

Effect of Ketoprofen Iontophoresis on Treating Postnatal Coccydynia

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ABSTRACT

This study was performed to investigate the effect of ketoprofen iontophoresis on treating postnatal coccydynia. Thirty volunteers multiparous women suffering from postnatal coccydynia for at least six weeks after vaginal delivery were participated in this study. They were referred from the outpatient clinic of gynecology and outpatient clinic of orthopedic in Kasr Aini Hospital. Their age ranged from 25 to 35 years old, parity from 2-3 times and their body mass index not exceed 30 kg/m². they were divided into two equal groups (A and B). Patients in group "A" received ketoprofen iontophoresis (200 mg) on the coccygeal region for 30 minutes /session, 3 times / week for four weeks (12 sessions) while patients in group "B" received ketoprofen intramuscular injection (200mg) day after day (12 ampoules). Both groups were advised to use a well padded seat with a gel cushion when sitting to decrease pressure on coccyx. In addition , to use stool softeners and increase both fibers and fluids in diet to decrease constipation . Patients in both groups were evaluated by present pain intensity (PPI) scale and plasma cortisol level before as well as after the end of treatment period . The results of this study showed highly significant decrease (improvement) in pain intensity and plasma cortisol level in group " A" than group "B" after treatment period. So, it could be concluded that ketoprofen iontophoresis is an effective physical therapy modality alternative to ketoprofen given by intramuscular injection for treating postnatal coccydynia.

Key words: Iontophoresis-Coccydynia-Plasma Cortisol Level.

INTRODUCTION

Coccydynia is a medical term means pain and inflammation of the coccyx or tail bone without any significant radiation or associated low back pain¹⁵. The ratio of coccydynia is 9:1 for female: male. It is more common in women, because the ischial tuberosities are more spread apart placing the coccyx at risk of injury. In

addition, the coccyx is more exposed and prominent in women than in men⁶. The coccyx serves an important function which being an attachment site for various muscles as levator ani muscles and gluteus maximus. Also, it is a weight-bearing structure with the bilateral ischium⁴. Coccydynia can frustrate patients and significantly impair quality of life. It is usually not permanent but may become very persistent and chronic if not controlled⁹. Various etiologies have been described for coccydynia. The most common are falls resulting in direct injury to the sacroccoccygeal junction. Another common etiology is childbirth which is usually related to damage of the sacroccoccygeal ligaments during vaginal delivery and passage of the fetus through birth canal which may cause acute trauma to the coccyx and this is further aggravated by forceps delivery¹. At the end of the 3rd trimester of pregnancy, certain hormonal changes enabled the sacroccoccygeal junction to soften and become more mobile. This increased mobility allows for more flexion and extension which may result in stretching and a permanent change in the resting tension of the ligaments and muscles that surround and attach to the coccyx¹⁴. Unlike fractures which can remodel, these injuries can cause repeated forced out of the sacroccoccygeal junction of its normal position causing repetitive trauma of the surrounding ligaments and muscles attached to the coccyx and resulting in inflammation of these tissues with pain and soreness when sitting or with straining. Its healing is prevented by continued movement resulting in further damage and perpetuation of the cycle²⁴.

The main symptom of coccydynia is localized pain, which may be severe and of long duration ranged from three months to few years²⁹. This pain is worsened with constipation. Also, hip extension activities as stair climbing and rapid getting from sitting to

standing increased the coccydyneal pain^{17,29}. In fact, treatment for coccydynia generally falls into either conservative management or surgical intervention^{18,30}.

Conservative management begins with the use of a non-steroidal anti-inflammatory drugs to reduce inflammation and pain coupled with a gel cushion when sitting to decrease coccygeal pressure and local irritation. If this therapy failed, topical injection of corticosteroid or non-steroidal anti-inflammatory drugs may be used^{5,10}. Also, digital manipulation of the coccygeal ligaments as well as massage of the pelvic floor muscles have been described to help decreasing pain but they were found to have only temporary effect²⁰. Ice or hot packs, laser, ultrasound and TENS application may be useful and may decrease symptoms of coccydynia^{8,16,20}.

If the coccydynia is of traumatic origin including delivery, it was advised to use non-steroidal anti-inflammatory drugs and non-constipating analgesia together with local application of ice^{23,24,27}. When patients have unrelenting pain, a surgical resection of the coccyx can be performed to remove the irritated bony prominence²⁶. Iontophoresis is a process that enhances the delivery of drug through a biological membrane via the application of low intensity electrical currents. It offered several advantages over oral and injection drug delivery²⁷. Iontophoresis is becoming widespread today with many pharmacist compounding solution for this mode of administration. It has been called as a method of making needle less injection. It is non-invasive, painless, sterile and tissue damage due to needle penetration is avoided. It has been successfully used to treat edema, inflammation, pain and various skin conditions^{7,28}. Ketoprofen is a non-steroidal anti-inflammatory medication. It is useful in treating pain and inflammation particularly osteoarthritis and musculo- skeletal injuries. It is an excellent alternative when corticosteroids are ineffective or contraindicated¹⁰. Usually ketoprofen iontophoresis solutions are used 3 times per week to treat acute or chronic conditions. It is safe to be used up to 4 times per day for several weeks and its effects usually occurs within 3 to 4 treatment

sessions¹³. This study was conducted to investigate the effect of ketoprofen iontophoresis on treating postnatal coccydynia.

SUBJECTS, MATERIALS AND METHODS

Subjects

This study was carried out on thirty volunteers multiparous women suffering from postnatal coccydynia for at least six weeks after vaginal delivery. They were referred from the outpatient clinic of gynecology and outpatient clinic of orthopedic in kasr Aini Hospital.

Patient with neurological diseases, skin diseases, genital prolapse, deformity of the back and / or coccygeal fracture were excluded. Their age ranged from 25 to 35 years old, parity ranged from 2-3 times and their body mass index not exceed 30 Kg/m².¹⁹ They were divided randomly into two equal groups (A and B). Group "A" consisted of 15 patients who received ketoprofen iontophoresis (200 mg) on the coccygeal region for 30 minutes / session, 3 times / week day after day for four weeks (12 sessions). Group "B" consisted of 15 patients who received ketoprofen intramuscular injection (200 mg) day after day for one month (12 ampoules). Additionally, both groups were advised to use a well padded seat with a gel cushion when sitting to decrease coccygeal pressure. Also, they were advised to use stool softeners and increase fibers, fluids in diet to decrease constipation. Informed consent form were signed by each patient before starting the treatment.

Materials

I. For evaluation:

A. Present Pain Intensity Scale: It is a graphic rating scale with numerical values placed equidistantly along the line. The descriptors and numbers help the patient to place her estimate on the line. (0 - 4).

It was used to assess pain for all cases in both groups (A and B) before and after the end of treatment periods.

B. Blood Sample Analysis: A sample of blood for each patients was drawn and analyzed to estimate plasma cortisol level for both groups

(A and B) before and after the end of treatment periods.

II. For treatment:

- 1- Iontophoresis: It is a light weight portable iontophoresis device Inc. model 6110 M in Houston, Texas, USA. It is a device provided direct current (0-5 mA) that connected with two disposable electrodes, one active and other one is dispersive electrode.
- 2- Plinth was used for iontophoresis application.
- 3- Pillows were used under the head and abdomen to support head and straighten the lumbar curve to comfort and relax the patient during treatment sessions.
- 4- Cotton and alcohol were used for cleaning the coccygeal area before electrodes placement.
- 5- Disposable syringes were used for drug injection into the active electrode and for drainage of venous blood samples to estimate plasma cortisol level for both groups (A and B) before as well as after treatment periods.

Procedures

I. Evaluative procedures:

A careful history taking and dynamic x-ray to confirm diagnosis were performed²⁵. Then, each patient was asked to score her intensity of pain by using present pain intensity scale. Also, a fasting blood sample of 5 cm³ was drawn from the anticubital vein and analyzed to estimate plasma cortisol level^{11,21}. This was performed for all patients of both groups (A and B) before and after treatment.

II. Treatment procedures:

Group (A): Each patient in this group was treated by ketophen iontophoresis (200 mg), 3 times / week for four weeks (12sessions)^{10,12,27}. The duration of each session was 30 minutes. The patient was asked to evacuate her bladder before starting the treatment session to make sure that she was relaxed. Then, she was instructed briefly and clearly about the nature of iontophoresis and its values in treating pain and inflammation to gain her confidence and cooperation throughout the study. Each patient was asked

to lie in a comfortable prone lying position on the plinth with pillows under the head and abdomen.

The basic principles for application of iontophoresis technique would be achieved by the following:

- The skin of the coccygeal area was prepared by cleaning with alcohol to decrease skin resistance and chance for skin irritation also.
- The ketoprofen solution (200 mg), was injected in small chamber of the active electrode.
- The active electrode had semi-permeable membrane which was adhered to the patient skin over the desired site of application with care to maintain a good contact between the skin and the electrode throughout the treatment session.
- The dispersive electrode was placed at near site with a suggested distance about one electrode between active and dispersive electrodes^{7,16}.

Session was started by low amplitude (1 – 2 mA) for the initial period of treatment (10 minutes) then the current was increased for the remainder of session (20 minutes). The intensity was increased gradually till the patient reported tingling sensation, if pain or burning sensation elicited, the intensity was decreased. The treatment was given 3 sessions / week for four weeks (12 sessions) each session was 30 minutes.

Group (B): Each patient in this group was treated by ketoprofen intramuscular injection (200 mg) day after day for one month (12 ampoules).

Both groups (A and B) were instructed to use a well padded seat with a gel cushion when sitting to decrease coccygeal pressure. Also, they were advised to use stool softeners and to increase fibers and fluids in their diet to decrease constipation.

Statistical Analysis

Data were summarized using mean, standard deviation and percentage of change. The student's t-test was used for comparing the data collected from both groups before and after treatment periods.

RESULTS

The results of this study revealed that the mean values of PPI scale before starting and after the end of treatment periods for both groups (A and B) were $(3.29 \pm 0.78, 1.20 \pm 0.89)$ and $(3.18 \pm 0.04, 2.50 \pm 0.53)$ respectively. The mean differences were (2.09 ± 0.98) and (0.68 ± 0.51) with percentage of change (improvement) equal 63.5% and 21.4% respectively in both groups A and B. Group (A) showed highly significant ($P < 0.001$) decrease after than before treatment. While, there was significant decrease ($P < 0.05$) only in group (B) after than before treatment. When comparing both groups together (A and B) after treatment, a highly significant ($P < 0.001$)

decrease (improvement) was found in group (A) than group (B) (Table 1 and Fig. 1,2).

The mean values of plasma cortisol level before starting and after the end of treatment periods for both groups (A and B) were $(9.38 \pm 2.86, 6.18 \pm 2.09)$ and $(9.26 \pm 2.91, 7.69 \pm 2.03)$ respectively. The mean difference were (3.20 ± 0.77) and (1.57 ± 0.88) with percentage of decrease (improvement) equal 34.12% and 16.95% respectively in both groups A and B. Group A showed highly significant decrease ($P < 0.001$) after treatment than before. While there was significant decrease ($P < 0.01$) in group B after treatment. When comparing both groups (A and B) together after treatment, a highly significant ($P < 0.001$) decrease was found in group (A) than group (B) (Table 2 and Fig. 3,4).

Table (1): PPI scale before and after treatment periods for both groups.

	Group (A)	Group (B)
Before treatment	$3.29 + 0.78$	$3.18 + 0.04$
After treatment	$1.20 + 0.80$	$2.50 + 0.53$
Mean Difference	$2.09 + 0.98$	$0.68 + 0.51$
T.Value	15.32	12.24
P.Value	< 0.001	< 0.05
% of change	63.5 %	21.4 %

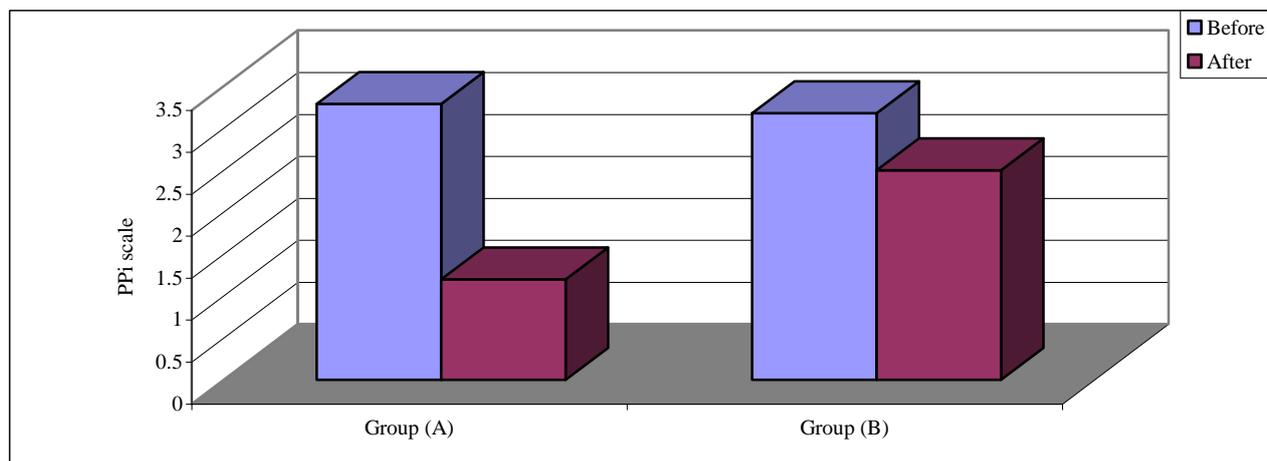


Fig. (1): PPI scale before and after treatment periods for both groups.

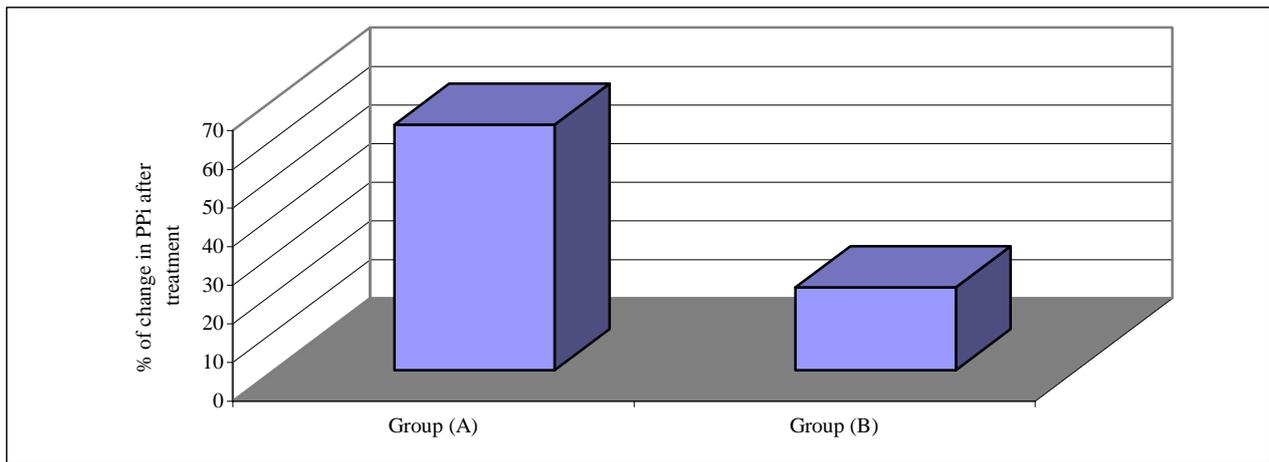


Fig. (2): Percentage of change (decrease) in PPI scale after treatment for both groups (A and B).

Table (2): Plasma cortisol level before and after treatment periods for both groups (A and B).

	Group (A)	Group (B)
Before treatment	9.38 + 2.86	9.29 + 2.91
After treatment	6.18 + 2.09	7.69 + 2.03
Mean Difference	3.20 + 0.77	1.57 + 0.88
T.Value	10.02	6.04
P.Value	< 0.001	< 0.01
% of change	34.12 %	16.95 %

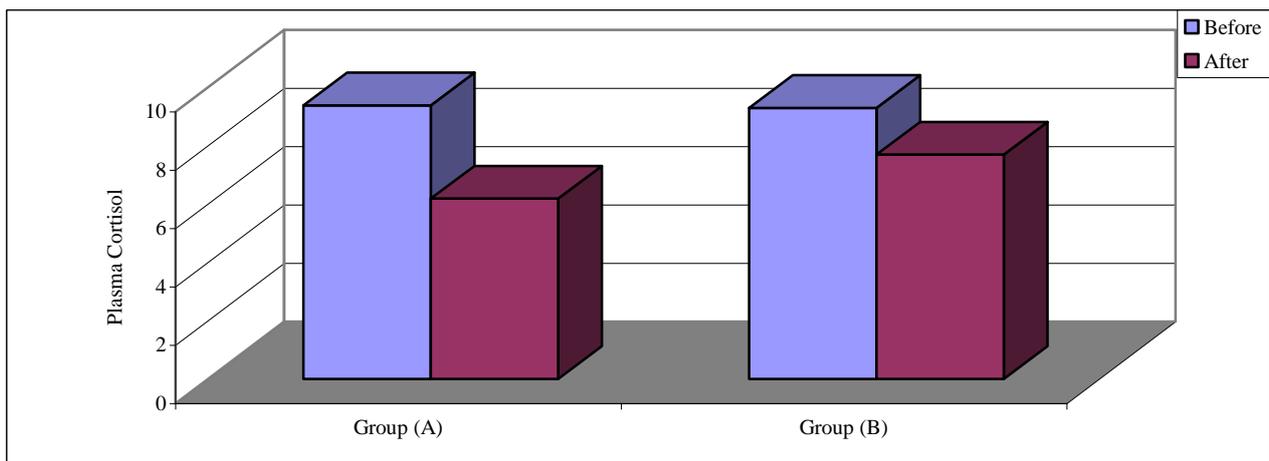


Fig. (3): Plasma cortisol level before and after treatment periods for both groups.

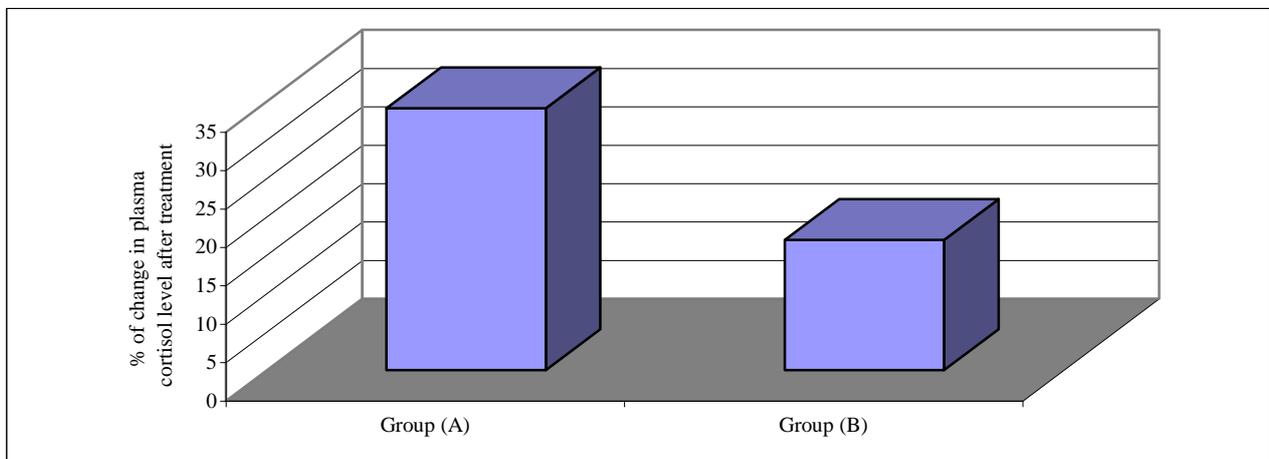


Fig. (4): Percentage of change (decrease) in plasma cortisol level after treatment for both groups (A and B).

DISCUSSION

Coccydynia is a painful condition of the terminal portion of the spine. It can result from varying number of causes, parturition being one of them^{17,24,26}. The condition is common in females than in males because the coccyx is more exposed and prominent in women than in men¹. The typical patient with coccydynia has been described as a female who has either sustained direct trauma to the coccyx or injured coccyx during child birth^{6,14}. This medical condition is often characterized by pain that worsens with constipation and may be relieved with bowel movement. Also, hip extension activities as stair climbing and rapid getting from sitting to standing increased the coccydyneal pain²⁹.

Many different treatment have been proposed for this condition including ultrasonic therapy^{18,20} heat or cold application, laser and TENS⁸. Rest, avoiding re-injury to the affected area, antiinflammation and pain medication can relieve symptoms. If coccydynia is persistent, it can be treated with topical anti inflammatory and analgesic injections. When pain is unrelenting a surgical resection of the coccyx can be performed^{20,22,30}.

Since sitting on the affected area may aggravate the condition, a cushion with a cut out at the back under the coccyx is recommended. Iontophoresis is a non-invasive technique used to deliver drugs across the skin for management of the inflammation and pain in various conditions^{2,3,7,8,10}. Key advantages of iontophoretic drug delivery include the avoidance of pain and the possibility for infection, inflammation and fibrosis associated with continuous needle injection^{10,23}. It reduces side effects of drug and permits its use with short biological half of life because the drug is delivered directly to the target organ. It eliminates gastrointestinal incompatibility, enhances patients compliance with convenient and non invasive regimen^{2,10}. This study was performed to investigate the effect of ketoprofen iontophoresis on treating postnatal coccydynia. The results of this study showed a statistically highly significant decrease in pain intensity and plasma cortisol level ($P < 0.001$)

in group "A" while, it showed significant decrease ($P < 0.05$ and $P < 0.01$) only in group "B" after treatment. So, the decrease was highly significant ($P < 0.001$) in patients who received ketoprofen iontophoresis (group A) than patients who received intramuscular ketoprofen injection (group B).

These results agreed with Grand et al., 2007¹⁰ who compared which is more effective, safe and easy, the fentanyl iontophoresis or intravenous analgesia with morphine for controlling pain after major abdominal or orthopedic surgery. They concluded that both methods have the same effect but fentanyl iontophoresis is safe as it enabled needle free, compact, self contained, self adhesive and it was applied to the patient's upper and outer arm or chest than intravenous injection.

Also, the effectiveness of naproxen (non steroidal anti-inflammatory drugs) applied by topical iontophoresis or by phonophoresis have been compared in the treatment of lateral epicondylitis. Their results suggested that both of them were equally effective electrotherapy methods to treat this condition³. Ketoprofen can decrease pain and inflammation through definite mechanisms as it inhibits prostaglandin synthesis and cyclooxygenase. Cyclooxygenase is an enzyme which catalyzes the synthesis of cyclic endoperoxidases from arachidonic acid to form prostaglandins²³. El-Kosery et al., 2006⁷ investigated the effect of dexamethasone sodium phosphate iontophoresis in treating chronic pelvic inflammatory disease in women. They found highly significant decrease in pain score as well as inflammation of the pelvis after the end of treatment program and it was concluded that iontophoresis is an effective physical therapy modality alternative to drug given orally or by injection in chronic pelvic inflammatory disease. Anderson et al., 2003² confirmed that iontophoresis application delivered greater amount of ketoprofen down to fascia compared with passive drug delivery. Maigne 2001¹⁸ concluded that iontophoresis is a useful and effective alternation to injections, oral medication and transdermal gels or patches. It provides a relatively painless option for patients who are reluctant to receive injection,

it minimized the potential for tissue trauma from injections with few side effects. The pronounced decrease in plasma cortisol level in group "A" is supported by Morgan et al., 2001²¹ who reported a decrease in cortisol level associated with decreased pain. Also, they found a positive correlation between visual analogue scale results and plasma cortisol level. So, it could be concluded that ketoprofen iontophoresis is an effective physical therapy modality alternative to drug given by intramuscular injection for treating postnatal coccydynia.

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الملخص العربي

تأثير التآين الكهربى بالكيتوبروفين فى علاج الآم العصعص لدى السيدات بعد الولادة الطبيعىة

أجريت هذه الدراسة لفحص تأثير التآين الكهربى بالكيتوبروفين فى علاج الآم العصعص لدى السيدات بعد الولادة الطبيعىة . شاركت فى هذه الدراسة ثلاثون سيدة متطوعة تعانين من الآم الفقرات العصعصية بعد الولادة الطبيعىة وقد تم اختيارهن من العيادة الخارجىة لقسم العظام وقسم أمراض النساء بمستشفى قصر عينى الجامعى . تراوحت أعمارهن ما بين 25-35 عاماً وعدد مرات الولادة بين 2-3 مرة ومعدل كتلة الجسم كانت لا تزيد عن 30كجم/2م لأي منهن . تم تقسيم المريضات لمجموعتين متساويتين فى العدد (أ،ب) وتم علاج المجموعه (أ) بواسطة التآين الكهربى بالكيتوبروفين (200مجم) على الفقرات العصعصية لمدة 30 دقيقة /الجلسة، 3 مرات أسبوعياً لمدة أربعة أسابيع (12 جلسة) بينما عولجت المريضات فى المجموعه (ب) بالكيتوبروفين عن طريق الحقن العضلى (200 مجم) يوم بعد يوم (12 امبول) لمدة اربعة أسابيع أيضاً . وقد نُصحت المريضات فى كلتا المجموعتين باستعمال مقعد جيد مزود بوسادة جل عند الجلوس لتقليل الضغط على العصعص وأيضاً باستعمال مسهلات التبرز وزيادة كلاً من الألياف والسوائل فى الطعام لتقليل حدوث الإمساك . وقد تم تقييم المريضات فى المجموعتين عن طريق مقياس شدة الألم وكذلك قياس نسبة الكورتيزول فى الدم قبل وبعد الانتهاء من فترة العلاج. وقد أسفرت النتائج عن وجود نقص (تحسن) ذو دلالة معنوية عالية فى الإحساس بشدة الآم العصعص وكذلك فى نسبة الكورتيزول فى الدم للمريضات فى المجموعه (أ) عند مقارنتها بالمريضات فى المجموعه (ب) بعد فترة العلاج . وبذلك يمكننا استنتاج أن العلاج بالتآين الكهربى بالكيتوبروفين هو وسيلة فعالة من وسائل العلاج الطبيعى البديلة للكيتوبروفين الذى يعطى عن طريق الحقن العضلى لعلاج الآم العصعص للسيدات بعد الولادة الطبيعىة .