Effect of Dexamethasone/Lidocaine Iontophoresis in the Treatment of Rheumatoid Arthritic Knees

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ABSTRACT

The aim of the current study was to determine the effect of dexamethasone iontophoresis with and without lidocaine on pain perception at rest and during movement, effusion, active range of motion (AROM) and patient s global assessment of treatment efficacy (PGA) in rheumatic arthritic knees. Thirty patients suffering from unilateral rheumatoid arthritis (RA) of the knee joint participated in this study. They were randomly and equally divided into three groups, placebo group received iontophoresis (saline), second and third groups received dexamethasone and dexamethasone/ lidocaine respectively for six treatment sessions during two weeks. The results of the study indicated that dexamethasone iontophoresis with and without lidocaine was found to be effective in reduction of pain perception at rest and during movement, increase of AROM, reduction of effusion of the affected knees and the PGA was good. Statistical analysis between the three groups revealed that patients in group III (dexamethasone/lidocaine) had the most highly significant improvement in all parameters and had improvement in their clinical conditions. So, the results of this study strongly support and recommend uses of dexamethasone lidocaine for treatment of clinical symptoms in patients with RA and it might be useful for other similar pathologies.

Key words: *Iontophoresis, Dexamethasone, Lidocaine, Rheumatoid arthritis.*

INTRODUCTION

Arthralgia is closely related to malfunction of joints in rheumatoid arthritis. Synovitis one of the main lesions, causes inflammatory pains which, in combination with spasm in periarticular muscles, lead to immobility of the unused joint and adhesion of the tissues in the joint induced by inflammation which in turn leads to ankylosis, joint laxity and bony ankylosis [6]. In addition, disused joints induce atrophy in particular muscle and bone, leading to osteoporosis and finally resulting in destruction of the joint. Eventually, complete articular dysfunction such typical permanent deformation and bony ankylosis is caused[1].

Rheumatoid arthritis RA is a subacute or chronic, non-suppurative inflammatory polyarthritis affecting mainly the peripheral joint, usually symmetrical, running a prolonged course of exacerbation and remission. Joints have shown certain characteristic features including pain and tenderness, swelling, limitation of movement, muscle atrophy and deformity in a differing degrees according to

the severity of the changes[16]. In general, during a fairly active phase of the disease, the patient presents, in addition to joint troubles, a picture of ill health. Continuous pain leads to a sense of frustration, development of marked depression as the patient finds, she cannot play her part in family life and the warries and the problems of life are liable to give her a flare-up of the disease[22]. In the second stage, pain is often less noticeable at rest but more marked on movement or weight bearing. So, walking is a real difficulty if the joints of the lower limb are involved. In addition limited movement is another serious features of the disease.

In spite of continuous research, no cure has yet been found for the disease. Treatment therefore has three main objectives: improvement of health and so the ability to fight the disease, relief of symptoms and maintenance of the function of the joints.

Drug therapy has important role in reducing the signs and symptoms of active inflammation in RA.[15,22,23] Corticosteroids are the most dangerous of the antirheumatoid drugs because of its side effects and are not unless the benefits that are likely to accrue are worth the hazards. When steroids are first given the patient feel so much better that the tendency is to overwork damaged joints[21,23]. This is the honeymoon period. Once on steroids, withdrawal is difficult and the patient has to be weaned very slowly because her adrenals are not functioning. While, it was reported that corticosteroids are potent anti-inflammatory drugs which provide rapid relief of inflammatory symptoms in R.A.[3,22] They are however not curative and is not possible to present changes but it is possible to limit them. These steroid can blockage of the accumulation of the neutrophile and monocytes at inflammatory sites, suppression of lymphocytes proliferative responses to antigens, and a decrease in leukotriene and prostaglandin synthesis by inhibition of archidonic acid release from tissue phospholipids.[14,20] They may be also interfere with adhesion of inflammatory cells to stimulate endothelium near the sites of inflammation.[8] Some physicians also used topical hydrocortisone and intra-articular steroid injection for relief of pain and resolution of inflammation in this condition. On other hand, it was reported in the literature that corticosteroid and local injection have many hazards and side effects. A safe alternative to these therapy is iontophoresis which is the introduction of ions into the human tissues or exchange of ions within the tissues, for therapeutic purposes by means of an electric current[14]. It is safe, noninvasive, aseptic, effective and desirable method for administration of steroids to a localized regions of pathology.[13,19]

This method minimize the potential trauma due to the injection and risk of infection associated with and also avoids the pain anxiety caused by needle insertion.[19] Also, it reduces systemic side effects because only minute amounts of the drug delivered reach the systemic circulation while a high local drug concentration is achieved. The amount of medication delivered can be accurately regulated by controlling the quantity of electric current applied[12]. Iontophoresis has gained growing acceptance for local therapy and has proven its efficacy in different inflammatory conditions such as temporomandibular disorders[13,17,19], post operative swelling[5], carpal tunnel syndrome[12], tendinitis[5,18] and osteoarthritis.[15,16]

The purpose of this study was to determine the effect of Iontophoresis of dexamethasone sodium phosphate with and without lidocaine on pain perception, effusion, active range of motion and on patients global

assessment of treatment efficacy in patients with unilateral stage II rheumatoid arthritis of the knee joint.

Materials and Methods

Subjects:

Thirty patients (6 males and 24 females) with RA participated in this study. Their age ranged from 42 to 54 years. They were recruited from El-Hussin and Kasr El-Aini University Hospitals. Criteria for sample selection were: a) Stage II rheumatoid arthritis, b) unilateral RA in the knee joint, c) the rheumatoid serum factor (Rose - Waaler test) is positive, d) the erythrocyte sedimentation rate is high, e) no past history of allergy to lidocaine or dexamethasone medications, and, f) the skin is intact in the affected knee. Participants were divided randomly into three groups of equal number (10 patients each).

Equipment and Materials:

1- Iontophore 611 OPM (life Tech. Inc.), with disposable pouch electrode was used for treatment.
2- Universal goniometer was used to measure the active range of motion (AROM) of flexion and extension of the knee joint.
3- Tape measurement was used for round measurement of the knee joint.
4- Visual Analogue Scale (VAS) was used to measure pain perception intensity.
5- Dexamethasone Sodium phosphate 4%, lidocaine Hcl 2%, saline and plastic syringe.
6- Linkert - type scale was used for patients global assessment of treatment efficacy.

Testing procedure:

The measurable parameters were tested three times before the first session and after the first week and at the end of the second weeks except the patient-s global assessment of treatment efficacy was measured two times after first and second weeks of treatment.

- Pain perception intensity was measured at rest and during movement by VAS which is represented by a line scaled from 0 position which means no pain to 10 position which means unbearable pain. The patient was asked to mark at a point which refer to the degree of pain he/she feels.
- AROM of the affected knee was measured by universal goniometer. Each patient during assessment sat down on the edge of the table with the popliteal fossa away from it and her/his leg dangling free. The stationary arm was placed parallel to the lateral midline of the femur on the line from lateral condyle to the greater trochanter. The moving arm was placed parallel to the lateral midline of the fibula toward the lateral maleolus while the fulcrum of the goniometer was centered in the region of the lateral condyle of the femur. The examiner supported the goniometer arms and asked the patient to flex and extend his/her knee.
- Knee effusion of the affected knee was assessed by round measurement using a tape measurement.
- For patients global assessment of treatment efficacy (PGA), a fine-point Likert - type scale was used to evaluate PGA. Patients were asked to choose a number which closely matched the present condition of their treated knee as compared to their first visit.

Treatment procedures:

Each patient in this study received six treatment sessions in alternative days for two weeks. Placebo group (GI) received 2ml of NaCl (Saline) via Iontophoresis. Dexamethasone group (GII) received 2cc dexamethasone while dexamethasone with lidocaine (GIII) received 2cc dexamethasone with lidocaine both via Iontophoresis. In all groups, the patient were laying in supine with both knees flexed in approximately 30°, by placing a small pillow under the knee. The area to be treated was prepared by rubbing it with alcohol, then drying it thoroughly. The negative (delivery) electrode was placed on the medial surface of the knee joint line while the disperse electrode was placed over the medial mass of the triceps surae were delivered via the Iontophoresis unit for the 20 minutes.

RESULTS

The collected data were statistically treated by means, standard deviations, analysis of variance (ANOVA) and Chi-square test at level of significance 0.05 to study the difference between the three groups and difference between variables. The following variables were studied: pain perception at rest, pain perception during movement, AROM (flexion / extension), effusion and PGA in patients with unilateral RA of the knee joint.

***Pain perception at rest*:**

Table (1) and figure (1) showed the results of pain perception at rest and during movement.

Pain at rest in pre treatment period was not statistically significant between the three groups. After one week of treatment, ANOVA test revealed a highly significant reduction of pain ($F=5.529$ and $P<0.001$) in group II (Dexamethasone) and in group III (Dexamethasone and Lidocaine) compared to group 1 (placebo group) ($F=4.34$ and $P<0.084$). While after two weeks of treatment ANOVA test revealed high significant decrease of pain ($F=5.96$ and $P<0.007$) in group II and III than placebo group and improvement was seen in group III than group II.

Pain perception during movement:

Pain during movement in pre treatment period was not statistically significant between the three studied groups. After one week of treatment, ANOVA test revealed a significant decrease of pain ($F= 3.734$ and $P<0.037$) in group II and in group III than in group I "placebo group". While after two weeks of treatment the ANOVA test showed high significant decrease of pain during movement ($F= 9.245$ and $P<0.0009$) in group II and III than placebo, and more improvement was seen in group III than group II.

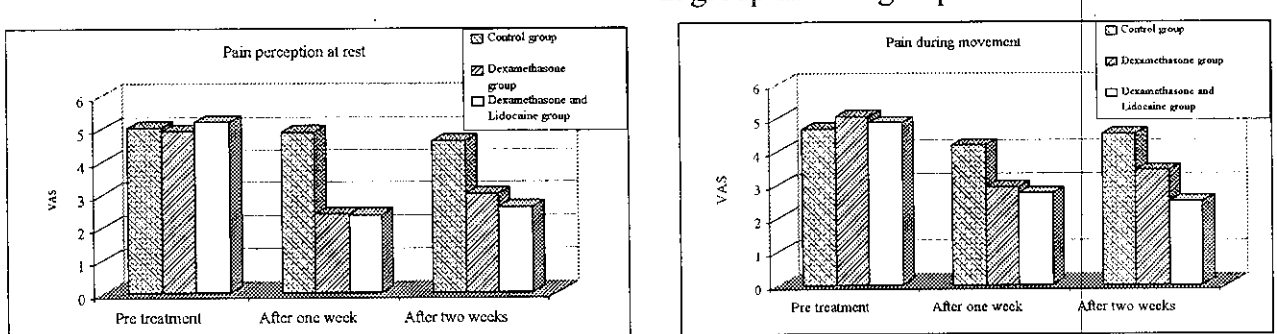

Fig. (1): Pain perception at rest and during movement for all groups.

Table (1): Means ± SD and ANOVA values for all groups.

	Pre-treatment			After one week			After two weeks		
	Group I	Group II	Group III	Group I	Group II	Group III	Group I	Group II	Group III
Pain at rest	5 ±1.088	4.9 ±0.772	5.19 ±0.904	4.87 ±0.914	2.41 ±0.569	2.35 ±1.203	4.6 ±0.87	3.01 ±0.59	2.6 ±1.19
F test & P value	F=2.34 & P<0.084			F=5.529 & P<0.001**			F= 5.96 & P<0.007**		
Pain during movement	4.65 ±1.164	5.03 ±0.923	4.84 ±0.912	4.18 ±1.745	2.91 ±0.81	2.72 ±1.166	4.51 ±1.233	3.43 ±0.718	2.49 ±1.131
F test & P value	F=0.537 & P<0.703			F=3.734 & P<.0.037*			F=9.245 & P<0.0009**		
AROM/flexion In degrees	101.1 ±7.49	100.7 ±8.166	99.3 ±7.602	102.5 ±6.948	108.3 ±7.227	104.3 ±8.206	102.7 ±6.881	108.4 ±7.489	107 ±7.557
F test & P value	F=0.148 & P<0.862			F=1.575 & P<0.225			F=1.594 & P<0.222		
AROM/extension In degrees	7 ±2	7.2 ±2.57	7.5 ±2.32	6.2 ±1.814	4.2 ±1.751	3.5 ±2.369	6.2 ±1.75	4.5 ±2.12	3.3 ±1.89
F test & P value	F= 0.119 & P<0.88			F= 4.922 & P<0.015*			F=5.722 & P<0.008**		
Round measurement of knee joint	40.1 ±4.812	43.04 ±4.811	39.49 ±2.807	40 ±4.84	42.25 ±4.523	37.55 ±2.904	40.08 ±4.752	42.12 ±4.673	36.1 ±5.06
F test & P value	F=1.995 & P<0.156			F= 3.339 & P<0.051*			F=4.013 & P<0.029*		

Active range of motion of the knee joint: Table (1) and figure (2) showed the results of flexion /extension AROM in all groups.

Knee flexion: There was no significant differences in ANOVA test between the three studied groups in pre treatment test, after one week and two weeks of treatment as appeared with ANOVA measures (F=0.148 and P>0.862), (F=1.575 and P>0.225) and (F= 1.594 and P>0.222) respectively. But statistically, as shown in the table there was increase in AROM of flexion within each group, that appeared clearly in the second and third group.

Knee extension: There was no significant differences in pre treatment measures (F=0.119 and P>0.88). While after one week of treatment the extension AROM was improved in group II and group III compared to group I (F=4.922 and P<0.015). After two weeks of treatment, group III showed highly significant improvement in extension AROM of knee joint, than group II, (F=5.722 and P<0.008).

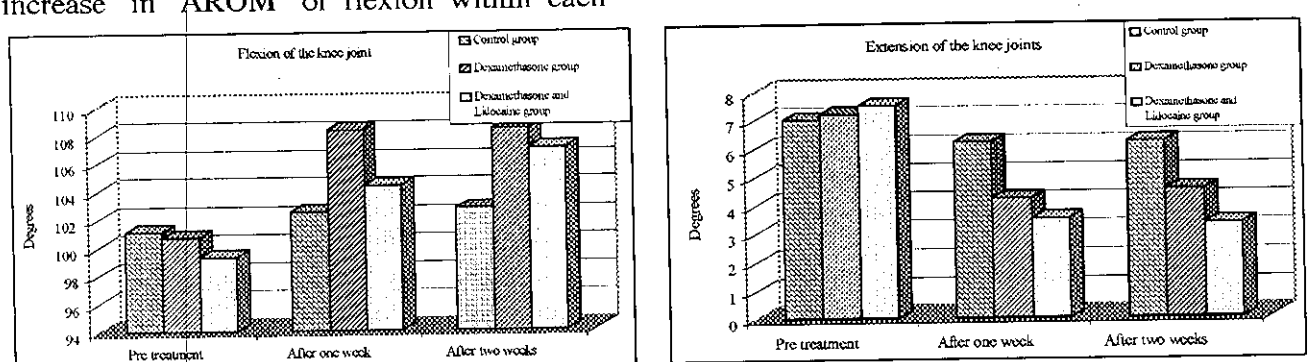

Figure (2): AROM of flexion and extension of the knee joints for all groups.

Knee effusion: After one week of treatment, ANOVA test as shown in table (1) and demonstrated in figure (3) revealed a significant decrease in knee effusion (F=3.339 and P<0.051) in group II and III than group I. Also, after two weeks from the initial treatment there was still significant decrease in knee effusion in group II and III (F=4.0.13 and P<0.029).

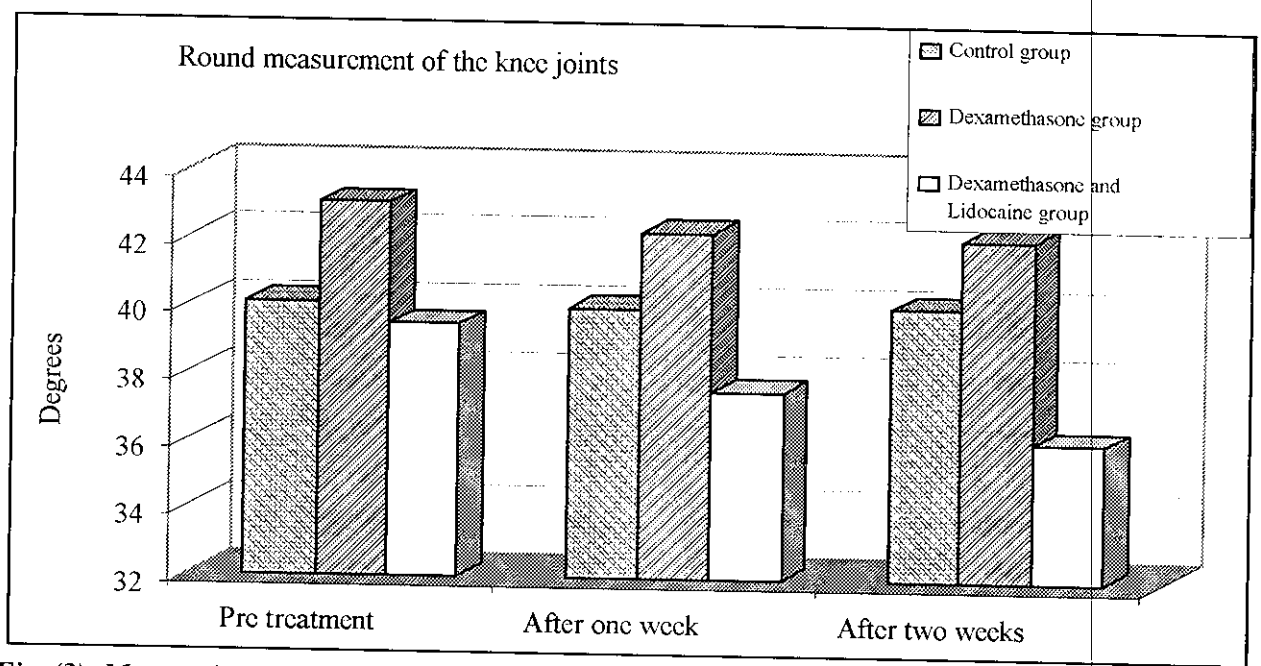

Fig. (3): Mean values for round measurement of the knee joint for all groups.

Patient s global assessment: After manipulating the data of the patients by total chi-square, there was significant improvement in PGA after one week (total Chi-square =14.467 and P<0.025) and after two weeks, (total Chi-square =14.939 and P<0.021). This significance appeared clearly in group III more than in group II. While in placebo group PGA was poor in the first and second weeks.

DISCUSSION

The main purpose of this study was to determine the effect of iontophoresis of dexamethasone with and without lidocaine on pain perception at rest and during movement, effusion, AROM and PGA in patients with unilateral RA of the knee joint.

The results of this study indicated that iontophoresis of dexamethasone with and without lidocaine was effective in reduction of joint pain at rest and during movement, increase of flexion/extension AROM, reduction of knee effusion and PGA was good. Statistical comparison by using ANOVA and chi-Square between the three groups showed that patients included in group III (dexamethasone / lidocaine) has the most highly significant improvement in their clinical condition compared to the other groups.

There were no available published research work on the effect of iontophoresis on RA for comparison. However similar results to

the present study were reported by other authors who used dexamethasone and lidocaine in the treatment of joint pain[14,15] and inflammatory conditions.[11,17,18,19] Therefore multiple assumptions were necessary in the design of this study.

Previous studies[2,7,20,24] have shown that lidocaine is considered to be a potent pain inhibitory agent while dexamethasone is considered to be steroidal anti-inflammatory agent. Therefore the results obtained in this study may be due to the double effect of lidocaine in pain inhibition and dexamethasone in reduction of local inflammation.[9] It was reported in the literature, when there is inflammation in the joint, the impaired synovial/lymphatic mechanism can congest the clearing of inflammatory by products, as well as compromising joint nutrition. A breakdown in this system can lead to a viscous cycle, in which inflammation leads to edema that promotes further damage by pressure and invokes more inflammation[13]. The inflammation-edema cycle causes aggravation and prevents resolution. Arthrodynamic impairment may lead to loss of function of the joint as in RA, the inflammation has exceeded its useful function and becomes harmful, leading to excessive destruction of the joint[10]. The inflammatory process also causes release of nociceptive promoting substances such as prostaglandin. Prostaglandin sensitize the nociceptors that are found in the capsule, ligament, and surrounding muscles, so that normal stimuli may become painful.[7]

This analgesic effect of lidocaine / dexamethasone in patients with RA may be due to suppression of a nociceptive process, presumably prostaglandin formation, and by reduction of inflammation and swelling which as a consequence of inflammation is considered another source of pain and restricted joint movement.

The benefit of steroid iontophoresis obtained by controlling the inflammation in and around the joint capsule may be due to slightly elevated steroid level that are probably resupplied for several hours by the higher concentration to the underlying structures[13,21,23]. The analgesic effect of lidocaine by blocking action of bradykinin and prostaglandin has been reported also by Passero et al.,[17]. Bertolucci[2] confirmed the effectiveness of both medication in reducing the signs and symptoms of osteoarthritis. Also, patients in the age above 45 years with primary diagnosis of cervical degenerative changes have demonstrated pain relief in shoulder tendinitis after steroid iontophoresis[18].

In the current study, it was appeared that dexamethasone/lidocaine iontophoresis reduce knee effusion, such reduction may cause reduction in pain perception resulting in recorded increase in flexion/extension AROM of the knee joint. Therefore, this treatment may provide an avenue to introduction of other treatment such as therapeutic exercise to maximize the therapeutic effect. The efficacy of dexamethasone lidocaine iontophoresis have been reported in the treatment of inflammatory conditions and joints pain supported our results. Hasson et al.,[11] stated that dexamethasone iontophoresis was effective in slowing the progression of muscle soreness and also its effect on reduction of edema was reported.[5,24] Hasson et al[10] found that dexamethasone iontophoresis was effective in improving the muscle performance as compared to the placebo in patients with RA of the knees. This result was confirmed recently by Lina et al.,[15]. For treatment of shoulder girdle myofascial syndrome, combined medication with iontophoresis administered

directly to the trigger point was found more effective than treatment with antispasmodic and analgesic medication.[4] Sabbahi and Nelson[19] have confirmed its effect also via-obtaining improvement of function and suppression of pain in TMJ patients.

It may be assumed that concentration of the medication in knee joint and a change in ions concentration in the extra-articular fluids had an effect which resulted in an improvement of clinical symptoms in this study. The anti-inflammatory action of dexamethasone occurs when it reaches the cellular membrane sites. It was reported in the literature that the depth of dexamethasone and lidocaine may mount to three centimeters which may be reach the joint capsule[20]. Also, Glass et al.,[9] showed that after dexamethasone was iontophoretically observed to monkey s skin, a small amount penetrated to the capsule and cartilage and hence may provide a useful in the treatment of inflammatory joint disease. Also, the duration of lidocaine action is 45 minutes while action of dexamethasone starts after 24-48 hours[14,20] which explained the superiority of improvement in the third group that combination of both drugs was iontophoretically delivered to the knee joint.

In the current study, iontophoresis with dexamethasone alone (group II) is less effective than that combined with lidocaine (group III). This effect of dexamethasone iontophoresis may be attributed to its degradation or its poor ionization. On other hand, it may have been iontophorized for a longer time than twenty minutes. In dexamethasone group, dexamethasone was delivered from (-ve) electrode, so the pH of drug solution will increase quickly to the level where dexamethasone may have been degraded and become less therapeutically effective.[14]

When mixed with lidocaine hydrochloride (+ve), the pH of the solution under the active electrode may not change.[8] It is reported that hydrochloride salts of local anesthetics conduct best at pH ~5[8]. This pH keeps almost all local anesthetic molecules in the positively charged form while increasing the pH tends to lower the conductivity by converting the positively charged molecules to unionized molecules[8,14].

Also, the significant clinical improvement in the knee joint could be attributed to the physiological effect of the direct current. The negative pole (cathode) produces an alkaline by reaction, is sclerolytic in effect and tends to increase nerve irritability, while the positive pole (anode) produces an acid reaction, is sclerotic in effect and tends to decrease nerve irritability[12]. Li and Seudds[14] stated that there was a mild heating effect secondary to vasodilatation elicited by the electrical stimulation. But this possibility was not completely true because the clinical improvement obtained in group II and group III did not found in the placebo group.

CONCLUSION

Based on existing data, iontophoresis of dexamethasone with and without lidocaine was found effective in reducing joint pain perception at rest and during movement, also in increasing flexion/extension AROM, reduction of knee effusion and PGA was good compared to placebo. Statistical analysis between the three groups revealed that patient in group III (dexamethasone and lidocaine) had the most highly significant improvement in all parameters and had improvement in their clinical conditions.

So the results of this study strongly support and recommend the uses of dexamethasone plus lidocaine for the treatment

of clinical symptoms in patients with RA and it might be useful for other similar pathologies due to its advantages.

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الملخص العربي

تأثير عمليه التأين بالديكسا مثيازون وليدوكاين في علاج الروماتويد بمفصل الركبة

يهدف هذا البحث دراسة تأثير عملية التأين باستخدام ديكساميثازون فوسفات الصوديوم وليدوكاين في علاج مرضى الروماتويد بمفصل الركبة. وقد أجريت هذه الدراسة على ثلاثين مريضا قسموا إلى ثلاث مجموعات متساوية العدد عشوائيا. كانت المجموعة الأولى هي الضابطة بينما أستخدم في علاج المجموعة الثانية عملية تأين الديكسا ميثازون أما المجموعة الثالثة فقد تم استخدام عملية تأين الديكسا ميثازون والليدوكاين. وقد تم علاج جميع المرضى في المجموعات الثلاثة في ثلاث جلسات أسبوعيا لمدة أسبوعين . أستخدم في عملية التقييم ما يلي: قياس شدة الألم أثناء الراحة وأثناء الحركة – قياس مدى حركة الثني والفرد للركبة. قياس محيط الركبة – قياس كفاءة العلاج في مستوى تحسن المريض العام. وقد تم التقييم على ثلاث مراحل. المرحلة الأولى قبل بداية العلاج والثانية بعد العلاج بأسبوع والمرحلة الثالثة في نهاية العلاج. وقد أكدت نتائج هذه الدراسة كفاءة العلاج بالتأين في مرضى الروماتويد وبمقارنه نتائج مستوى التحسن في المجموعات الثلاث كانت هناك فروقا ذات دلاله إحصائية عالية في المجموعة الثالثة وأيضا فروقا ذات دلاله إحصائية في المجموعة الثانية أما المجموعة الضابطة فلم يكن لها دلاله معنوية. وبذلك يعد العلاج بالتأين علاجا فعالا وبديلا للوسائل العلاجية الأخرى لما له من مميزات تفوقها. وينصح باستخدام العلاج بالتأين باستخدام ديكسازون وليدوكاين معا في علاج مرضي الروماتويد ومع الأمراض الأخرى المشابهة لما حققه من نتائج فعالة ذات دلاله إحصائية عالية.