Effect of fluoroscopically guided corticosteroid injection versus oral nonsteroidal anti-inflammatory drugs for treatment of coccydynia: A randomized, controlled, single-blind study

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ABSTRACT

Background:
Coccydynia is a major cause of coccyx pain that can result in chronic pain as well as reduced functional performance in patients. The aim of this study was to compare the efficacy of fluoroscopically guided corticosteroid injection with an oral nonsteroidal anti-inflammatory drug (NSAID) to relieve coccyx pain.

Methods:
In a clinical trial study, 28 patients with coccydynia who were randomly divided into two groups and matched based on sex, age, and body mass index. One group was treated with celecoxib 200 mg (every 12 hr) for 1 mo along with regular use of a tailbone pillow while sitting on hard surfaces. The second group received local periarticular injection of methyl-prednisolone acetate 40 mg along with lidocaine 1%, which was fluoroscopically guided. The patients were followed for 4 mo.

Results:
There was a significant difference in pain severity of the patients when compared with their condition at the beginning of the study in each group ($P < 0.001$). The final pain severity of NSAID group and steroid group was 37.9 ± 14.2 mm and 38.7 ± 16.1 mm, respectively, which was not significantly different. Also the trend of pain severity was similar between the two groups.

Conclusions:
Corticosteroid injection for coccydynia treatment at least has the same advantages of oral NSAID medication. Regarding its single-dose administration and reasonable price, it can be considered as an alternative modality in treatment of this disease if the target patient is selected correctly.

Level of Evidence:
Level I.

Key Words
coccydynia, steroid injection, fluoroscopy, nonsteroidal anti-inflammatory drugs

INTRODUCTION

The term "coccydynia" was first introduced by Simpson in the mid nineteenth century and refers to pain in coccyx area.[1] Coccydynia has various causes, such as trauma, contusion, fracture, or hard labor.[1] In most patients it is accompanied with subluxation of the coccyx or a coccyx that is too mobile; this pathologic instability has been considered as a cause for inflammatory alterations. The majority of patients report a history of a traumatic event related to instability of the coccyx, especially after subluxation.[2–4] Idiopathic coccydynia has been described as occurring without any evident coccyx-involving pathogenic causes. In these patients, the pain could be due to spasticity or any abnormal issue involving the musculoskeletal structure of the pelvis. Patients usually present to clinics with complaints of pain over or in vicinity of coccyx without any back pain or radiating pain.[5,6] Classically, this pain is related to sitting and intensifies by standing from a seated position. Many patients also mention repetitive defecation or painful defecation.[6] Management includes physiotherapy or rectal manipulation, application of anti-inflammatory drugs, coccygectomy, and fluoroscopically guided steroid injection.[6] A limited number of studies have assessed conservative treatments in management of idiopathic coccydynia. The aim of this study was to investigate and compare the efficacy of fluoroscopically guided steroid injection with oral nonsteroidal anti-inflammatory in relieving coccyx pain in idiopathic coccydynia. We hypothesized that steroid injection is more

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effective than oral nonsteroidal antiinflammatory drugs in reducing pain levels in patients with coccydynia.

MATERIALS AND METHODS

Ethical Review and Study Design

This randomized controlled, single-blind study was done in complete accordance with the 1964 Helsinki Declaration and its later amendments and was approved by the Ethics Committee, Urmia University of Medical Sciences, Urmia, Iran. This study was based on residential thesis with code of 95-01-32-2468 recorded in Urmia University of Medical Science. Written consent was obtained from the participants, and they entered the study completely voluntarily.

Participants

This clinical trial considered 28 patients with coccydynia who presented to the orthopaedic clinic from October, 2015 to December, 2017. Idiopathic coccydynia was defined as pain in the coccyx or the surrounding area for unknown cause, without propagation to other regions, and which mainly occurred when changing position from sitting to standing. Inclusion criteria were an age range of 25 to 70 yr, no consumption of anti-depressant drugs, no malignancy, a body mass index (BMI) of less than 30, no history of severe trauma in the pelvic region, no history of lumbar vertebral column surgery, no problem with the use of corticosteroids or oral NSAID, no narcotic abuse, no use of NSAIDs in last 3 mo, and no rectal or digestion problems. Patients entered the study upon their informed consent and could leave the study whenever they chose. Treatment duration less than 6 mo was considered as acute while those taking more than 6 mo were considered as chronic cases.[7]

Based on the study of Mitra *et al.*,[7] the sample volume of 24 patients was obtained considering a power of 80%, accuracy coefficient of 0.1 using Stata 14 software. Twelve patients were in the fluoroscopically guided steroid injection group, while the remaining 12 patients were placed in the oral NSAID group. Classification into treatment groups was random and based on the serial number of patients' insurance files (odd number in one group and even number in another group). Sampling was carried out in successive manner, and 10% loss was considered, which resulted in a total of 28 samples. The two groups were matched in terms of age, sex, and BMI (Figure 1).

Intervention

The NSAID group received celecoxib 200 mg capsules (every 12 hr) for 1 mo along with the use of a tailbone pillow for seating on hard surfaces. The other group was treated with a local injection of methylprednisolone 40 mg along with 1% lidocaine 20 mg 92 cc, which added up to 3 cc injection (periarticular) in the coccyx in a way that half of the volume (1.5 cc) was injected into one site and the other half into another site in the coccyx (Figure 2). The injection was fluoroscopically guided in the operating room.

Data Collection

At the beginning of the study, demographic data were recorded. Patient BMI was calculated using a fixed formula:

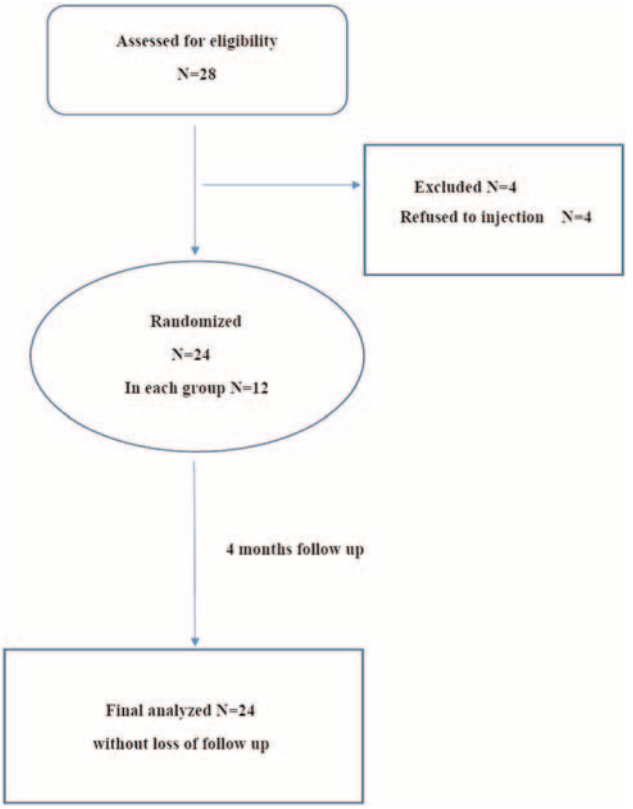

FIGURE 1. Flow diagram of the study protocol.

patients' height, weight, and waist circumference were clinically examined before intervention; eight were assessed by a wall-mounted stature meter with an accuracy of 0.1 cm;

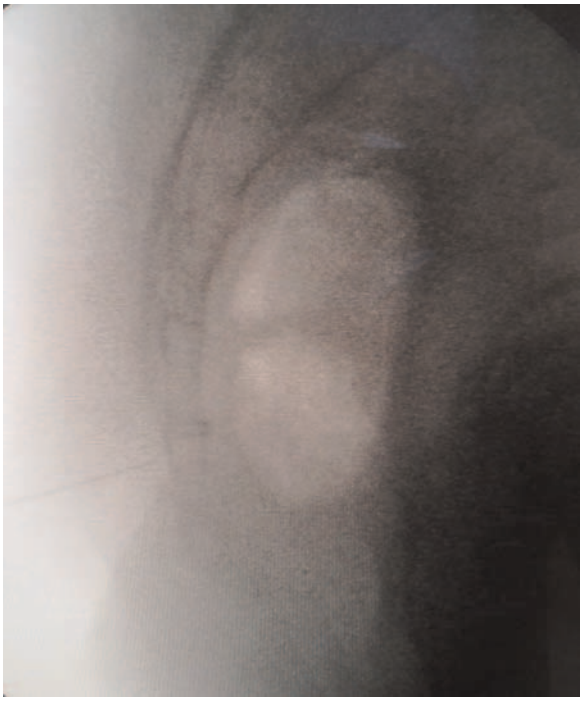

FIGURE 2. Fluoroscopic image of coccygeal injection.

and weight was evaluated by a Sega scale at an accuracy of 0.5 kg. A visual analogue scale (VAS) was determined according to an international standard, where a 100-mm line was drawn for each patient at each time of VAS determination. Patients were asked to mark their pain in the coccyx based on the 100-mm line. In this scale, 100-mm represents maximal pain, while the length of 0 refers to no pain. Pain severity was measured before intervention and at 2, 3, and 4 mo after intervention. Patients were followed-up for at least 4 mo. Pain reduction more than 50% was considered as a proper treatment response.

Statistical Analysis

Descriptive statistics, including mean ± standard deviation (SD), frequency, and percentage were used. The categorical variables were compared by chi-square test and if necessary by an exact Fischer test. Quantitative data were also evaluated and compared by an independent t test. Paired T test was used to compare the pain severity before and after intervention in each group, and the two groups were compared using a repeated measure test. A *P* value less than 0.05 was considered statistically significant. Statistical analyses were done using SPSS software (Statistical Package for the Social Sciences, version 16.0, SPSS Inc., Chicago, III, USA).

RESULTS

Based on Table 1, demographic findings of the two groups were not significantly different. Coccydynia duration was also similar between the two groups. Pain severity at the beginning of the treatment showed a significant difference at the end of the follow-up procedure in both groups ($P < 0.001$). The trend of these variations, however, was not significantly different between the two groups (Figure 3). In the NSAID group, the reduction in pain severity was more than 50% in eight of 12 (66.6%) patients. This reduction was observed in seven of 12 (58.3%) patients in corticosteroid injection group.

In the corticosteroid group, all of the four patients with acute pain and three of eight patients with chronic pain responded well to the corticosteroid injection. The difference in response to corticosteroid injection among patients with chronic or acute pain was statistically significant ($P = 0.038$). Thus, patients with acute pain responded better to corticosteroid injection than patients with chronic pain. In the oral NSAID group, five of six patients with acute pain and three of six patients with chronic pain responded to the treatment, but the difference was not significant ($P = 0.221$). Also, in both the NSAID and corticosteroid groups, we observed no statistically significant association between response to the treatment and other variables listed in Table 1.

TABLE 1. Comparison of demographic and clinical characteristics between two treatment groups

Variables	NSAID treatment N = 12	Corticosteroid injection N = 12	*P*
Age (yr)	37.9 ± 14.2	38.7 ± 16.1	0.5
Sex (m/f)	2/10	4/8	0.3
BMI(kg/m^2)	25.9 ± 2.3	25.2 ± 2.8	0.1
Acute pain (< 6 mo)	6 (50%)	4 (33.3%)	0.4
Chronic pain (> 6 mo)	6 (50%)	8 (66.7%)	
Duration of pain (wk)	28.9 ± 12.8	29.8 ± 10.6	0.3
Severity of pain before intervention	67.08 ± 8.5	68.5 ± 7.6	0.2
Severity of pain in final follow-up	37.9 ± 14.2	38.7 ± 16.1	0.4

BMI, body mass index; NSAID, nonsteroidal anti-inflammatory drug.

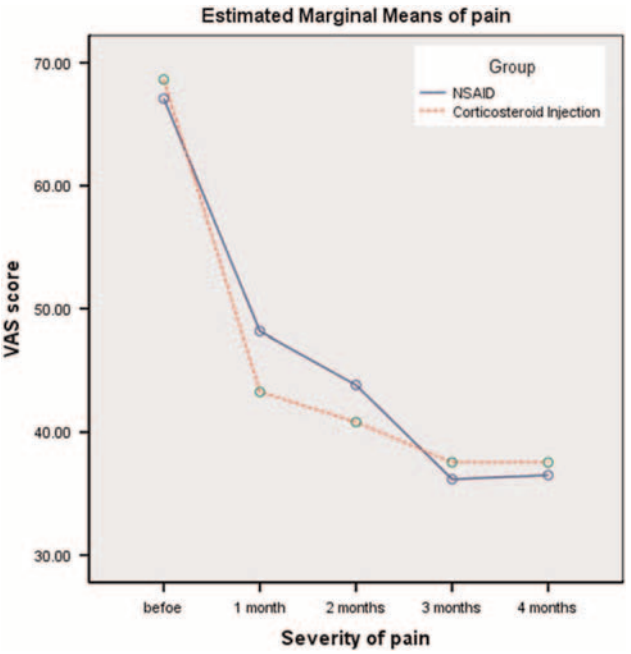

FIGURE 3. Comparison of severity of pain between two groups.

DISCUSSION

Management of coccydynia includes physiotherapy or rectal manipulation, administration of anti-inflammatory drugs, coccygectomy, and fluoroscopically guided steroid injection.[7,8] Nonsurgical strategies have still remained as the gold standard treatment for coccydynia.[9] Interrectal manipulation physiotherapy in the long-term does not exhibit effectiveness.[10–14] The effect of coccygectomy on coccydynia treatment varies, and various studies have reported success rates of 60% to 91%.[9–15] A limited number of studies evaluated conservative treatment methods in coccydynia management whose results are contradicting.[12–16] In this regard, the present study was conducted to compare the efficacy of fluoroscopically guided steroid injection with that of oral NSAIDs for relieving coccyx pain in patients with coccydynia. In this study, both methods (fluoroscopically guided steroid injection and oral NSAIDs) resulted in improvement of pain severity after 1 and 3 mo from the intervention. There was no significant difference in pain reduction between the two treatment modalities.

Coccydynia etiology included trauma, labor, obesity, lack of activity, coccygeal spicules as well as spinal canal stenosis. Intervertebral disc herniation also has been known as a potential etiology for coccydynia. Numerous cases of coccydynia do not have a specific etiology and are considered as idiopathic.[16–19]

Many cases of coccydynia and simultaneous local tenderness could have inflammatory nature; therefore, antiinflammatory drugs (oral or injection) can be employed for treatment of this problem.[16–19]

Conservative management of coccydynia includes use of tailbone pillow (a doughnut-shaped pillow), NSAIDs, sitting in warm water, and physiotherapy.[19] Manipulative treatments have not been highly successful in coccydynia.[15] It was also shown that rectal manipulation along with physiotherapy is not successful in the long-term for treatment of this disease.[8] Positive outcome predictors include a fixed coccyx, shorter duration of symptoms, traumatic etiology, and a low score in McGill University questionnaire for coccydynia evaluation.[8] Previous studies on steroid injection are limited. Wray *et al*.[16] randomly treated coccydynia patients by either local injection or injection combined with manipulation. They concluded that patients receiving 40 mg methylprednisolone acetate along with 10 mL bupivacaine 0.25% showed higher improvement when having coccyx manipulation (59% vs. 85%).[16] It must be noted that steroid injection in this study was blinded, and it was administered into the soft tissue and not into the joint. The recovery rate after steroid injection at 3 mo was about 58% (7/12), which is similar to the aforementioned study. Although it was expected that using fluoroscopy for injection would result in higher recovery rates, the difference in follow-up and type of the steroid injection as well as evaluation criteria, could explain these differences. In another study, Mitra *et al*.[7] reported rapid improvement in coccydynia pain immediately after steroid injection ($P = 0.02$). Three weeks later, only patients with acute pain (less than 6 mo of pain duration) reported pain improvement. It was not statistically significant, but it was close.[7] In the present study, there was no significant difference in pain severity of the patients after 3 mo (from injection). This improvement also was not related to the pain duration. Based on our findings, there was no significant difference in pain improvement between the two study groups. However, because of low compliance in patients taking oral medications, a single-dose local steroid injection is an attractive alternative to the conventional treatments. Selecting suitable cases for coccyx steroid injection is vital. The patient should not have any rectal or pelvic pathology for local steroid injection. In a group of patients studied in terms of these pathological issues, no evidence of abdominal pain, tenesmus, diarrhea or constipation, dysmenorrhea, hemorrhoids, or melena were found. None of the patients had symptoms of radiating pains, pressure on nerves, facet tenderness, or pain worsening with bending or lateral rotation. The patients had local tenderness in the coccyx, which was in accordance with their pain location.

The most important limitation of the current study is the small sample size. Thus we recommend further studies with larger sample sizes, especially those investigating the effectiveness of corticosteroid injection compared with placebo injection.

CONCLUSIONS

Fluoroscopically guided corticosteroid injection for coccydynia treatment at least has the same advantages of oral NSAID. Regarding its single-dose administration, it can be considered as an alternative modality in treatment of this disease if the target patient is selected correctly especially in patients having low compliance with oral drugs. Since there was no significant difference between the two groups, our hypothesis was not proved in the study.

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