided injections of the sacroiliac joint to provide prolonged pain relief and to help increase both mobility and the tolerability of physical therapy. Maugars et al. [7] first reported fluoroscopy-guided sacroiliac injections in 1990. Fluoroscopy-guided corticosteroid injections of the joint improved sacroiliac pain by approximately 50 to 64% [8,9]. Other studies report good to excellent clinical response in about 50-70% of patients after sacroiliac injection guided by computed tomography (CT) [10–12]. CT and fluoroscopy are both time-consuming interventions that involve the risk of allergy to contrast products and exposure to ionizing radiation for both physicians [13] and patients [14]. X-ray exposure must also be considered, especially since many patients with sacroiliitis are of reproductive age [15,16]. A new technique uses magnetic resonance imaging (MRI) to guide sacroiliac injections, and its results are similar to those with CT. Its main advantage is the absence of exposure to ionizing radiation [17,18]. But MRI is an expensive procedure, and its use is limited in obese patients and those with claustrophobia or internal metallic implants. Thermal injury and biological effects produced by electromagnetic waves after exposure to high static magnetic fields are also possible.

We found for the first time that unguided sacroiliac injection was a safe and useful method for improving pain and inflammatory changes to the sacroiliac joints in patients with spondyloarthropathies.

Methods

Study design
This study was an open-label trial conducted from September 2004 to January 2007 and followed each patient for 20 weeks. The protocol was explained completely to the patients and all of them signed an informed consent at enrollment. We injected
both joints of each patient’s sacroiliac with triamcinolone acetonide 40 mg.
Sacroiliitis was confirmed by an experienced radiologist based on pelvic anteroposterior (AP) radiography. Patients were divided according to the New York criteria into four groups (sacroiliitis grades 0, I, II, and III) [24]. The sacroiliac joints underwent MRI at the first appointment and at the end of the study.

Patients
Our patients were recruited from a rheumatology clinic connected to Tabriz University of Medical Sciences, in Tabriz, Iran. Patients were required to meet the European Spondyloarthritis Study Group criteria for spondyloarthropathies [25] and have inflammatory buttock pain. Given the absence of validated activity criteria for refractory inflammatory buttock pain in patients with spondyloarthropathies, we defined the inclusion criteria as:

1. The presence of inflammatory buttock pain for at least 4 months (typical night pain and morning stiffness) despite treatment with any of the following drugs: nonsteroidal antiinflammatory drugs, corticosteroids, and disease-modifying anti-rheumatic drugs, such as methotrexate, sulfasalazine, and azathioprine.

2. Tenderness over the sacroiliac joint: pain over the sacroiliac sulcus with 4-5 kg/cm² direct pressure [26].

Exclusion criteria included:

1. Spinal infections (such as brucellosis).

2. Local infection at the injection site.

3. Sacroiliac ankylosis, determined by pelvic radiography (sacroiliitis grade III).

4. Patients who had received anti-TNF, corticosteroid pulses, or an investigational drug within the previous two months.

Patients were allowed to continue nonsteroidal antiinflammatory drugs, sulfasalazine, and azathioprine.

Outcome assessment
Patients were evaluated at baseline and at 4, 8, 12, 16, and 20 weeks after injection. At each visit the following variables were evaluated:

(A) Laboratory tests: ESR (erythrocyte sedimentation rate) and CRP (C-reactive protein).

(B) Patient assessments of:

Buttock pain (100 mm visual analog scale; VAS), sleep disturbance (4-point Likert scale assessing back pain during the night: 1 = not bothered, no feeling of pain at all; 2 = bothered a little, pain is felt part of the time, but mild; 3 = bothered a lot, steady or intermittent feeling of pain, which usually interferes with sleep; 4 = bothered terribly, the night pain is constant, causes marked disturbance of sleep and the patient is quite miserable); duration of morning back stiffness (in minutes).

(C) Clinicians’ assessments:

The physicians assessed sacroiliac pain (1 = no pain on firm palpation, no limitation of FABER maneuvers; 2 = slight pain on firm palpation, no more than slight limitation of FABER maneuvers; 3 = moderate pain on moderate palpation, no more than slight limitation of FABER maneuvers; 4 = moderate to severe pain on slight palpation, moderate to severe limitation of FABER maneuvers; 5 = extreme pain with inability to withstand even slight palpation, severe limitation of FABER maneuvers), change of finger to floor (cm) and Schober tests (mm).

Sacroiliac MRI views were taken at baseline and after 20 weeks. Structural changes on MRI were scored by an experienced radiologist according to the Spondyloarthritis Research Consortium of Canada (SPARCC) MRI index for scoring inflammatory lesions in the sacroiliac joints [28]. Each joint on each consecutive coronal slice (n = 6) was scored (0-6) from posterior to anterior, for a maximum score of 72 (36 for each joint).

Statistics
Data were analyzed with descriptive statistics [mean ± SD & N (%)], including parametric and nonparametric repeated-measure ANOVA. The Wilcoxon test was used to compare...
MRI scores before and after sacroiliac injection. The association between different variables was evaluated with the Spearman correlation coefficient, and the normal distribution of variables with the Kolmogorov-Smirnov test [29]. A p value of <0.05 was defined as significant. All of the statistical analyses were conducted with SPSS software, version 14.

Results

In all, 29 patients (18–41 years) were recruited. The injection failed in two patients, both with grade III sacroiliitis. Intention-to-treat analysis was conducted of all 29 patients with refractory sacroiliac pain due to spondyloarthropathies (table 1). The initial evaluation showed significant improvement in morning stiffness, the patients’ VAS, and sleep disturbance assessments, and the sacroiliac examination scores over time (table 2) (figure 1). Throughout the study, there was a clear correlation between the patient’s VAS score and the physician’s sacroiliac examination score ($\rho = 0.75$, $P_0 < 0.0005$ & $\rho = 0.172$, $P_4 < 0.012$ & $\rho = 1.86$, $P_8 = 0.001$ & $\rho = 0.28$, $P_{12} = 0.043$ & $\rho = 0.63$, $P_{16} < 0.0005$ & $\rho = 1.37$, $P_{20} = 0.031$).

Pain relief was sustained through week 20 in two patients with grade III sacroiliitis. The Schober and finger-to-floor tests showed no significant improvement. The clinician’s sacroiliac examination score at week 8 increased slightly but not significantly for two patients, one with ankylosing spondylitis and the other with psoriatic arthritis. The MRI inflammatory score was significantly associated with the patient’s VAS score (rho = 0.46, $P_0 = 0.019$ & rho = 0.60, $P_{20} < 0.0005$) and sleep disturbance (rho = 0.98, $P_0 = 0.001$ & rho = 1.02, $P_{20} = 0.021$) at baseline and at week 20.

Comparison of the MRI results at the beginning and end of the study revealed a significant decrease in the inflammatory index. MRI scores at the lower end of the SPARCC scoring range indicate some fusion or minimal inflammatory activity [30], while higher scores may predict the greater efficacy of corticosteroid injections in preventing future destruction. All of the patients reported to have sacroiliitis grade 0 on radiography were found to have sacroiliitis on MRI. The absence of any significant change in ESR and CRP levels during the follow-up period indicates that the injections had no systemic effects.

No joint infection or local or systemic complication related to the injections was reported. Eight patients reported minor adverse events during the trial, which included: vertigo ($N = 3$), headache ($N = 2$), palpitations ($N = 1$), flushing ($N = 1$), and dyspepsia ($N = 1$). None of these events led to interruption or withdrawal from the study.

### Table 1

**Patient’s characteristics**

<table>
<thead>
<tr>
<th></th>
<th>Number</th>
<th>Male/female ratio</th>
<th>Age (years)</th>
<th>Disease duration (years)</th>
<th>Sacroiliitis grade 0</th>
<th>Sacroiliitis grade 1</th>
<th>Sacroiliitis grade 2</th>
<th>Sacroiliitis grade 3</th>
<th>Concomitant use of DMARD</th>
<th>Concomitant use of oral NSAID</th>
<th>Concomitant use of corticosteroid</th>
<th>Psoriasis arthritis</th>
<th>Reactive arthritis</th>
<th>Ankylosing spondylitis</th>
<th>Undifferentiated spondyloarthopathy</th>
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<tr>
<td></td>
<td>29</td>
<td>20/9</td>
<td>27.1 (6.6)</td>
<td>5.0 (2.3)</td>
<td>4 (14)</td>
<td>8 (27)</td>
<td>11 (38)</td>
<td>6 (21)</td>
<td>12 (41)</td>
<td>22 (76)</td>
<td>8 (27)</td>
<td>6 (21)</td>
<td>8 (27)</td>
<td>12 (42)</td>
<td>3 (10)</td>
</tr>
</tbody>
</table>

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### Table 2

**Comparison of assessments in 29 spondyloarthropathy patients at periodic evaluations after injection**

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Baseline</th>
<th>4th week</th>
<th>8th week</th>
<th>12th week</th>
<th>16th week</th>
<th>20th week</th>
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<tr>
<td>Pain visual analogue score</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Sleep disturbance score</td>
<td>10.4</td>
<td>10.3</td>
<td>10.2</td>
<td>10.1</td>
<td>10.0</td>
<td>10.1</td>
<td>&lt;0.005</td>
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<tr>
<td>Morning stiffness (min)</td>
<td>2.0</td>
<td>1.9</td>
<td>1.8</td>
<td>1.7</td>
<td>1.6</td>
<td>1.5</td>
<td>0.005</td>
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<tr>
<td>Physician sacroiliac exam score</td>
<td>3.0</td>
<td>3.0</td>
<td>2.9</td>
<td>2.8</td>
<td>2.7</td>
<td>2.6</td>
<td>0.005</td>
</tr>
<tr>
<td>Schober test for spinal flexion (mm)</td>
<td>28.9</td>
<td>28.7</td>
<td>28.5</td>
<td>28.3</td>
<td>28.1</td>
<td>28.0</td>
<td>0.005</td>
</tr>
<tr>
<td>Finger to floor test (cm)</td>
<td>36.5</td>
<td>36.3</td>
<td>36.1</td>
<td>35.9</td>
<td>35.7</td>
<td>35.5</td>
<td>0.043</td>
</tr>
<tr>
<td>MRI score** (SPARCC)</td>
<td>48</td>
<td>34-65</td>
<td>32-59</td>
<td>30-61</td>
<td>28-58</td>
<td>26-57</td>
<td>&lt;0.0005</td>
</tr>
</tbody>
</table>

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*Data shown as: Mean ± SD & N (%). NSAID: nonsteroidal antiinflammatory drug; DMARD: disease-modifying antirheumatic drug.

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Discussion

The progressive nature of spondyloarthropathies makes their management challenging. To date, no available treatment definitively alters their underlying mechanism of inflammation. The conventional treatments currently available are palliative than curative and often fail to control disease progression or structural destruction in the long term. The sacroiliac joint is the leading joint involved in ankylosing spondylitis and perhaps also in other spondyloarthropathies. Inhibition of ankylosis of the sacroiliac is important in maintaining functional mobility and health status. The efficacy of injecting long-acting corticosteroids into the sacroiliac joint under fluoroscopic, CT guidance [31], or MRI [32] guidance has been shown. We investigated the safety and efficacy of outpatient unguided sacroiliac injection in patients with spondyloarthropathy. Buttock pain is one of the principal complaints and disabling factors in this rheumatic disease, and it was assessed in this study of patients with sacroiliac joint involvement by a simple VAS scale to evaluate its intensity. The power of the study to assess the procedure’s efficacy in controlling pain was increased by recording pain intensity as assessed by patients with the VAS and by physicians with the sacroiliac examination score.

A 50% reduction on the VAS (0-100) was assumed to indicate clinically significant pain relief. Pain improvement was thus seen in 59% of the patients, similar to the results of imaging-guided sacroiliac injections [33]. A more precise comparison with previous studies is difficult, since they used numeric pain scales instead of a VAS [34,35], or involved different levels of corticosteroid efficacy and different inflammatory conditions [36], or included heterogeneous simultaneous systemic treatments. Although results of the Schober and finger-to-floor tests were not improved by the sacroiliac injection, the improvement in pain and morning stiffness enabled patients to maintain their daily activities and helped their physical therapy. The efficacy of sacroiliac injection was probably not as good in patients who have developed prominent chronic changes (sclerosis and joint space narrowing). We therefore suggest sacroiliac injections preferentially in patients with early stages of sacroilitis and refractory buttock pain. The injections took place in an outpatient setting, and the entire procedure lasted about 10 minutes; patients were discharged immediately afterward.

Previous studies report that the efficacy of placebos in spondyloarthropathies ranges from none [37] to a maximum 20-25% [38]. Our data indicate that the overall periods and intensity of pain reduction were at least equal to those achieved with imaging guidance and better than with placebo. The risks of exposure to ionizing radiation in CT or fluoroscopy guidance and to electromagnetic waves in MRI must not be underestimated. Unguided sacroiliac injection is thus particularly useful in younger patients with spondyloarthropathies. The open trial design of this study means that we cannot compare our results with other treatment options for refractory buttock pain in these diseases. Furthermore, the lack of an obvious difference between the subgroups of spondyloarthropathies in response to sacroiliac injection may be due to the small number of patients enrolled (due to the restrictive inclusion criteria). Further studies are thus needed. We conclude that unguided sacroiliac injections are an effective, easy, and rapid treatment for spondyloarthropathy patients with refractory sacroiliac pain.

Conflicts of Interest: none

Ethical approval: Approval of this trial was obtained from our local ethics committee (5/4/6466) and Clinical Trials.gov (NC100829543).

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References


