Management of Chronic Pelvic Inflammatory Disease with Ketoprofen Phonophoresis

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ABSTRACT

This study was conducted to determine the effect of ketoprofen phonophoresis in treating patients suffering from chronic pelvic inflammatory disease. Twenty patients were participated in this study their ages ranged from 21 to 35 years with a mean value of 27.20±4.12. All patients were non pregnant and complaining of lower abdominal pain radiating to the back with abnormal vaginal discharge, they diagnosed as having chronic pelvic inflammatory disease. All patients underwent a course of ketoprofen phonophoresis for 10 minutes per session, for 18 sessions (3 sessions per week, for 6 weeks), interrupted only by patient's menstrual cycle. The outcome measures included visual analogue scale (VAS), white blood corpuscles (WBCs) count and erythrocyte sedimentation rate (ESR), before starting the study and after the end of the 18th treatment session. The results of this study showed a statistical highly significant (P<0.001) decrease in the intensity of the experienced pain, WBCs and ESR count. So, it could be concluded that ketoprofen phonophoresis is an effective physical therapy modality in treating chronic pelvic inflammatory disease.

Key words: *Ultrasound, Phonophoresis, Pain, PID, NSAIDs.*

INTRODUCTION

Pelvic inflammatory disease (PID) is a major medical, economic and public health problem. It is a common and morbid condition that affects about 8-11% of women during their reproductive period[26].

PID is a broad term used to cover upper genital tract infection. These infections usually spread from the vagina or cervix through the uterine cavity[6], infection can also, ascend and spread, via lymphatics in parametrial tissue and broad ligament to reach the tubes and adnexa as well as, tend to be unilateral in contrast to other types of inflammatory diseases[6,37].

The most common causes of PID are chlamydia trachomatis or neisseria gonorrhoea infection in lower genitl tract and bacterial vaginosis[1,23]. Surgical instrumentation through uterine cervix including termination of pregnancy, vaginal douches[16,17] and uterine evacuation[13], as well as, the intrauterine contraceptive device (IUCD) has been linked to increase risk of PID and subsequent complications such as infertility[29,34,36] and ectopic pregnancy[33].

So, PID is a clinical condition representing infection and inflammation of all or some of pelvic organs. It begins with cervicitis and progress leading to serious

clinical consequence including endometritis, pelvic peritonitis, infertility, tubal obstruction, ectopic pregnancy, pelvic adhesion, pelvic absecess and chronic pelvic pain[26,35]. Chronic pelvic pain is non acute constant or cyclically presistant pain, located in the pelvic area for at least 6 months[28].

However, the most common clinical presentation of PID is bilateral lower abdominal pain and tenderness especially with walking and coitus, low back pain, deep dyspareunia, abnormal vaginal discharge, chill and fever, less common symptoms include irregular vaginal bleeding, dysuria, nausea and vomiting[35].

There are several pharmacological classes of medications which have been used to alleviate pain in patients with chronic PID syndromes, one of them is non steroidal anti-inflammatory drugs (NSAIDs). NSAIDs are available as creams or ointments, their transdermal absorption provides high concentrations of drug near the site of pain[14].

Because of the irritant nature of NSAIDs on the gastro-intestinal tract when used orally. It seems that the rationale approach is to combine physical and pharmaceutical treatments for improving the management of these conditions. Over the last few decades, application of ultrasound has been attempted to enhance transdermal transport of several drugs, a method referred to as "phonophoresis"[2,5].

However, phonophoresis considered a non-invasive procedure[18], consists of using ultrasound to drive a drug through the skin and into the underlying tissues, and it appears to be a frequent choice as an adjunct to the management of inflammatory conditions. So, it offers the potential advantage of delivering a pharmacological agents in a relatively safe, painless and easy manner to structures that lies some what deep within the body[3,9].

Hence, phonophoresis is one of the fastest ways to distribute the drug into the system once it diffuses through the outer most layer of the skin, the stratum corneum, which is the primary rate limiting factor[25]. The stratum corneum is responsible for the low permeability of skin. The stratum corneum is made up of multi-layers of horney cells that are compacted, flattened and keratinized. The water of the stratum corneum is only 20%, so drug transport across the stratum corneum may be trans-cellular, inter - cellular and appendageal. For most compounds the intercellular route is the predominating path[11].

Accordingly, phonophoresis act by disordering the structural lipids in the stratum corneum and thus, affect the skin structure to provide skin penetration enhancement[21].

Medications commonly used in phonophoresis include: local anaesthetics, vasodilators, corticosteroids and non steroidal anti-inflammatory drugs[3,4]. Ketoprofen is one of the currently available NSAIDs gel preparation, that provide efficient couplants during ultrasound treatments[14].

As chronic PID cases are not routinely referred to physical therapy until the condition is found to be resistant to medical treatment so, the need to have a new method as ketoprofen phonophoresis is considered an acceptable method to be used in the management of cases complaining of chronic PID.

So, the purpose of the present study was to determine the efficacy of ketoprofen phonophoresis in treating patients complaining of chronic pelvic inflammatory disease.

SUBJECTS, MATERIAL AND METHODS

Subjects

Twenty regular menstruating patients

diagnosed as having chronic PID. They were selected from the outpatient clinic of Obstetrics & Gynaecology department of Kasr EL-Aini University Hospital, to determine the efficacy of ketoprofen phonophoresis in treating such cases. Their ages ranged from 21 to 35 years with a mean value of 27.20±4.12, and their body mass index (BM1) was not exceed 30 kg / m^2 with a mean value of 27.08±2.53.

All patients were free from diabetes, trbuo-ovarian abscess, gynaecological haemorrhage, pelvic tumors and spinal as well as, sacroiliac joint pain. Also, none of the patients was pregnant or using IUCD and all of them complained from lower abdominal pain radiating to the back with abnormal vaginal dischage as well as, they not responded to any previous medical treatment and were not taken any medication for pain and / or inflammation, all through the study.

They underwent a course of ketoprofen phonophoresis for 10 minutes a session, for 18 sessions (3 sessions per week for 6 weeks) interrupted by patient's menstrual cycle.

Informed consent had been signed from each patient before starting the study, indicating her voluntary participation in this study. Summary of the patients physical characteristics summarized in table (1).

Table (1): Statistical summary of physical characteristics of the patients.

Variables	Mean	SD
Age (yrs)	27.20	±4.12
Weight (Kgs)	71.30	±7.48
Height (Cms)	160.56	±4.39
BMI (Kg/M^2)	27.08	±2.53
Parity (no.)	3.80	±1.76

Instrumentations

1- Visual analogue scale (VAS): Is a graphic rating scale incorporates a 10cms line, one end lebeled (No pain) and the other end labeled (worst pain). So, patient was asked to estimate on the line, the point corresponding to her perception of pain[7].
2- Ultrasound device used was physioson-03 (physiomed-Elektvomedizin Gm bh, Nr: P_3 – 9006810 gb). The device is a microprocessor controlled unit for continuous and pulsed US therapy. It permits adjustment of the intensity between 0 and 2 w/cm^2 with a frequency of 1 MHz. The US device consists of mode selector (continuous or pulsed), automatic timer control, and having an ultrasoud head with a diameter of 5 cm^2 .
3- Ketoprofen gel. 2.5% ketoprofen [2-(3-benzoylphenyl) propionic acid), which is one of the currently available NSAID gel preparations that provide efficient couplants during ultrasound therapy and has an analgesic as well as, anti-inflammatory effects[2].
4- Aquasonic – gel. This gel was used as a couplant for the transmission of US.

Procedures

A- Evaluative Procedures: which included:

- Personal data: Name, age, height, weight, parity, address, telephone, mobile, occupation, complaint and site of pain were taken from each patient in this study.
- History taking: A detailed medical history and gynaecological history were taken from each patient to confirm that the only cause of pain was PID and rule out other

pathological conditions.

- Pelvic ultrasonography: All patients were screened before starting the study by using ultrasonography to exclude any pelvic pathologic lesions as pelvic tumors, endometriosis and ovarian abscess.
- Visual analogue scale (VAS): Was done for every patient before starting the study and after the end of the 18th treatment session of ketoprofen phonophoresis.
- Blood samples: Was taken from each patient by vein puncture from the right brachial vein to count WBCs and estimate ESR, before starting the study and after the end of the 18th treatment session to evaluate the prognosis of the treated cases.

B- Treatment Procedures:

- Each patient was asked to empty her bladder before starting the treatment session and then relaxed on supine lying position with small cushions under head and back to accommodate body curves.
- The skin of supra pubic region was cleaned, then approximately 5 gms of ketoprofen gel was distributed on the skin of this region and was left for a contact period of 5 mins to help saturation of the outer layer of the skin before starting ultrasound application.
- Ultrasound device with a frequency of 1 MHz was adjusted to be used with a continuous, high intensity (1.5 w/cm^2) waves. And, a small amount of transmission gel (aquasonic gel) was applied on the ultrasound head generator. Then, the treatment session started by moving the ultrasound head in a series of over lapping circles, over the skin of supra pubic region for 5 mins then, extending upwards and laterally to the right and left iliac fossae for 2 mins for each side, then return again to the supra pubic region for 1 min. Each treatment session lasted for 10 mins, applied every other day for 18 sessions, interrupted only by the menstrual cycle of the patient.

Statistical analysis

Descriptive statistics was used for the collected data to calculate the mean, standard deviation. Inferential statistical analysis were used in the form of student pared t-test and chi-square test for comparing between pre and post treatment measures. The acceptance level of significance was 0.05.

RESULTS

In the present study, the efficacy of ketoprofen phonophoresis on treating chronic pelvic inflammatory disease was investigated. The intensity of pain experienced by the patients according to VAS, initially before starting the treatment, was found as the majority of cases (85%) had severe and unbearable pain (55% & 30% respectively), and a few of cases (15%) had moderate pain. While, after the end of the study (after 18th treatment session) the majority (55%) of cases had complete pain relief (no pain) and the rest of cases (45%) experienced mild pain, Table (2). Comparison between before starting the treatment and after the end of the study, using chi-square test, the difference was found to be statistically highly significant ($P<0.001$) decrease.

Table (2): Intensity of the experienced pain according to visual analogue scale (VAS) before starting the treatment and after the end of the study.

	Before treatment		After study	
	(no.)	%	(no.)	%
No pain	(--)	(--)	(11)	55%
Mild pain	(--)	(--)	(9)	45%
Moderate pain	(3)	15%	(--)	(--)
Severe pain	(11)	55%	(--)	(--)
Unbearable pain	(6)	30%	(--)	(--)
t- value	-4.034			
P- value	< 0.001			

Table (3) and Fig. (1), represents the mean values of WBCs count before starting the study and after the end of the 18th treatment session.

The mean values of WBCs count before treatment was (6468±160.90) and after the end of the study was (5500 ± 90.40) with a mean difference of 968.00 and the percentage of change was 14.16%. These differences were found to be statistically highly significant (P < 0.001) decrease.

Table (3): The Mean Values of WBCs Count before and after the study.

	WBCs (10^3 / mm^3)	
	Before treatment	After treatment
Mean	6468	5500
S.D	± 160.90	± 90.40
Mean difference	968.00	
Percentage	14.16%	
t- value	8.05	
P- value	< 0.001	

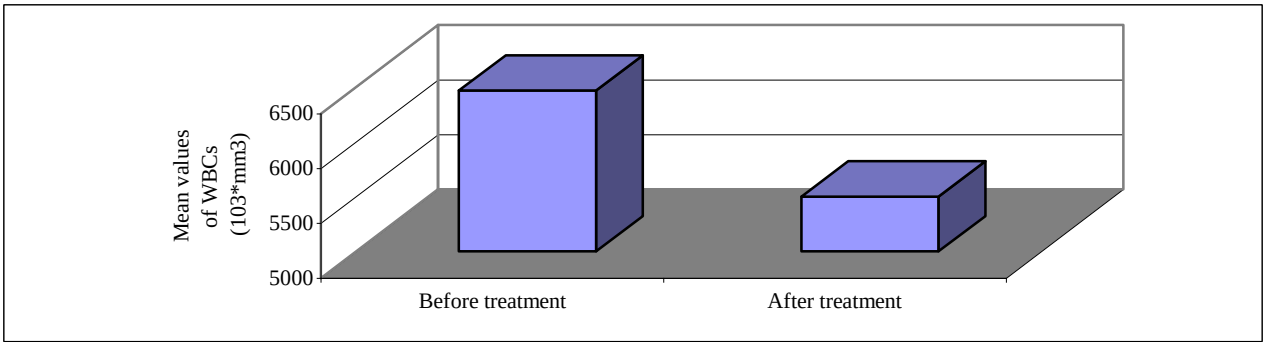

Fig. (1): The Mean Values of WBCs Count before and after the treatment.

And, in table (4), the mean values of ESR at the first hour before starting the treatment was (17.85±10.14) and after the end of the study was (10.25±6.08) with a mean difference of 6.60 and the percentage of change of 37.69%. These differences were found to be statistically highly significant (P<0.001) decrease, while the mean values of

ESR in the second hour before starting the treatment was (32.20±12.36). And after the end of the study it was (22.80±7.68) with a mean difference of 9.40, and the percentage of change was 29.37%. These differences were found to be highly significant (P<0.001) decrease, Fig. (2).

Table (4): The Mean Values of ESR before treatment and after the end of the study.

		Mean	SD	Mean difference	Percentage	t- value	P- value
ESR (mm/hr) at the first hour	Before treatment	17.85	±10.14	6.60	37.69%	3.98	< 0.001
	After Study	10.25	±6.08				
ESR (mm/hr) at the second hour	Before treatment	32.20	±12.36	9.40	29.37%	4.39	< 0.001
	After Study	22.80	±7.68				

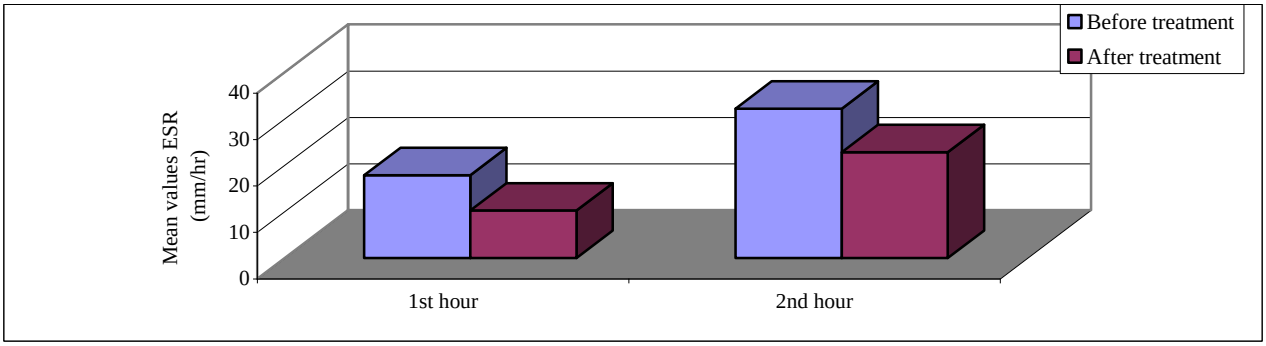

Fig. (2): The Mean Values of ESR before treatment (1st & 2nd Hrs) and after the end of the study (1st & 2nd Hrs).

DISCUSSION

Pelvic inflammatory disease, is the most serious and costly transmitted infection, affecting more than 10% of reproductive age women[22]. Chronic PID is the residual debilitating illness that follows an episode of pelvic infection and result in adverse sequelae[24].

The most common symptom occurring in > 90% of patients with PID are, pain in lower abdomen and pelvis, mucopurulant cervical discharge, and abnormal vaginal bleeding[27].

Ultrasound and a topical NSAID product could potentially be combined not only to provide an additive or synergistic effect but also, to enhance skin penetration of the NsAID (phonophoresis), thereby optimizing the treatment of the treating conditions[15].

So that, phonophorisis appears to be a frequent choice as an adjunct to the management of inflammatory conditions[9], through which the radiation pressure from ultrasound beam forces the ketoprofen away from the transducer into the target tissue, then the sound waves increase the kinetic energy of the molecules, enabling ketoprofen to diffuse more easily into the underlying tissue. So, the heat created by the ultrasound enhances the

diffusion potential of the tissue and dilates the blood vessels, however, the streaming created by ultrasound, changes cell premeability and enhances tissue diffusion[5].

The results of the present study revealed a highly significant (P<0.001) decrease in the intensity of pain experienced by the patients, WBCs count and ESR values, after the end of the 18th treatment session of ketoprofen phonophoresis.

So, pain relief or the reduction of the experienced pain can be explained according to the clinical interventions that may ultimately exert an effect of both ketoprofen and ultrasound.

Hence, according to the mechanical effects of ultrasound is thought to increase the activity of large nerve fibers, thereby closing the "pain gate" at the substantia gelatinosa and so, reintroducing inhibition of the smaller unmediated fibers[30].

Another explanation for this finding is based on ultrasound effects, is that the increased pain reduction that occurs following ultrasound application can be attributed to the heat produced by ultrasound that could result in counter irritation, heat cavitation of large diameter fibers, or an altering of the response to stimulation of pain receptors[12,20,38].

Also, local heating, activates somatovisceral reflex arcs stimulation of cutaneous thermo receptors, decreases the activity of sympathetic nervous system and produces a vasodilation in deeper blood vessels[19].

Also, NSAIDs inhibit prostaglandin synthesis from arachidonic acid by inhibiting cyclo-oxygenase (Cox) enzyme, that means less sensitization of nociceptive nerve endings[31].

So, NSAIDs in regular dosages have both a long analgesic and anti-inflammatory effect, which makes them useful for the treatment of continuous or regular pain associated with inflammation[8].

And, Ness et al., (2002b)[26] added that NSAID are used successfully in the treatment of women with chronic PID which help to alleviate pain in a given individual patient. Also, they mentioned that when pain become chronic, it is often more useful to approach analgesic medication in a very different fashion and as regular as possible to provide the greatest degree of pain relief overtime.

Also, the results of this study showed a highly significant (P<0.001) decrease in WBCs count and ESR values after the end of the 18th treatment session of ketoprofen phonophoresis, and these results could be attributed to the theraputic effect of ultrasound as an accelerator of the inflammatory process through increasing the release of mitogenic and antigenic growth factors from mast cells, platelets and macrophages[10]. As macrophages are important cells in the immune response to chronic inflammation. So, the optimal use for the ultrasound during chronic inflammation rather than during acute inflammation[39].

In addition, the thermal effect of US is beneficial for chronic inflammation as heat increase blood flow and thereby, increases microvascular hydrostatic pressure that assist in the reabsorption of late inflammatory exaudates and debris[32].

Accordingly, it was found that ketoprofen phonophoresis considered as one of the efficient alternative physical therapy methods in treating chronic pelvic inflammatory disease.

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الملخص العربي

علاج التهابات الحوض المزمنة بواسطة مادة الكيتوبروفين المدخلة بواسطة الموجات فوق الصوتية

أجريت هذه الدراسة لمعرفة تأثير مادة الكيتوبروفين المدخلة بواسطة الموجات فوق الصوتية على التهابات الحوض المزمنة . اشتركت في هذه الدراسة عشرون مريضة تراوحت أعمارهن ما بين 21 إلى 35 عاماً ، تعانين من آلام أسفل البطن والظهر ووجود إفرازات مهبلية ، وتم تشخيص حالتهن على أنها التهابات مزمنة بالحوض. تم علاج جميع المريضات باستخدام مادة الكيتوبروفين المدخلة بواسطة الموجات فوق الصوتية لمدة 10 دقائق لكل جلسة علاجية على مدى 18 جلسة، بواقع ثلاث جلسات أسبوعياً لمدة ستة أسابيع، يتخللها فترة الدورة الشهرية لكل مريضة. وقد تم استخدام القياسات التالية ، مقياس شدة الألم- وعدد كرات الدم البيضاء وقياس سرعة ترسيب كرات الدم الحمراء قبل بدء الدراسة وبعد الانتهاء من الجلسة العلاجية الثامنة عشر. وقد أوضحت النتائج أن هناك انخفاضاً ذو دلالة معنوية عالية في شدة الإحساس بالألم وأيضاً عدد كرات الدم البيضاء وسرعة ترسيب كرات الدم الحمراء. وهكذا يمكن أن نستخلص أن مادة الكيتوبروفين المدخلة بواسطة الموجات فوق الصوتية تعتبر إحدى وسائل العلاج الطبيعي الفعالة في علاج التهابات الحوض المزمنة .

الكلمات الدالة : الموجات فوق الصوتية - تحفيز امتصاص المادة الفعالة (الكيتوبروفين) بواسطة الموجات فوق الصوتية - الألم- التهابات الحوض المزمنة- مضادات الالتهابات الغير الإستيرويدية .