



Acupuncture in Adjunction to Corticosteroid Injection in Coccydynia Treatment: A Randomized Clinical Trial

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ABSTRACT

Background: Coccydynia is a painful disorder that usually resolves with conservative treatments. Corticosteroid injection is a common treatment. However, acupuncture has been considered an efficacious way of reducing chronic pain especially in musculoskeletal diseases. In this study we have assessed the efficacy of acupuncture in conjunction with corticosteroid injection in coccydynia treatment, and compared it with corticosteroid alone.

Methods and Materials: Patients ages 18 to 75 with at least 2 months of pain, Visual Analogue Scale (VAS) score of ≥ 4 , and pain on intra-rectal examination of coccyx were considered eligible. Eligible individuals were randomized to take either corticosteroid (CS) or corticosteroid plus acupuncture (CSA). Acupuncture sessions were conducted 2 times per week over a 4weeks period. VAS scores for pain were measured before injections and 4 and 12 weeks after injections. Also Dallas Pain Questionnaire (DPQ) was utilized at baseline and 4 weeks after injections.

Results: The VAS scores decreased in CSA and CS groups respectively with no significant differences between the groups. DPQ scores improved in all patients but the CSA group showed better scores in daily and work/leisure activities axes.

Conclusion: While no additional pain controlling effects was found with acupuncture, it was shown to be effective in enabling coccydynia patients to do daily and work/leisure activities.

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INTRODUCTION

Coccydynia refers to pain and discomfort in coccygeal area which is worst when sitting or standing up from the sitting position [1]. Coccyx is a triangular bone at the terminal part of the vertebral column. It serves as the insertion site for sacrococcygeal, sacrospinous, and sacrotuberous ligaments providing structural support and integrity in the pelvic area. Levator ani muscle is attached to the coccyx helping in voluntary control of bowel movements [2]. The coccyx along with ischial tuberosities provides the main support while seated [2].

Coccydynia is mostly considered as a symptom that can occur due to a variety of causes [1]. Single major trauma (e.g. childbirth, falling down) or repeated minor trauma (e.g. sitting in a poor posture) are both known as main etiologies of it [3] Postacchini and Massobrio [4] reported different coccyx configurations and proposed morphology as a probable underlying cause of the disease. Maigne et al [5] suggested luxation and hypermobility of the coccyx as possible etiologies of coccydynia. They also described obesity as a risk factor and reported 51% posterior luxation of the coccyx in obese patients. Some studies reported degeneration of disc and articular cartilage in coccyx [6] Sacral nerve root pathologies, muscle spasm, and inflammation of the soft tissue surrounding the coccyx, neoplasm, calcium crystal deposition, infections, and somatization disorder are other reasons that have been stated to cause coccydynia [2, 6].

To date, no epidemiologic studies have been performed to determine the overall incidence and prevalence of coccydynia. Obesity and female gender are considered as risk factors (5 times more common in women) and the mean age of onset of the disease is estimated 40 years [5, 7].

The diagnosis is mostly clinical. Other than classic symptom of coccygeal pain, the patients may present with dyspareunia and pain on defecation [2] Careful inspection and palpation for any sign of probable infection (e.g. pilonidal cysts) are necessary. During rectal examination moving the coccyx may elicit pain. Common blood tests and imaging studies help to rule out fractures, malignancies, and infections [2, 6] Mobility status of the coccyx can be determined via imaging studies [8].

Available treatment options are as diverse as the causes. A great number of patients respond to conservative measures like wedge-shaped coccygeal cushions, sitting posture correction, as well as hot and cold application, laxatives, and nonsteroidal anti-inflammatory drugs [2, 6] For more resistant cases minimally invasive treatments are being used, including: ganglion impar blocks or radiofrequency

thermocoagulation, intra-rectal manipulation and massage, extra-corporeal shockwave therapy, and local injections of anesthetics and steroids [2, 6, 9-11] A literature review in 2010 considered steroid injection superior to ganglion impar block and radiofrequency treatment [12] Fair treatment responses and few side effects (e.g. calcium deposition) with steroid injections have made them a favorite treatment choice [2, 13-15] Despite popularity of injections, there is no agreed preferred site or protocol for this approach [2] In few cases which all other measures fail, coccygectomy is the treatment of choice. Although good success rates have been reported with surgery, some authors propose longer periods of conservative therapy until we can consider surgery [6, 7] That is due to negative outcomes of surgery like post-surgical infections and the invasive nature of this approach [7]

Acupuncture is a traditional Chinese way of approaching diseases by needling the skin at specific points. They believed that life energy (known as qi) circulates in the body with a quality of Yin or Yang and any imbalance between these two creates diseases. Also they defined the specific points of acupuncture along the path of the qi known as meridians. Acupuncture has been valued in western medicine for years with various proposed mechanisms including: gate control theory of pain, diffuse noxious inhibitory control, neuropeptide and endogenous opioids release enhancement.[16, 17] Despite lack of an agreed explanation, evidence supports its effectiveness in treating chronic pain in different diseases [17, 18].

A number of clinical trials assessed the use of acupuncture in musculoskeletal disorders [19, 20]. In 2004, Trinch et al [21] reviewed 6 high quality clinical trials and strongly suggested acupuncture in acute relief tennis elbow pain. Another review by Vickers et al[18] considered it effective for pain control in back and neck pain, osteoarthritis, chronic headache and shoulder pain. Other authors also confirmed the efficacy of acupuncture in chronic knee and low back pain [22, 23].

Acupuncture is mostly considered a safe approach.[24-26] Infections, organ and nerve damage are complications that are waning due to more professionally trained acupuncturists [25].

According to its pain controlling properties we aimed to study the efficacy of acupuncture in conjunction with corticosteroid injection in coccydynia treatment and compared it with corticosteroid alone. We hypothesized that adjunctive acupuncture therapy can reduce the pain and improve the physical function of coccydynia patients. A Russian study (in 1989) assessed the use of acupuncture in the treatment of coccydynia in addition to physiotherapy, procaine-alcohol blockades, and massage of the

coccyx and the pelvic floor muscles and reported good response in most of the patients [27] To date we have not found any study assessing benefits of acupuncture in adjunction with steroids in coccydynia patients.

MATERIALS AND METHODS

This study was a parallel group randomized clinical trial with 1:1 allocation ratio. An experienced physiatrist visited all the patients with pain in coccygeal area. Individuals aged 18 to 75 with at least 2 months of pain, Visual Analogue Scale (VAS) score of ≥ 4 in any position (sitting, standing, or lying) and pain on intra-rectal examination of the coccyx were considered eligible. Patients with the following criteria were excluded from the study: sign of fracture on imaging, history of injection or manipulation in coccygeal region during last 6 months, diabetes, rheumatoid arthritis, malignancies, inflammatory bowel disease, sacral dislocation, myelomeningocele or spina bifida, infections in coccygeal area (e.g. pilonidal cyst), external hemorrhoids and anal fissures, radiating low back pain, pelvic floor muscle biofeedback for other problems, and coagulopathies.

The study was conducted in physical medicine and rehabilitation (PM&R) clinic of Firoozgar Hospital in Tehran, Iran, from April 2107 to March 2018. The protocol of the study was approved by the Ethical Committee of Iran University of Medical Sciences. All participants signed their written informed consent after receiving an explanation of the purpose and design of the study.

Participants were assigned to corticosteroid (CS), or corticosteroid plus acupuncture (CSA) groups. Baseline data were gathered after careful examination. Following prepping and draping, 2 ml of 2% lidocaine was injected in the coccygeal area for local anesthesia. Then 1 ml of 40 mg methylprednisolone was injected (with a 20gauge needle) in the maximal point of tenderness for individuals in both groups. Forty-eight hours after injections acupuncture sessions were started for the CSA group. These sessions were conducted 2 times per week over a 4week period. Needles were inserted at B48 and B27-34 acupuncture points and in trigger points of gluteal area (if there were any). The sizes of the needles were 0.4mm \times 60mm and 0.4mm \times 80mm for acupuncture points and trigger points respectively (diameter \times length). All interventions including injections and acupuncture were done by an experienced physiatrist.

All patients were prohibited from prolonged sitting until 48 hours after injections. During this period acetaminophen and cold application were prescribed for pain control. Everyone was provided with a wedge-shaped cushion and a thorough written and oral explanation of the Kegel

exercises. After 48 hours all participants were asked to perform Kegel exercises on a daily basis for a period of 4 weeks and to use wedge-shaped cushions in case of prolonged sitting.

Before interventions baseline data including age, gender and body mass index were gathered. The primary outcome of this study was a significant change in VAS scores. The VAS for pain was measured before the injections and 4 and 12 weeks after them. Dallas Pain Questionnaire (DPQ) was as secondary outcome measure. It was utilized at baseline and 4 weeks after injections to assess the impact of pain on different aspects of patients' lives. All assessments were done by a 2nd year PM&R resident. The VAS measures the quantity of pain in a subjective manner (ranging from 0 to 10). The DPQ assesses the degree of low back pain by measuring the following four aspects: daily activities, work/leisure activities, anxiety/depression and social interests.[28] It consists of 16 questions. The answering choices for each question comprised of 4 to 8 segments, labelled with percentage (0% to 100% from left to right). Moving from left to right, the point for each segment increases (starting from 0). The points of the questions measuring the same aspect are added and multiplied by a constant. The lower the final score is, the lesser that aspect is affected by pain.

To have a power of 0.80 with an α value of 0.05 and a β value of 0.20 and accounting for 10% dropout, a sample of 18 participants was calculated for each group.

Allocation sequence was generated using Excel 2016. Due to small sample size block randomization was performed with random block sizes of 4. Concealment of the allocation sequence from the aforementioned PM&R resident (who did the enrollment and all the assessments) was done using sequentially numbered, opaque and sealed envelopes. The envelopes were kept closed until the patients were introduced to the central office of the clinic for the interventions. Due to the design of the study only the outcome assessor and the statistician were blinded to the treatment groups.

All data were analyzed by means of SPSS version 24. The distribution of the baseline data was assessed using one-sample Kolmogorov-Smirnov test. T-test was used for normally distributed data and Mann-Whitney test for the other ones. Outcome assessment data were analyzed via mixed design ANOVA. The time of measurements was considered as a within-subjects factor and the group of treatment (CS, CSA) as a between-subjects factor. Also Bonferroni procedure was utilized for post hoc analysis. A p value of less than 0.05 was considered statistically significant.

RESULT

Out of 87 assessed individuals 43 patients were identified as eligible. Four patients did not participate in the study due to personal issues and three patients refused to sign the written consent. So 36 individuals were recruited and randomized to take either CS (n=18) or CSA (n=18).

Participants were all female with the age of 35.44± 10.91 and 37.88± 10.18 years in CSA and CS groups respectively (mean± SD). All 36 individuals successfully finished the study.

As demonstrated in Table 1, the baseline data did not differ significantly between groups.

Table 1: Descriptive statistics of the patients' baseline characteristics, and their comparison

Characteristic	Corticosteroid plus acupuncture (n=18) [°]	Corticosteroid (n=18) [°]	P value (t -test)
Age (year)	35.44 ± 10.91	37.88± 10.18	0.492*
BMI (kg/m ²)	25.88± 6.29	23.27± 2.90	0.152
Visual analogue scale for pain	6.11± 1.23	6.28± 1.07	0.650
Dallas Questionnaire Scores			
Day activities	42.33± 17.52	40± 11.31	0.424
Work/leisure activities	61.44± 19.29	53.94± 18.51	0.355
Anxiety/Depression	41.5± 19.5	45.84± 22.49	0.226
Social Interest	30.56± 17.39	39.72± 20.93	0.323

*Mann-Whitney U test

[°]Mean± SD

The results for VAS scores revealed only a significant main effect of time, F (1.7, 57.52) =217, p<0.001 (see Table 2, and Fig.1).

Table 2: Descriptive statistics of Visual Analogue Scale (VAS) and time-group interaction effects on it

Variable	Time of intervention	Study groups	Mean± SD	P-value for time-group interaction
Pain (VAS)	Baseline	Corticosteroid plus acupuncture	6.11± 1.23	0.691
		Corticosteroid	6.28± 1.07	
	After 4 weeks	Corticosteroid plus acupuncture	1.83± 1.04	
		Corticosteroid	2.33± 1.08	
	After 12 weeks	Corticosteroid plus acupuncture	2.78± 1.35	
		Corticosteroid	3.11± 1.56	

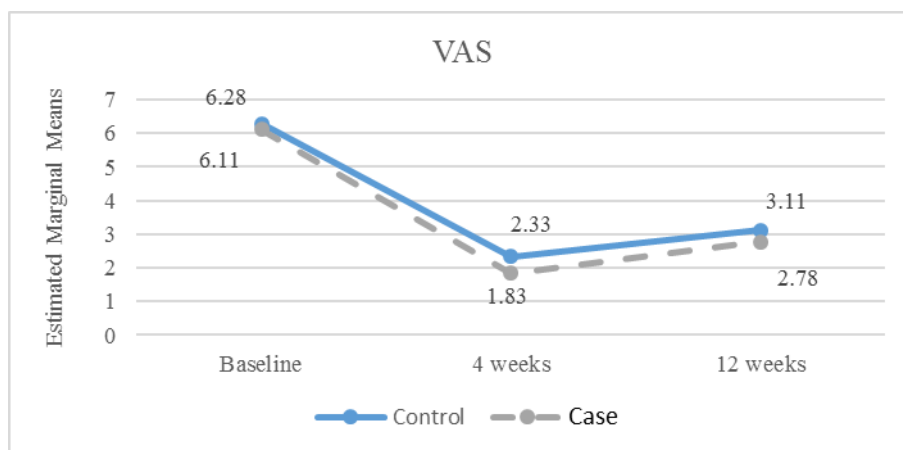


Fig.1: Comparison of the means of Visual Analogue Scale (VAS), between corticosteroid, and corticosteroid plus acupuncture groups, over different time points

Pair wise comparisons between the different time points (without group interaction), showed significant differences for all pairs (p<0.001 for all). Comparing baseline with 4 and 12-week

values, improvements were found inside each group (p<0.001 for both comparisons). Similarly, 12-week data improved in comparison to 4-week

values ($p=0.009$ and $p=0.001$ in CS and CSA groups, respectively)

Regarding DPQ scores a significant time-group interaction was observed in daily and work/leisure activities, $F(1, 34) = 7.9$, $p=0.008$, and $F(1, 34) = 7.65$, $p=0.009$, respectively (see Table 3). A main effect of time was also observed in

anxiety/depression and social interest axes, $F(1, 34) = 4.8$, $p=0.036$, and $F(1, 34) = 12.8$, $p=0.001$, respectively (see Table 3). Assessing the scores inside each group revealed meaningful changes of all axes (except the anxiety/depression one) in CSA group, and the daily activities axis in CS group (see Table 3).

Table 3: Descriptive statistics and mean differences of Dallas Pain Questionnaire values, before and 4 weeks after the interventions

Study Outcomes		Study groups	Before treatments	4 weeks after treatments	P value	Mean difference	P value
Dallas Pain Questionnaire	Daily Activities	Corticosteroid plus acupuncture	42.33±17.52	26.89±14.57	<0.001	15.44±7.81	0.008
		Corticosteroid	40±11.31	33.72±13.44	0.032	6.27±11.39	
	Work/Leisure Activities	Corticosteroid plus acupuncture	61.44±19.29	43.72±17.23	<0.001	17.72±8.53	0.009
		Corticosteroid	53.94±18.51	48.33±15.02	0.167	5.61±16.5	
	Anxiety/Depression	Corticosteroid plus acupuncture	41.50±19.5	36.11±16.46	0.057	5.39±11.19	0.489
		Corticosteroid	45.83±22.50	43.06±24.87	0.308	2.77±11.22	
	Social Interest	Corticosteroid plus acupuncture	30.56±17.39	37.67±13.99	0.007	-7.11±9.92	0.261
		Corticosteroid	39.72±20.93	43.39±21.49	0.070	-3.66±8.03	

Significance level_ 0.05

DISCUSSION

Coccydynia refers to pain around the coccyx. Due to severe discomfort in different positions including sitting down or standing up it has a great effect on patients' everyday life activities. The treatment is usually conservative. When the pain persists we consider using corticosteroids. Some cases may require more than one injection and coccyx manipulation. For more refractory cases surgery is the preferred choice of treatment.

Wray et al [1] compared steroid injection and coccyx manipulation with injection alone and reported 85% success in the manipulation group versus 60% of the injection group. Baloch et al [29] also reported a response of 70.7% with injection and manipulation in recalcitrant cases. In our study adding acupuncture to corticosteroid injection did not show any additional pain controlling effects. The VAS scores for pain improved significantly in all patients with no difference between the groups. A mild increase was also observed in the 12-week versus 4-week VAS scores which was again common between the groups. This increase may be due to short-term efficacy of corticosteroids in treating musculoskeletal disorders, which is also reported by many authors [30-32].

In daily and work/leisure activities axes of DPQ, CSA group showed better improvement. Shao-Chen Lu et al [33] stated that acupuncture has benefits for patients with spine associated pain by improving pain and physical functioning. The latter is in agreement with our study. Daily and work/leisure activities like sitting, walking, standing and personal care are strictly related to physical status of a person which is impaired in coccydynia patients.

This study was not designed to assess the use of corticosteroids in coccydynia but we should consider the significant effect of them in our study. After one month of injections we detected more than 40% decrease in the intensity of pain in both groups.

Small sample size was the major limitation of our study. Basic characteristics of individuals can greatly affect the final outcome. For example, it has been stated that acupuncturists consider 15% to 30% of patients as non-responders [34] Similarly, some animals do not respond to acupuncture. Non-responder rats were found to have higher levels of an anti-opioid molecule [34].

CONCLUSION

Despite no additional pain controlling effects, acupuncture was found to be efficacious in improving the ability of coccydynia patients to do everyday life and work activities. Future studies with larger sample sizes can help to draw firmer conclusions.

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