RESEARCH ARTICLE

Ultrasound-Guided vs. Blind Coccygeal Corticosteroid Injections for Chronic Coccydynia: A Randomized, Clinical Trial

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Abstract

Background: Corticosteroid injection is frequently used for chronic coccydynia management. Ultrasonography can be used to improve the accuracy of the injection. This study aims to assess the clinical outcome of ultrasound-guided compared to blind coccygeal injection in chronic coccydynia.

Methods: Thirty patients with chronic coccydynia were randomized into two groups and received a coccygeal corticosteroid injection at maximum tenderness point: 15 patients with and 15 patients without ultrasound guidance. The patient's pain was evaluated with the visual analog scale (VAS) at 1-, 4-, 8-, and 24-week postinjection. Furthermore, the Dallas Pain Questionnaire was assessed before injection; also, four and eight weeks after treatment. The quality of life of patients was evaluated before an assessment and four weeks after the intervention by the SF-36 questionnaire.

Results: The VAS score decreased significantly 24-week after the intervention in both ultrasound-guided and blinded groups ($P < .001$), without any significant difference between the groups ($P = .964$). Similarly, the Dallas pain scale had a significant decrease at eight weeks after intervention in both groups ($P < .001$) with no significant difference between the groups ($P = .972$). Although there was a significant improvement in the patient's quality of life in each group eight weeks after the intervention, it was not significantly different between the two groups. Neither of the treatment groups had any adverse effects associated with the injection.

Conclusion: There were no significant differences in the clinical outcome of coccygeal ultrasound-guided vs. blind steroid injection for chronic coccydynia.

Level of evidence: I

Keywords: Coccyx, Injections, Interventional ultrasound, Pain management, Ultrasonography

Introduction

Coccygodynia or coccydynia is "defined as pain in and around the coccyx that does not significantly radiate" or worsen by sitting or standing up from the sitting position. The coccyx has more than a few essential functions despite its small size. It provides positional support to the anus and weight-bearing support in the seated position along with the ischial tuberosities. It is also the insertion site for multiple muscles, ligaments, and tendons of the pelvic floor.[1]

There is no published data for the exact prevalence and incidence of coccydynia; however, it has been reported five times more common in females.[2] Obesity with insufficient pelvic rotation can increase the risk of posterior luxation and trauma. On the other hand, rapid

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weight loss can be a risk factor because of the loss of mechanical cushioning.[3] External or internal trauma is the most common etiology of coccydynia. External trauma typically happens due to a backward fall, leading to a bruised, dislocated, or broken coccyx.[4] The location of the coccyx makes it susceptible to internal injury during childbirth, especially during a stressful or instrumented delivery. Minor trauma can also occur from prolonged sitting, especially in the leaning-back position on hard or uncomfortable surfaces.[5] Nontraumatic coccydynia can be related to several causes, including degenerative joint or disc disease, hypermobility or hypomobility of the sacrococcygeal joint, infectious etiology, and variants of coccygeal morphology.[6] It has been reported that women with coccydynia had a significantly more ventrally curved coccyx, a higher frequency of bony spicule formation, and a lower prevalence of sacrococcygeal joint fusion than expected.[7] Coccydynia can also be presented by referred or radicular pain, although this type of pain often is not accompanied by coccygeal tenderness on physical examination. Less commonly, primary coccygeal neoplasms and pelvic organ tumors have been associated with coccydynia.[8] Nonorganic causes, such as central sensitization, somatization disorder, or other psychological disorders, can also be associated with coccydynia.[9,10]

Several conservative treatment options are available for coccydynia, which is successful in 90% of cases, and many issues can be resolved without further intervention.[11] The first-line treatment options include activity modification, seat cushions, physical therapy (e.g., hot/cold modalities, extracorporeal shock wave therapy, ultrasound therapy, and laser therapy), manual therapy, and pelvic griddle/pelvic floor exercises. Nonsteroidal anti-inflammatory drugs are the most common analgesic prescribed for coccyx pain. However, opioids generally are not recommended and are reserved for severe pain (usually from an acute injury) that is not responsive to other measures.[12-14] Local corticosteroid injection alone or with manipulation has been shown to have a success rate of 60% and 85%, respectively.[15] Local anesthetic with steroid injections around the coccyx, usually at the sacrococcygeal junction or around the sacrococcygeal ligaments, can be diagnostic and therapeutic.16 Surgical coccygectomy may cause significant improvements in severe refractory patients but with a high risk of infection.[17] Caudal epidural steroid injections and fluoroscopic ganglion impar block are also reported for refractory patients.[18,19] The evidence suggests that chronic coccydynia has a higher chance of improvement through more invasive interventions such as injections or surgical removal of the coccyx. However, conservative treatments must be considered first and continued along the course of treatment.[14]

Ultrasound is a non-invasive, portable, cost-effective imaging technique that can provide high-resolution images of superficial soft tissues and allows for dynamic evaluation of structures. ,Therefore, it is effectively improving the safety and accuracy of office-based invasive procedures.[20] Reported research suggests ultrasonography-guided injections in different musculoskeletal conditions to enhance accuracy and decrease the injection-related side effects.[21-23] For injections around the coccyx, ultrasound imaging guidance is recommended in some articles because of its particular position relative to sensitive structures, especially the rectum that lies just anteriorly so it can add accuracy and safety to the injection.[24]

By now, few, even if any, controlled studies have been reported to evaluate using imaging guidance to improve the clinical effect of coccygeal steroid injection. Hence, we designed this clinical trial to compare the efficacy of the blind and ultrasound-guided injections to help reach a consensus regarding the application of imaging modalities as guidance for coccydynia.

Materials and Methods

Setting

This double-blind Randomized Clinical Trial was conducted in the Physical Medicine and Rehabilitation clinic of Firoozgar Hospital, Tehran, Iran, from March 2017 to October 2018.

Participants

Eligible participants in this study were 30 patients (30 women) aged between 19 and 64 years (mean age: 43.33 ± 11.37 years) with chronic coccydynia referred to the Physical Medicine and Rehabilitation clinic. A total of 30 participants were enrolled in the study, and All patients were informed of the process and possible side effects (such as infection, skin pigmentation, and transient elevation of blood glucose) and signed a written consent form before the study. Patients were assessed for eligibility based on the criteria listed below.

Inclusion criteria included:

- Patients aged 18-65 years old
- Chronic coccydynia (≥ 6 months)
- Pain VAS score ≥ 4
- The patient's pain has not been reduced by first-line treatment (physical therapy/oral medication)

Patients who had any of the following criteria were excluded from the study.

- The history of injection or manipulation in 6 months
- Poor control of diabetes mellitus
- Rheumatoid diseases
- Mechanical or non-mechanical low back pain
- History of myelomeningocele or spina bifida
- Coccygeal dislocation (confirmed by X-ray)
- Fecal incontinence or urinary incontinence
- Skin disease at the site of injection

Intervention

A total of 30 patients were assigned into two intervention groups by block randomization (15 patients in each group). In the first group, we injected a mixture of triamcinolone and lidocaine at the point of maximum tenderness by the ultrasound guide (ultrasound group). We injected without ultrasound guidance in the second group (blind injection group). Coccygeal tenderness was confirmed by surface examination and by digital rectal examination. The skin was disinfected with betadine,

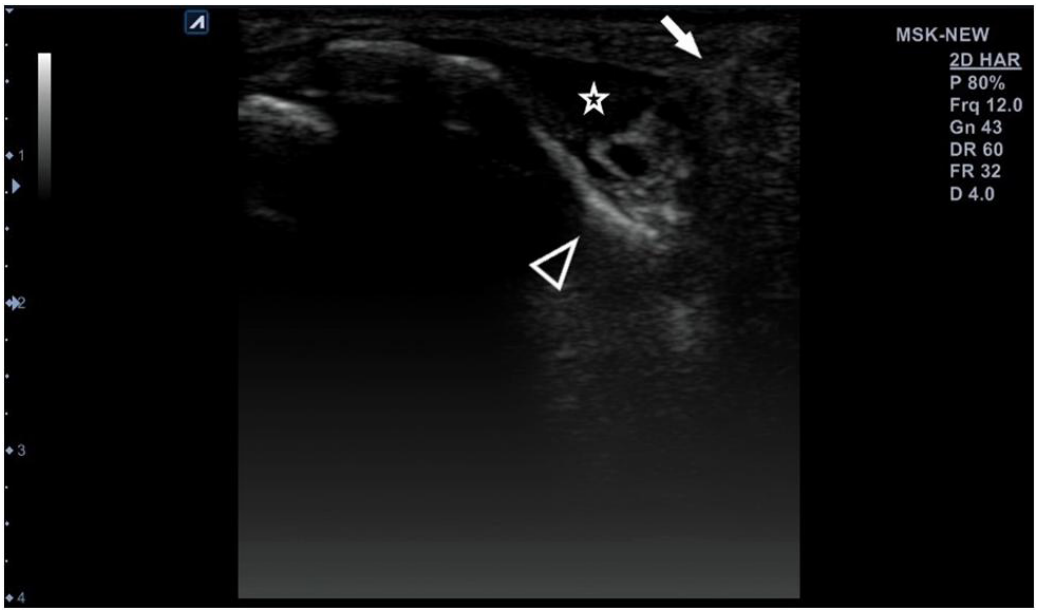

Figure 1. The needle (arrow), the injected solution (star), the coccyx (arrowhead).

and injections were performed in a prone position. The ultrasound transducer was covered with a sterile sheath containing ultrasound gel. A low frequency (4-5MHz) curved array transducer was positioned longitudinally along the coccyx bone (long-axis view) in both groups while the probe was inactive in the blind group. The injection was performed using 1 ml of triamcinolone (40 mg/ml) and 2 ml of lidocaine (2%) with a 22-gauge needle [Figure 1].

Outcome measures

Dallas Pain Questionnaire, SF-36 quality of life questionnaire, and VAS were used to compare the effectiveness of treatment in two groups.

The SF-36 measures eight scales, including physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health. The Dallas Pain Questionnaire has four parts: first, second, third, and fourth refer to the daily activities, work/leisure activities, anxiety/depression status, and social interest of the patient, respectively. .

Follow-up time points

VAS: before the intervention, week 1, week 4, week 8, week 24

SF36 questionnaire: before the intervention, week 4

Dallas questionnaire: before the intervention, week 4, and week 8

To make the assessor blind, the injections were done by one specialist (the interventionist), and the follow-up assessments were done by another specialist blind to the type of intervention. The participants were also made blind by using an inactive sonography probe on the area in the blind injection group. The statistical analyzer was blind to the groups similarly, as they were signed as A and B in the data.

Statistical analysis

Statistical analyses were done using SPSS software version 21 (SPSS Inc., Chicago, IL) for Microsoft Windows. An independent t-test was used to compare the mean of qualitative variables between the two groups before treatment. The Chi-square test was used to compare the frequency distribution of qualitative variables. The mixed ANOVA test investigated the interaction effects of time and group. The significance level was considered to be less than 0.05.

Results

In this study, a total of 30 participants, including two groups of 15, completed the study. None of the patients dropped out of the study. There were no significant differences between the two groups in age, body mass index, and pain duration [Table 1]. As shown in Table 1, there was no statistical difference in the baseline VAS, Dallas, and SF-36 questionnaire scores between groups. The most frequent place of the maximum point of tenderness (the injection site) was at the coccygeal tip (%73.3), and there was no significant difference between the two treatment groups for the injection site (*P=0.215*).

VAS

In the blind injection and ultrasound-guided groups, VAS changes at all four follow-up visits compared to the baseline VAS showed significant improvement. The changes were insignificant for other time intervals between follow-ups in both groups [Table 2].

There was no significant difference in pain reduction in our study during either follow-up visit between the two groups [Table 3].

Table 1. Baseline Participants characteristics by Treatment Group

Characteristic	Blind, Mean (SD)	Guide, Mean (SD)	*P-value* (t-test)
Age (y)	42.47 (13.01)	44.20 (9.84)	0.314
BMI (kg/m^2)	26.95 (4.48)	26.35 (4.14)	0.515
Pain duration(mo)	13.80 (13.83)	24.80 (44.82)	0.967*
Dallas			
Daily activities	55.3(25.55)	48(21.06)	0.398
Work/leisure activities	58.2(27.2)	58.67(18.94)	0.957
Anxiety/Depression	39.1(30.59)	45.67(17.91)	0.478
Social Interest	35.7(31.78)	35.3(21.9)	0.974
Quality of life			
Physical functioning	56.67 (27.94)	61.33 (28.19)	0.652
Role physical	31.67 (39.49)	21.67 (36.43)	0.477
Role emotional	24.44 (38.76)	28.88 (43.39	0.770
Energy/fatigue	52.33 (18.50)	41.67 (14.09)	0.087
Emotional well-being	59.67 (18.38)	51.2 (13.37)	0.170
Social functioning	56.67 (25.82)	55 (27.87)	0.866
Pain	35.67 (24.63)	37.67 (25.64)	0.829
General health	44 (18.34)	43.33 (24.25)	0.933
Total	44.47(18.31)	42.59 (20.43)	0.770

*Mann-Whitney U test

Dallas pain

The Dallas score for all four domains of daily activity, work/leisure, anxiety/depression, and social interest improved significantly in the blind injection group at four weeks and eight weeks after the intervention compared to the pretreatment evaluation. Results were similar in the ultrasound group, with no statistical difference between groups [Tables 2; 3].

Quality of life

Quality of life of patients was evaluated in eight areas at the baseline and four weeks postinjection. The comparison of patient's quality of life improvement between groups was not statistically significant in any of the health domains (*P> 0.05*) [Table 4]. In contrast, in both groups, the quality of life in all areas before and after treatment was improved significantly.

Table 2. Within groups differences of VAS, Dallas questionnaire

Measure	Blind		Guide	
	Time	*P-value*	Time	*P-value*
VAS	Visit1 vs. Visit 2	0.003	Visit1 vs. Visit 2	<0.001
	Visit1 vs. Visit 3	<0.001	Visit1 vs. Visit 3	<0.001
	Visit1 vs. Visit 4	<0.001	Visit1 vs. Visit 4	<0.001
	Visit1 vs. Visit 5	0.001	Visit1 vs. Visit 5	0.001
	Visit2 vs. Visit 3	0.407	Visit2 vs. Visit 3	0.136
	Visit2 vs. Visit 4	0.074	Visit2 vs. Visit 4	0.110
	Visit2 vs. Visit 5	0.788	Visit2 vs. Visit 5	1.000
	Visit3 vs. Visit 4	0.174	Visit3 vs. Visit 4	1.000
	Visit3 vs. Visit 5	1.000	Visit3 vs. Visit 5	1.000
	Visit4 vs. Visit 5	1.000	Visit4 vs. Visit 5	0.667

Table 2. Continued

Dallas				
	Visit1 vs. Visit 2	<0.001	Visit1 vs. Visit 2	<0.001
Daily activities	Visit1 vs. Visit 3	<0.001	Visit1 vs. Visit 3	<0.001
	Visit2 vs. Visit 3	0.149	Visit2 vs. Visit 3	0.405
	Visit1 vs. Visit 2	0.001	Visit1 vs. Visit 2	0.003
Work/leisure	Visit1 vs. Visit 3	<0.001	Visit1 vs. Visit 3	<0.001
	Visit2 vs. Visit 3	0.031	Visit2 vs. Visit 3	0.077
	Visit1 vs. Visit 2	0.002	Visit1 vs. Visit 2	<0.001
Anxiety/dep.	Visit1 vs. Visit 3	<0.001	Visit1 vs. Visit 3	<0.001
	Visit2 vs. Visit 3	0.067	Visit2 vs. Visit 3	0.711
	Visit1 vs. Visit 2	0.005	Visit1 vs. Visit 2	0.007
Social interest	Visit1 vs. Visit 3	<0.001	Visit1 vs. Visit 3	0.003
	Visit2 vs. Visit 3	0.075	Visit2 vs. Visit 3	0.740

Visit 1: before injection, visit 2: week 1, visit 3: week 4, visit 4: week 8, visit 5: week 24

Table 3. The results of the Blind and Guided intervention on the intensity of VAS, Dallas questionnaire

Variable	Time of intervention	Study groups Mean (SD)			*P-value*
		Blind	Guided		
	Before treatment	7.3(1.71)	7.9(1.75)		
	After 1week	4.3(3.39)	4.3(3.20)		
Pain (VAS)	After 4 weeks	2.8(3.11)	2.5(2.59)	Group and time interaction	0.759
	After 8 weeks	2(3.18)	2.1(2.85)		
	After 24 weeks	2.4(3.15)	3.1(3.55)		
	Before treatment	55.3(25.55)	48(21.06)		
Daily activities	After 4 weeks	23.60(10.21)	18.8(9.36)	Group and time interaction	0.788
	After 8 weeks	18(6.81)	14.6(8.37)		
	Before treatment	58.2(27.2)	58.67(18.94)		
Work/leisure activities	After 4 weeks	27.33(11.72)	31(16.13)	Group and time interaction	0.876
	After 8 weeks	18(12.11)	23(10.63)		
	Before treatment	39.1(30.59)	45.67(17.91)		
Anxiety/Depression	After 4 weeks	17(9.26)	18.3 (7.76)	Group and time interaction	0.692
	After 8 weeks	9(5.37)	14.33(8.7)		
	Before treatment	35.7(31.78)	35.3(21.9)		
Social Interest	After 4 weeks	15.3(6.31)	15.7(4.93)	Group and time interaction	0.730
	After 8 weeks	7.33(4.37)	11.67(5.12)		

Table 4. Changes in study outcome measures before and 4 weeks after the trial and the mean differences between groups (mean (SD))

Study Outcomes		Study groups	Before treatments	4 weeks after treatments	*P-value*	Mean difference	*P-value*
SF36 Questionnaire	Physical functioning	Blind	56.67 (27.94)	76.67(24.32)	0.001	20(19.36)	0.760
		guided	4 61.33 (28.19)	79(25.94)	0.003	17.6(21.94)	
	Role physical	Blind	31.67 (39.49)	61.66(13.11)	0.006	30(21.62)	0.419
		guided	21.67 (36.43)	63.33(14.56)	<0.001	41.66(24.98)	
	Role emotional	Blind	24.44 (38.76)	66.67(23.64)	0.001	42.2(30.75)	0.784
		guided	28.88 (43.39)	68.68(19.87)	0.002	37.7(36.91)	
	Energy/fatigue	Blind	52.33 (18.50)	71.66(14.84)	0.001	19.3(16.67)	0.226
		guided	41.67 (14.09)	70(18.52)	<0.001	28.3(22.65)	
	Emotional well-being	Blind	59.67 (18.38)	77.06(15.52)	0.001	17.6(17.12)	0.427
		guided	51.2 (13.37)	74(17.22)	<0.001	22.8(18.20)	
	Social functioning	Blind	56.67 (25.82)	75.83(20.30)	0.003	19.2(18.81)	0.560
		guided	55 (27.87)	79.16(26.16)	<0.001	24.2(23.92)	
	Pain	Blind	35.67 (24.63)	70.83(21.52)	<0.001	35.1(30.30)	0.943
		guided	37.67 (25.64)	73.66(27.10)	<0.001	36(32.67)	
	General health	Blind	44 (18.34)	57.67(16.99)	0.003	13.6(12.45)	0.913
		guided	43.33 (24.25)	57.67(22.9)	0.002	14.3(15.40)	
	Total	Blind	44.47(18.31)	69.84(20.29)	<0.001	25.1(14.92)	0.715
		guided	42.59 (20.43)	70.43(23.59)	<0.001	27.8(23.87)	

Safety

In the present study, we observed no injection-related side effects such as infection, allergic reaction, osteonecrosisin either group.

Discussion

Coccygeal pain is a disorder that occurs at the very extremity of the spine. As it exacerbates with sitting and daily activities, it dramatically affects the person's performance and quality of life. The second-line treatment for coccydynia is the local injection of various materials, 2 including corticosteroids or dextrose, even though steroid injection is suggested as the first-line treatment of coccydynia with inter-coccygeal disc calcium crystal deposition.[24,25]

The ultrasound-guided injection has been studied in several musculoskeletal conditions. Many studies have reported the superiority of ultrasound -guided injections to blind ones due to significantly lower VAS, improved range of motion and function, better symptom severity/ functional status scores, and fewer adverse effects.[21,22,26,27] Regarding accuracy and safety, ultrasound may improve the result of coccygeal injection with a deep-lying coccygeal tip adjacent to the rectum and sacral plexus.

In this study, blind and ultrasound -guided coccygeal steroid injections significantly decreased patients' pain scores at all subsequent visits. Despite significant positive intra-group outcomes, the intergroup analysis showed no statistically significant difference between the two groups regarding pain reduction in the VAS, Dallas pain score, and quality of life improvement.

In the study of Cunnington et al. on 184 patients with inflammatory arthritis, the accuracy and clinical outcome of ultrasound -guided and non- ultrasound -guided steroid injections being compared. Although they found ultrasound -guided injections more accurate, there was no significant difference in clinical outcomes between the two groups.[22] The ultrasound -guided shoulder injections compared to blind ones are reported in two studies by Raeissadat et al. and Naredo et al. The results of the first study on frozen shoulder showed that injection with and

without ultrasound guidance has the same statistical effectiveness in controlling pain and improving patients' performance despite better clinical (shoulder extension) results in the ultrasound -guided injection group. On the other hand, the second study on subacromial injection of the painful shoulder had shown that patients who underwent ultrasound injections had significantly higher improvements.[26,28] Similarly, in the study of Park et al. on acromioclavicular osteoarthritis patients on the effectiveness of blind injections in this joint, 100 patients were injected, 50 patients in each group. They showed a higher degree of VAS and patient performance improvement in the group injected by ultrasonography guidance and suggested injection accuracy as a significant outcome predictor at six months.[27] There is not much evidence for routine application of ultrasound in musculoskeletal interventions. The investigations also need to consider the hypothesis of different sonographic injection outcomes regarding the joint we are injecting and the injection purpose. Most ultrasound-guided procedures in this area are trials about ganglion impar block or caudal injections.[29,30]

The coccygeal blind injection can be accurate enough to reach the deep-laying palpable coccyx. Practitioners should consider that a noticeable amount of blind injections could be accurate. The experience of physicians in either ultrasound -guided or blind injection, the anatomy of the area, the background pathology, and the cost-effectiveness of the procedure are the factors to consider in the proper injection technique.

In conclusion, regardless of the technique (ultrasound -guided or unguided), a steroid injection is effectively used to manage chronic coccydynia. The therapeutic effect of both interventions remained up to 24 weeks after the intervention.

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