

Evaluation of Treatment of Coccydynia using Local Injection of Betamethasone-17 α ,21-dipropionate and 21-Disodium Phosphate versus Oral NSAIDs and Physiotherapy

Tarek Abdalla Ahmed, MD.

Orthopaedic Surgery Department, Faculty of Medicine, Minia University, Minia, Egypt.

ABSTRACT

Background Data: Coccydynia is defined as pain in the coccyx or tailbone area, usually caused by sitting acutely on a hard object. Because it often runs a chronic course, the management of this medical problem remains controversial. Different therapeutic options are available for the treatment of this condition.

Purpose: To evaluate the effectiveness of a local betamethasone-17 α ,21-dipropionate and 21-disodium phosphate injections versus NSAIDs and physiotherapy in its management.

Study Design: Prospective clinical cases study.

Materials and Methods: Forty-eight patients who presented with pain in the tailbone area for more than four weeks were recruited for the study. They were subdivided randomly into two groups: Group I patients were treated with a local injection with betamethasone-17 α ,21-dipropionate and 21-disodium phosphate (n = 24), whereas Group II were treated with oral NSAIDs and physiotherapy (n = 24). Oral diclofenac sodium (150 mg/day) with physiotherapy program was given to patients in Group II for six weeks. Clinical evaluation was based on the severity of the coccyx pain by Visual Analog Scales (VAS) at 1-, 3-, 6-, and 12-month follow-up and comparison to the baseline pain at presentation.

Results: The incidence was more in the third decade (52%, n = 25), with female overbalance (85%, n = 40). In Group I, the mean of VAS was 8.1 before treatment and after one month of treatment, the score reached 3.9 and improved to 0.2 at the end of one year. However, in Group II, the mean of VAS was 7.5 before treatment; then after one month, it changed to 6.6 and improved to 2.5 at the end of one year.

Conclusion: The reported outcome in this study suggests that local betamethasone-17 α ,21-dipropionate and betamethasone 21-disodium phosphate injections are more effective than NSAIDs and physiotherapy for the treatment of coccydynia. (2020ESJ224)

Keywords: coccydynia, local steroids injection, coccyx pain.

Address correspondence and reprint requests: Tarek Abdalla Ahmed, MD.
Orthopaedic Surgery Department, Faculty of Medicine, Minya University, Minia, Egypt.
Email: tarekabdallaahmed@gmail.com

Submitted: July 13th, 2020.

Accepted: September 10th, 2020.

Published: October 2020.

The article does not contain information about medical device(s)/drug(s).

No funds were received in support of this work.

The authors report no conflict of interest.

INTRODUCTION

The coccyx is believed to be a vestigial tail, or in other terms, the “tail bone.” The name coccyx is acquired from the Greek word for cuckoo due to its beak-like appearance. Coccydynia takes place in the lowest part of the spine due to sudden impact of a fall on a hard object, sitting improperly thereby straining the coccyx, or after childbirth pressure in women and rarely due to the undiagnosed presence of a sacrococcygeal teratoma.¹⁴ Women are affected five times more than men and it can occur at any age.¹⁴ There are no race associations with coccydynia. The onset of symptoms is attributed to putting direct stress on the coccyx. This area is affected by horseback riding, bicycling, or any activities that increase the pressure on the coccyx. Coccydynia is often characterized by pain that worsens with constipation. Sexual intercourse can aggravate symptoms, but pain may be relieved with bowel movement. Betamethasone-17 α ,21-dipropionate and 21-disodium phosphate is a glucocorticoid steroid with immunosuppressive and anti-inflammatory abilities.¹ There is no consensus on its coherent effectiveness as an anti-inflammatory and immunosuppressive.²

The purpose of this study is to evaluate the effectiveness of a local betamethasone-17 α , 21-dipropionate and 21-disodium phosphate injection versus oral and topical NSAIDs and physiotherapy in its management.

MATERIALS AND METHODS

This study was carried out at our university hospital between June 2015 and June 2017. It was a prospective randomized study of forty-eight patients presenting with coccyx pain with a mean duration of 6.2 ± 2.5 (range, 2–10) weeks. They were subdivided into two groups. Before starting the study, we explained the diagnosis and treatment options, their advantages and disadvantages,

and the strategy of our study. Written informed consent was taken from all patients; then, we asked every patient to choose one of the sealed envelopes for treatment allocation. The first group included 24 patients (5 men and 19 women) with a mean age of 43.5 ± 5.2 (range, 31–68) years, while the second group included 24 patients (3 men and 21 women) with a mean age of 44.25 ± 3.6 (range, 30–72) years. Most of them had taken some form of local treatment in the form of massage or icing. Five patients in Group I and four in Group II had a history of trauma with unremarkable radiographs. All patients who had pain on the coccyx aggravated by activities (horseback riding and bicycling), sitting that put direct pressure on the coccyx, constipation, and sexual intercourse and improved with bowel movement for at least two weeks were included. The exclusion criteria were as follows: a history of receiving previous treatment, abnormal radiographs, history of treatment with corticosteroids either locally or generally, history of contraindications to corticosteroids, suffering from piles, anal fissure or anal fistula, spinal canal stenosis, lumbar disc herniation or metastatic lesions, and duration of symptoms less than two weeks. Patients gave informed consent for their procedures and the study was approved by our hospital’s ethical committee.

Plain X-ray AP and lateral views were taken at first to exclude old fractures or deformities; then, an injection of local anesthetic was administered to the area to test whether the coccyx is involved or not. If immediate relief of pain in the coccyx had occurred, the anesthetic test was considered positive.¹² Then, a dynamic (sit/stand) X-ray and MRI were ordered to show whether the coccyx dislocates when the patient sits.⁴ The value of using dynamic X-rays on 48 patients who gave positive results with the anesthetic test was expressed as follows: no abnormality detected hypermobility, posterior luxation, anterior luxation, and spicule. At the same time, MRI was used to rule out pain referred from higher up the spine. Then, the patients were subdivided into two groups: Group I (n = 24) was treated by injection of 2 ml of betamethasone-

17 α ,21-dipropionate and 21-disodium phosphate mixed with 1 ml of 2% lidocaine given at the site of maximum tenderness. Group II (n = 24) was treated conservatively by oral analgesic anti-inflammatory drugs in the form of diclofenac (100–150 mg/day) and local application of diclofenac sodium 1% topical gel q.i.d. for six weeks without massage and physiotherapy in the form of pulsed ultrasound for 18 sessions (10 min each) in six weeks, three sessions/week. The Ultrasonic apparatus used was Phyaaction 190; average pulsed ultrasound intensity was 1.5 W/cm² at 1 MHz,

Patients were evaluated clinically after one month, three months, six months, and one year. The visual analog scale (VAS) was measured at the end of these intervals to follow the degree of improvement.

RESULTS

A total of 48 patients participated and completed this study after the exclusion of 7 patients who could not complete the follow-up. Eight patients (16.6%) were males and 40 (83.4%) were females. Comparing the sex distribution using the chi-square x²-test for categorical data resulted in statistical significance ($p < 0.001$). The condition is found to be more common in the age group of 30–39 years, followed closely by 40–49 years, indicating high prevalence in the third and fourth decade. The mean age in Group I was 44.8 ± 11.3 (range, 35–

68) and in Group II was 46.3 ± 12.3 (range, 30–72) ($p = 0.76$). Of them, five patients had controlled diabetes mellitus, three in Group I and two in Group II, and another two patients in Group I had osteoporosis. The pretreatment epidemiological and clinical data were homogeneous in both groups (Table 1).

Descriptive statistics was evaluated regarding the VAS scoring in the two groups. In Group I, results evaluated within one year revealed that before treatment, the mean of VAS was 8.1; after one month of treatment, the score reached 3.9; after three months, the VAS score reached 1.9; after six months, it reached 0.6; at one year, it improved to 0.2. On the other hand, in Group II, before treatment, the mean of the VAS was 7.5; after one month, it changed to 6.6; after three months, the VAS became 5.2; after six months, it changed to 3.9; at the end of one year, it improved to 2.5. Analysis of VAS improvement by comparing the deducted score points after one year in both groups revealed that the improvement in Group I was significantly more than that in Group II (Table 2). Moreover, statistically significant differences were observed when comparing the mean VAS before the treatment and after one year in both groups (Tables 3 and 4).

Pre- and posttreatment VAS scores show variation between the two groups in each follow-up visit; scoring indicates continuous improvement of all patients with rapid and more improvement in Group I than that in Group II (Figure 1).

Table 1. Preprocedural epidemiological parameters.

Parameters	Group I (n = 24)	Group II (n = 24)	p value
Age/years	44.8 ± 11.3 (35–68)	46.3 ± 12.3 (30–72)	0.76**
Male/female	5/19	3/21	0.27*
Duration of symptoms/weeks	6.4 ± 2.2 (3–10)	5.6 ± 2.9 (2–8)	0.12**
History of trauma	5	4	0.2**
Baseline VAS	8.1 ± 5.1	7.5 ± 4.9	0.15**

*Chi-square x²-test, **Mann–Whitney U test: for nonparametric quantitative data. Significant if p value < 0.05

Table 2. Comparison between both groups' Visual Analog Score before and after treatment.

	Before treatment		Posttreatment							
	Group I	Group II	1 month		3 months		6 months		1 year	
			Group I	Group II	Group I	Group II	Group I	Group II	Group I	Group II
Mean	8.1	7.5	3.9	6.6	1.9	5.2	0.6	3.9	0.2	2.5
Standard deviation	0.51	0.49	0.62	0.41	0.72	0.48	0.65	0.46	0.53	0.72
<i>p</i> value	0.15		<0.0001 *		<0.0001 *		<0.0001 *		<0.0001 *	

*Mann–Whitney *U* test: for nonparametric quantitative data.

Significant if *p* value < 0.05.

Table 3. Group I Visual Analog Score before and after treatment

1 year 0.2		Posttreatment				Before treatment
		6 months	3 months	1 month		
		0.6	1.9	3.9	8.1	
1 year posttreatment	0.2					
6 months posttreatment	0.6	0.029 *				
3 months posttreatment	1.9	<0.0001 *	<0.0001 *			
1 month posttreatment	3.9	<0.0001 *	<0.0001 *	<0.0001 *		
Before treatment	8.1	<0.0001 *	<0.0001 *	<0.0001 *	<0.0001 *	

*Mann–Whitney *U* test: for nonparametric quantitative data.

Significant if *p* value < 0.05.

Table 4. Group II Visual Analog Score before and after treatment.

1 year 2.5		Posttreatment/months				Before treatment
		6 months	3 months	1 month		
		3.9	5.2	6.6	7.5	
1 year posttreatment	2.5					
6 months posttreatment	3.9	<0.0001 *				
3 months posttreatment	5.2	<0.0001 *	<0.0001 *			
1 month posttreatment	6.6	<0.0001 *	<0.0001 *	<0.0001 *		
Before treatment	7.5	<0.0001 *	<0.0001 *	<0.0001 *	<0.0001 *	

*Mann–Whitney *U* test: for nonparametric quantitative data.

Significant if *p* value < 0.05.

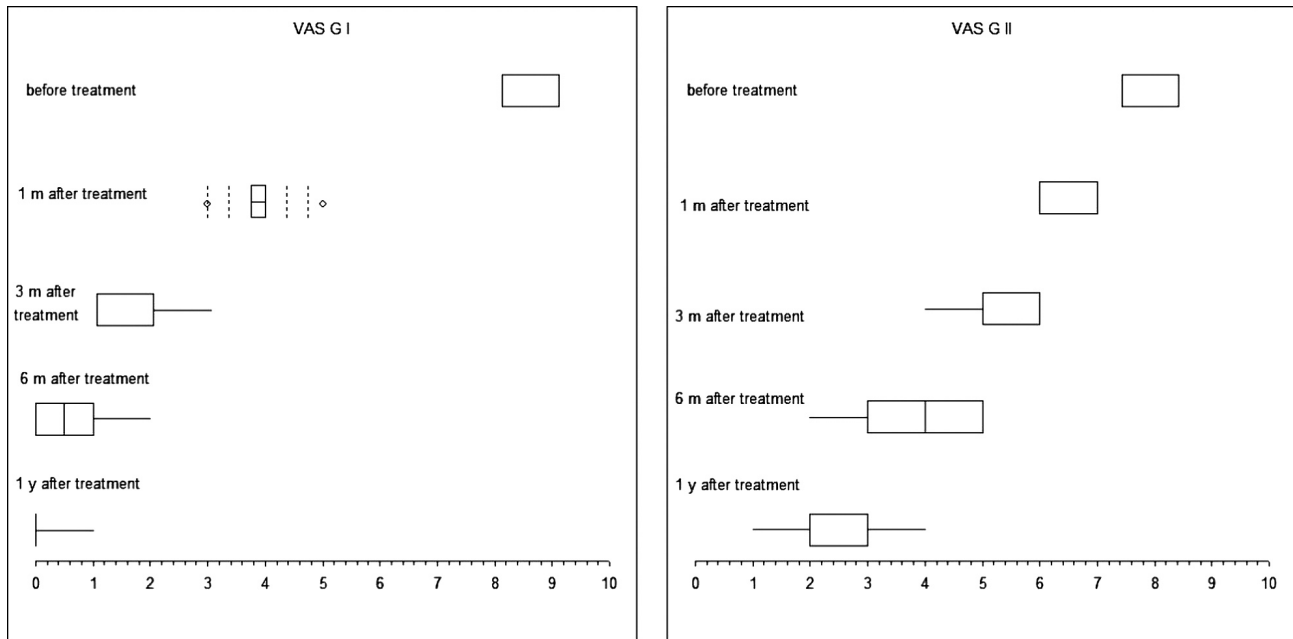


Figure 1. Box plots of pre- and posttreatment VAS scores show variation between the two groups in each follow-up visit; scoring indicates continuous improvement of all patients with rapid and more improvement in Group I than that in Group II. Right and left whiskers represent 1.5 times and -1.5 times interquartile range; right and left hinges represent 25% and 75% quartiles; middle represents median or 50% quartile.

DISCUSSION

Coccydynia is an expression meaning pain in the tailbone area, which is known as the coccyx.⁹ Usually, it is effectuated by sitting too precipitously, while sometimes overstressing the coccyx is induced while doing daily activities, like horseback riding and sitting on hard surfaces for a long period. It is also termed coccygeal pain, coccygodynia, coxalgia, and coccyx pain.⁹

It occurs in the lowest part of the spine, which is considered a vestigial tail, or the “tail bone.” Due to its beak-like appearance, it is called the coccyx, which is a name derived from the Greek word for the cuckoo. The coccyx itself consists of 3–5 vertebrae, some of which may be fused.¹⁶ The anterior aspect of the coccyx is concave, whereas the posterior aspect is convex. Both sides have transverse grooves that show where the vestigial coccygeal units had previously fused. The coccyx is attached to the sacrum from the dorsal grooves, being attached with either a symphysis or a true

synovial joint and the gluteus maximus muscle, the coccygeal muscle, and the anococcygeal ligament.⁸

The most common two causes of coccydynia are sudden impact due to fall and childbirth pressure in women. For the coccydynia diagnosis of the coccyx, we must determine if the pain is related to the coccyx and/or the attached muscles. This can be done by rectal examination and radiologically by MRI scans or high-resolution X-rays to exclude the other causes unrelated to the coccyx, such as Tarlov cysts and pain referred from higher up the spine.⁶ By the injection of local anesthetic into the area of the coccyx, we can say that the pain relates to the coccyx if immediate relief of pain occurred.¹² If the previous test is positive, we can do a dynamic (sit/stand) X-ray or MRI scan to reveal if the coccyx subluxates or dislocates when the patient sits.¹³

Maigne et al.⁹ worked on 208 patients using dynamic X-rays that were positive with the anesthetic test; the results were as follows: in 31% of the patients, not possible to identify the cause

of pain; 27%, hypermobility (excessive flexing of the coccyx forwards and upwards when sitting); 22%, posterior luxation (partial dislocation of the coccyx backward when sitting); 14%, spicule (bone spur) on the coccyx; 5%, anterior luxation (partial dislocation of the coccyx forwards when sitting). They also found that obese patients were most likely to have posterior luxation of the coccyx, while coccygeal spicules usually occur in thin patients.

Activities that put pressure on the affected area are bicycling, horseback riding, and other activities such as increased sitting that puts direct stress on the coccyx. The medical condition is often characterized by pain that worsens with constipation and may be relieved with bowel movement. Rarely, even sexual intercourse can aggravate symptoms.¹⁰ Because sitting on the tailbone area may increase the pain in the coccyx, it is recommended to use a pillow with a cutout back to be under the coccyx. Laxatives and fiber-rich diet that make the stool soft can be used if there is coccyx pain with bowel movements; anti-inflammatory drugs such as NSAIDs and skeletal muscle relaxants can be used if the pain persists.¹⁴

Thiele and George¹⁷ reported that in a series of 169 coccydynia patients, the cure rate was 63% for those patients who suffered from coccydynia after a frequent massage to the muscles attached to the coccyx via the anus, given by a physical therapist, chiropractor, or osteopath.

Foye et al.³ reported that treatment of coccydynia cases by the repeated injection and even a single injection at the ganglion impar by temporary or permanent nerve block sufficiently relieves pain. Foye et al.³ recommended the use of mesotherapy, which is used for various painful conditions for the treatment of coccydynia. Mesotherapy is done using many small injections of various substances in small amounts. Injections are made just under the skin with short needles or an electronic injector locally at the site of pain.

Prolotherapy can also be used for coccydynia; it is a ligament repair treatment done by injecting an

irritant solution such as glucose solution into the ligaments and the ligament/bone interface, and this solution causes inflammation that results in shorter and stronger ligaments. Khan et al.⁵ found that by treating 37 patients with prolotherapy, 30 patients experienced good pain relief, while the other seven patients had no improvement.

Clemens Franzmayr¹⁸ reported that injection of local anesthetic (lignocaine 1%) to trigger points, in cases of coccydynia repeatedly up to five times, has the same results as cortisone injections, but with no side effects. Betamethasone-17 α ,21-dipropionate and 21-disodium is a long-acting corticosteroid and a strong anti-inflammatory drug. In patients with coccyx pain, an injection of corticosteroid can reduce or eliminate the pain for a period of a month to a year, but not permanently for most patients. Repeated injections of corticosteroids can cause thinning of the tissue, so it is not recommended to give more than two or three injections¹⁴

Surgical treatment by excision of the coccyx (coccygectomy) can be done after failure of the conservative treatments to improve the coccydynia.⁷ Moreover, in cases of cancer of the coccyx, a coccygectomy can be done. If the pain persists after surgery, the drugs for chronic pain, such as tricyclic antidepressants, can be used to improve the pain.^{4,15}

In our study, the locally treated group showed better outcomes relative to the systemically treated group according to follow-up VAS results. Maigne and Tamalet¹¹ treated 86 coccydynia patients by local injection under fluoroscopic guidance and reported that 50% of the patients with subluxation or hypermobility and 27% of the patients with no visible abnormality experienced improvement, while Foye et al.³ reported that local injection at ganglion impar will lead to relief of pain in some cases and even after a single injection.

The limitations of the study include the small sample size of patients and the short follow-up period of the study; thus, we recommend a large size study group of patients for long-term follow-up, which includes other methods of therapy.

CONCLUSION

The reported outcome in this study suggests that local betamethasone-17 α ,21-dipropionate and 21-disodium phosphate injections are more effective than NSAID and physiotherapy in treating coccydynia.

REFERENCES

1. Betamethasone. The American Society of Health-System Pharmacists. Archived from the original on 2015-12-08. Retrieved Dec 2, 2015
2. Dvorak Z, Pavek P: Regulation of drug-metabolizing cytochrome P450 enzymes by glucocorticoids. *Drug Metab Rev* 42(4):621–635, 2010
3. Foye P, Buttaci C, Stitik T, Yonclas P: Successful injection for coccyx pain. *Am J Phys Med Rehabil* 85(9): 783–784, 2006
4. Howard PD, Dolan AN, Falco AN, Holland BM, Wilkinson CF, Zink AM: A comparison of conservative interventions and their effectiveness for coccydynia: a systematic review. *J Man Manip Ther* 21:213–219, 2013
5. Khan SA, Kumar A, Varshney MK, Trikha V, Yadav CS: Dextrose prolotherapy for recalcitrant coccygodynia. *Journal of Orthopaedic Surgery* 16(1):27–29, 2008
6. Kim NH, Suk KS: Clinical and radiological differences between traumatic and idiopathic coccygodynia. *Yonsei Medical Journal* 40(3):215–220, 1999
7. Kwon HD, Schrot RJ, Kerr EE, Kim KD: Coccygodynia and coccygectomy. *Korean J Spine* 9:326–333, 2012
8. Lin SF, Chen YJ, Tu HP, Lee CL, Hsieh CL, Wu WL, et al: The effects of extracorporeal shock wave therapy in patients with coccydynia: a randomized controlled trial. *PLoS One* 10:e0142475, 2015
9. Maigne J, Doursounian L, Chatellier G: Causes and mechanisms of common coccydynia: role of body mass index and coccygeal trauma. *Spine* 25(23):3072-3079, 2000
10. Maigne JY, Lagauche D, Doursounian L: Instability of the coccyx in coccydynia. *J Bone Joint Surg Br* 82:1038–1041, 2000
11. Maigne JY, Tamalet B: Standardized radiologic protocol for the study of common coccygodynia and characteristics of the lesions observed in the sitting position. *Spine* 21:2588–2593, 1996
12. Marx FA: Coccydynia/Levator syndrome, A therapeutic test. *Techniques in Coloproctology* 4(1), 1996
13. Mitra R, Cheung L, Perry P: Efficacy of fluoroscopically guided steroid injections in the management of coccydynia. *Pain Physician* 10:775–778, 2007
14. Patel R, Appannagari A, Whang PG: Coccydynia. *Current Reviews in Musculoskeletal Medicine* 1(3–4):223–226, 2008
15. Patrick O, Boudewijn VH: Antidepressant-induced analgesia in chronic non-malignant pain: a meta-analysis of 39 placebo-controlled studies. *Pain* 49(2):205–219, 1992
16. Postacchini F, Massobrio M: Idiopathic coccygodynia. Analysis of fifty-one operative cases and a radiographic study of the normal coccyx. *J Bone Joint Surg Am* 65(8):1116–1124, 1983
17. Thiele, GH: Coccygodynia: Cause and treatment. *Diseases of the Colon & Rectum* 6:422–436, 1963
18. www.coccyx.org>medical papers, Dr Clemens Franzmayr: Therapies successful on pain in coccygeal area, Article published in *New Zealand Doctor* 1999, reprinted here with the permission of the author, accessed on 12/12 /2020

الملخص العربي

تقييم علاج ألم العنق عن طريق الحقن الموضعي للبيتاميثازون 17α و 21 ديبروبيونات و 21 ثنائي فوسفات الصوديوم مقابل NSA و العلاج الطبيعي.

البيانات الخلفية: يُعرّف العنق على أنه ألم في العنق أو منطقة عظم الذنب ، يحدث عادةً بسبب الجلوس بطريقة حادة على جسم صلب. نظرًا لأنها غالبًا ما تسير في مسار مزمن، تظل إدارة هذه المشكلة الطبية مثيرة للجدل.

الغرض: تقييم فعالية حقن بيتاميثازون 17 و 21 ديبروبيونات و 21 ثنائي فوسفات صوديوم مقابل NSA و العلاج الطبيعي في إدارتها.

تصميم الدراسة: دراسة حالات سريرية مستقبلية

المرضى والطرق: 48 مريضًا كان متوسط عمرهم ، (31 إلى 72 عامًا) ، يعانون من ألم في منطقة عظم الذنب لمدة تزيد عن أربعة أسابيع ، تم تجنيدهم للدراسة. كان معدل الإصابة أكثر في العقد الثالث 52 % (ن = 25) ، مع زيادة التوازن بين الإناث 85 % (ن = 40). يتم تقسيمها إلى مجموعتين. تم توزيع مرضى المجموعة الأولى على التوالي على العلاج بحقن موضعية مع بيتاميثازون 17α و 21 ديبروبيونات و 21 ثنائي فوسفات الصوديوم (ن = 24) ، بينما تم علاج المجموعة الثانية بواسطة مضادات الالتهاب غير الستيروئيدية عن طريق الفم والعلاج الطبيعي (ن = 24). أعطيت المجموعة الأولى حقن 2 مل من بيتاميثازون 17α و 21 ديبروبيونات و 21 فوسفات ثنائي الصوديوم ممزوجة مع 2 مل من 2 % ليدوكائين لكل مريض في موقع أقصى قدر من الألم. وتم إعطاء في المجموعة الثانية (150 ملغ ديكلوفينات صوديوم) أو (20 ملغ بيروكسيكام / يوم) أو إيبوبروفين (1200 ملغ / يوم) مع برنامج العلاج الطبيعي للمرضى.

النتائج: يعتمد التقييم على شدة ألم العنق والحنان ومقياس (VAS visual analog scale) بعد شهر وثلاث أشهر وستة أشهر وبعد مرور عام ، والمتابعة والمقارنة مع السمات السريرية الأساسية و عند العرض تم تقييم النتيجة في غضون عام واحد، في المجموعة الأولى ، كان متوسط VAS 8.1 سم قبل العلاج وبعد شهر واحد من العلاج وصلت النتيجة إلى 3.9 سم ، وبعد ثلاثة أشهر وصلت درجة VAS إلى 1.9 سم ، وبعد 6 أشهر وصلت إلى 0.6 سم وتحسن VAS إلى 0.2 سم في نهاية عام واحد. بينما في المجموعة الثانية ، كان متوسط VAS 7.5 سم قبل العلاج ثم بعد شهر واحد تغير إلى 6.6 سم ، وبعد ثلاثة أشهر أصبح VAS 5.2 سم ثم تغير إلى 3.9 بعد ستة أشهر وتحسن إلى 2.5 سم بعد عام واحدة.

الخلاصة: إن حقن البيتاميثازون الموضعي 17 ألفا و 21 ديبروبيونات و 21 ثنائي فوسفات الصوديوم أكثر فعالية من العلاج الطبيعي و NSA ، لعلاج ألم العنق.