
Effectiveness of ketoprofen phonophoresis in the management of chronic low back pain

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Abstract: Low back pain is considered as the most common musculoskeletal disorder among Libyans and most countries of the world. Treatment of low back pain depends mainly on eliminating the patient's pain and restoring the normal function of patient's low back. Phonophoresis is one of the widely techniques used in physiotherapy protocols for managing

Low back pain. However, determining the appropriate dose of topical medications that must be added to the phonophoresis technique is still under study . In this practical study, ketoprofen phonophoresis was added to the treatment protocol to evaluate its effectiveness on pain intensity and function disability in patients with chronic nonspecific low back pain.

This study conducted on a random sample of 12 patients with chronic low back pain who were receiving treatment in physiotherapy department at Tripoli Medical Hospital and Zakary Clinic. The patients were classified in two groups with the same patients' number, experimental and control group. Both groups received the same physiotherapy protocol consists of infrared therapy, therapeutic ultrasound, stretching and strengthening exercises. The experimental group placed on ultrasound phonophoresis therapy with ketoprofen, instead of Aqua sonic gel in control group. The outcome measures used to determine the change in pain intensity and a patient's permanent functional disability pre and post- treatment protocol were (VAS) and (ODQ) .

The results of the study showed a significant improvement in the treatment plan provided to patients with the use of ketoprofen phonophoresis by 82% for VAS and approximately by 19% for ODQ compared to control group.

Finally, it could be concluded that treatment protocol with specific doses of ketoprofen ultrasound phonophoresis, can reduce pain intensity and restore the normal functional activity of chronic low back pain patient.

Keywords: Ultrasound, Infrared, Chronic nonspecific low back pain, Phonophoresis, Exercise, VAS, ODQ, ketoprofen.

Introduction.

Lower back pain is a very common everyday problem which most people experience at some point in their life [1]. Low back pain is a leading cause of disability, Interferes with quality of life and work performance and is the common reason for medical consultations [2]. Studies in the United Kingdom identified back pain as the most common cause of disability in young adults [3].

Back pain can be specified and non-specified lumbar back pain. Most patients present without any specific underlying cause of back pain, however in about 10% of cases there is a specific known cause [4]. Specific back pain usually related to specific causes as tumour, fracture, inflammatory disease or any other disease. While non-specific back pain (NSLBP) varies with changes in posture and activity, and not related to any disease. For this reason it

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also known as mechanical low back pain, and it presented with pain, spasm and tenderness in lumbar back[5,6].Chronic NSLBP refers to an episode that limiting the patient's activity of low back and lasts for three months or more [7].

Treatment of low back pain focuses on relieving symptoms, improving physical function, reducing pain and prevention of chronic complaints [8]. Treatment may include a combination of a pharmacology and non-pharmacology options. Physiotherapy is one of the recommended non-pharmacological management options, which involves the use of physical modalities as therapeutic ultrasound (TUS) and therapeutic exercises [9, 10].

Non-steroidal anti-inflammatory medications are generally used for treatments muscle skeleton disorder. Non-steroidal anti-inflammatory drugs (NSAIDs) are a group of compounds with similar biological effect. NSAIDs as ibuprofen, ketoprofen, diclofenac, and naproxen have anti-inflammatory, analgesic and antipyretic properties. The mechanisms of action of NSAIDs have not yet been fully elucidated, but evidence suggests that their anti-inflammatory effects are achieved by inhibiting the enzymatic production of prostaglandins. [11]. Using these drugs orally or parentally can be associated with systemic side effects or injection site mobility [12].Therefore, alternative methods such as iontophoresis and phonophoresis along with topical applications of drug are preferred to use for improve treatment efficacy [13,14].

Phonophoresis (PP) is technique employs the use of ultrasound waves to accelerate percutaneous absorption of drug delivery, by activation of micro channels within stratum corneum layer [15]. Phonophoresis first used in 1954 to delivery of hydrocortisone ointment into inflamed areas in patients with polyarthritis of the hand [16], since then PP has been used in treatment of various dermatological and musculoskeletal disorder [17].

Several authors suggested (PP) technique to enhance the absorption of analgesics and anti-inflammatory agents [18, 19]. Shin and choi (1997) [20] concluded that indomethacin (PP) reduce the pain and increases the pressure pain threshold in the (PP) group compared with the placebo group on the relief of temporomandibular joint pain. Piroxicam (PP) also found to be more effective than US therapy in reducing pain and improving knee functioning in patients with knee osteoarthritis [21]. In contrast Kozanoglu et al, (2003) [22] reported that both the (TUS) and (PP) are effective and ibuprofen (PP) not superior to conventional (TUS) therapy in patients with knee osteoarthritis. Therefore, the current study aims to evaluate the effectiveness of ketoprofen phonophoresis along with physiotherapy protocol in managing of chronic non-specific low back pain.

Methodology.

The study was conducted in Tripoli City at Tripoli Central Hospital and Zakary Clinic. The study approved by Faculty of Medical Technology department of Physiotherapy in Tripoli University. Before collecting data, all information about the study was provided to the patients, and the privacy of patients was taken into consideration.

• Study Sample Design:

Random clinical trail of twenty female patients, suffering from chronic non-specific low back pain, were enrolled in this study. The participants were classified into two groups control group and experimental group ten for each group. One patient from control group and three from experimental group dropped out after the 6th session, due to personal issues. Four other patients (one patient from the experimental group and three patients from the control group) excluded from this study because one of them has pain, which was VAS below 3, and the other three were below the age 30. Figure (1) shows a flow chart of participants.

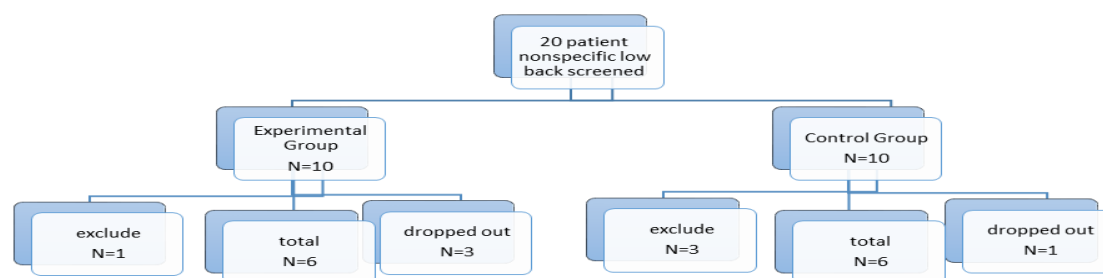


Figure (1); a flow chart of all participants.

Patients included in this study were 30 to 50 years old, presented with pain that according to VAS was above three, have no sensitivity to ketoprofen gel, and were diagnosed with chronic non-specific low back pain.

While patients excluded in this study were presented with mild pain that according to VAS was lesser than three, having inflammatory disease, disc herniation, radiculopathy, vertebral fracture, spinal degenerative changes and in some cases were pregnant.

The patients in the control group received routine treatment in clinic consists of infrared therapy (IR), therapeutic ultrasound (TUS) with aqua sonic gel and physical therapy (stretching and strengthening exercises). While the patients in the experimental group, received therapeutic ultrasound with ketoprofen gel along with same protocol treatment in control group. Participants in each group received 10 sessions of treatment on day to day within four weeks. The pain intensity level was recorded by visual analogue scale (VAS), and Oswestry Disability Questionnaire (ODQ) recorded daily life activities. Pain intensity and Functional level were measured pre and post 10 sessions of treatment.

• **Treatment protocol:**

Infrared therapy: Infrared therapy was applied for participants in both groups. Infrared waves were between 800 nm and 1.4 Mm. The patients received infrared therapy in comfortable prone position with continuous 10 minutes.

Stretching and Strengthening exercises: Patients for both groups were instructed to perform stretching exercises prone on elbow: rise on their elbows as much as possible while keeping their hips on floor. Patients were also instructed to perform Strengthening exercise bridging: supine lying on their back with bents knees and feet flattened on the floor. Then they squeeze their abdominal and buttock muscles and lift their buttock off the floor.

Ultrasound application: The participants in control group received (TUS) in comfortable prone position. Aqua sonic gel was applied on paravertebral region of lumbar spine at 1MHz frequency, and intensity was 1.5 w/cm² on continuous mode in circular movement for 10 minutes (Ebadi et al, 2012) [10] And (Adesola O et al, 2015) [23] used the same parameters while conducting their studies . On the other hand, the patients in experimental group received, same (TUS) parameter's along with ketoprofen gel 2.5% (5 cm for approximately 49 cm²) mixed with aqua sonic gel and spread on paravertebral region of lumbar spine [24].

Outcome measures:

All out come measures were recorded pre and post intervention for both groups. These were relied on measuring the severity of the pain that the patients suffer and the level of functional performance that they can perform, by using the pain intensity scale (VAS) and the ODQ scale. The VAS scale can determine the level of pain intensity according to the response of the patient. The level of pain that the patient feels has been divided into three graded levels, the pain is minor when VAS indicates 0-3, the pain is moderate when the VAS is scored 3-7, and severe when the gradient of the VAS is recorded 7-10, this depends on the level of pain response that the participants define. While Oswestry low back pain

Disability Questionnaire was used to know the rate of functional performance of the activities that, the patient practices during his daily life, such as walking, sitting, standing, bathing, pain intensity, social life, mobility, personal care, employment status. According to this indicator, the level of disability suffered by low back pain patients classified into four types: mild disability with a rate between 0-20%, moderate disability and its percentage between 21% -40%, severe disability 41% -60%, and crippled disability 61% - 80% and if the disability percentage exceeds 81% the patients will be either exaggerated their symptoms or bed-bound.

Results.

Descriptive statistics of mean percentage, P value were done for all outcomes, which were pain score and disability index. All statistics parameters were calculated using SPSS version 24.

• Demographic Feature of Patients:

Based on 12 Out of 20 Cases. All participants were women with the mean age of 41 Years. The demographic features of the patients as shown in the (table 1), indicated that there was no significant difference between two groups with respect to the mean age, pre VAS and ODQ scores.

Table (1); Demographic features of all participants.

Demographics Feature	Control group	Experimental group
Age	42 years	40 years
Pre VAS	6.33	7.5
Pre ODQ	34.41%	42.20%

• Clinical differences between the treatment groups:

The outcomes variables after ten treatment sessions (about one month) presented in the (table 2). From the outcome results, it can be indicated that there was a significant difference between two groups in the mean % values of VAS and ODQ scores in pre and post treatment. The improvement in VAS was significantly superior in the experimental group, which was about 62.3%. In addition, there was improvement in the pain values in the control group with the percentage of 34.3%.The improvement in ODQ was clearly found in both groups. However, slightly a statistical difference was observed between the two groups, Which was approximately 54.6% for control group and 62.2% for experimental group as can be seen the (table 2).

Table (2); Comparison of pre &post-treatment pain intensity and ODQ for both groups.

Variables	Control group		Experimental group		P value
	pre	post	pre	post	
VAS	6.33	4.16	7.5	2.83	< .00001
ODQ	34.41%	15.55%	42.2%	14.69%	< .00001

Discussion.

The main aim of this study was to find out the effectiveness of topical application of anti-inflammatory drug on treatment protocol for reduction pain and improvement of daily life

activities in chronic nonspecific low back pain patients. Regarding to the pain and ODQ score, the current study found significant improvement in pain and ODQ values regarding the base line value in both groups. Improvement was significantly superior in VAS value for experiment group that is about 82.5% than control group. In addition, there was a significant improvement in ODQ for both groups after one month of treatment. Both group exhibit similar treatment efficacy with slightly more in experimental group by approximately 19.4%. The results of the present study has come in agreement with [23,25] studies who compared the efficacy of ketoprofen and aqua sonic gel in management of non-specific low back pain. "They concluded that ketoprofen gel phonophoresis with stretching and strengthening exercises is more effective than the aquasonic gel ultrasound in the management of non-specific lower lumbar back pain". Moreover, the results of this study were also consistent with many researches results showed that therapeutic efficacy of anti-inflammatories gel (PP) treatment is superior to conventional (TUS) in short term for LBP patients. (Altan et, al 2019) [26] studied the Efficacy of diclofenac & thiocolchioside gel (PP) comparison with ultrasound therapy on acute low back pain, results showed that PP treatment is superior than conventional (TUS) at short term in LBP patients. (Adesola O, et al, 2015) [27] Conducted study to examine the therapeutic efficacy of Lofnac Gel in the management of nonspecific low back pain. It reported that there was improvement in VAS score and disability index in the exercise with Lofnac phonophoresis group (experimental group) greater than that in the control group after 3 weeks of treatment. Astiata and his collagists [24] also concluded in their study that voltaren phonophoresis improves the effectiveness of treatment procedure in reducing pain and improving knee ROM in patients with knee osteoarthritis.

In this study, it can be seen that to obtain the desired effects of topical medication for treatment of chronic LBP. Phonophoresis technique was used on the paravertebral lumbar region, by parameters that were suitable for deep tissue and large area [23]. The continuous ultrasound technique used has a frequency of 1 MHz and an intensity of 1.5 W/cm² with ketoprofen gel in a conductive medium for 10 minutes. Delivery of the drug was successful in these parameters and increased the ability of the ketoprofen gel to penetrate more deeply into inflamed areas. Thus, the drug efficacy has accelerated via phonophoresis, and producing more localized effects. This may have an additional effect on the treatment protocol, by promoting the performances of stretching and strengthening exercises more effectively in experimental groups than control group, which in turn reflected on reduction in pain intensity and disability level for experimental group.

The limitation of the current study is the study group is very vas. Therefore, future researches should be conducted with more number of patient.

Conclusion.

It can be concluded that ketoprofen phonophoresis, improves the effectiveness of the treatment protocol and recommended to use in reduction of pain intensity and functional disability level on people who suffering from chronic nonspecific low back pain.

فاعلية الترحيل الصوتي للكيتوبروفين في علاج آلام أسفل الظهر المزمنة.

المستخلص: آلام أسفل الظهر من الأمراض الشائعة التي تصيب الجهاز الهيكلي للإنسان بين مختلف الفئات العمرية في ليبيا ومعظم دول العالم. علاج آلام أسفل الظهر يعتمد أساساً على إزالة الألم التي يعانيها المريض مع استعادة المريض لحركته الوظيفية الطبيعية المعتادة. تقنية الترحيل الصوتي أحد التقنيات العلاجية الواسعة الانتشار، المعتاد استعمالها لإيصال جرعات الدواء الموضعي إلى داخل الجسم في برنامج العلاج الطبيعي لألم أسفل الظهر، ولكن تحديد مقدار الجرعة المناسبة من الدواء التي يجب إضافتها لازال قيد الدراسة. في هذه الدراسة العملية أضيفت جرعة من الكيتوبروفين حل إلى أسفل ظهر المريض باستخدام تقنية الترحيل الصوتي ضمن برنامج العلاج الطبيعي لمعرفة تأثيرها في إزالة الألم وإعادة الحركة الوظيفية للمصابين بالألم أسفل الظهر المزمن. أجريت الدراسة على عينة عشوائية تتكون من 12 مريض ممن يتردوا على مستشفى طرابلس الطبي وعبادة زكريا لتلقي العلاج. تم تقسيم العينة المشاركة في الدراسة إلى مجموعتين متساويتين، المجموعة المرجعية ومجموعة التجربة. المجموعتان أخذتا نفس برنامج العلاج الطبيعي والذي يتكون من التعرض للموجات فوق الحمراء والذبذبات فوق الصوتية بالإضافة إلى قيام المريض بتمارين الاستطالة وتقوية العضلات. لكن في الوقت الذي اقتصر برنامج المجموعة المرجعية على استعمال جهاز الموجات الصوتية مع الجل المخصص للجهاز كما هو معتاد، خضعت مجموعة الدراسة (التجربة) للعلاج بإضافة 5 سم من جل الكيتوبروفين 2.5% على مساحة 49 سم² مع الجل المعتاد استعماله مع الجهاز. أجريت قياسات شدة الألم التي يعانيها المريض وقيست الحركة الوظيفية لظهر المريض قبل العلاج وبعد العلاج باستخدام VAS و ODQ. النتائج التي توصلت إليها الدراسة بينت تحسن ملحوظ في الخطة العلاجية المقدمة للمرضى في مجموعة التجربة بنسبة 82% VAS و 19% ODQ عن المجموعة المرجعية.

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