

ORIGINAL ARTICLE

EFFECTIVENESS OF THERAPEUTIC ULTRASOUND WITH AND WITHOUT KETOPROFEN GEL AMONG THE PATIENTS OF NON-SPECIFIC LOW BACK PAIN

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ABSTRACT

Background: Lower spinal back pain, a very common everyday problem, experienced by most people in their life, is usually nonspecific low back pain and varies with changes in posture and activity. It is also called mechanical low back pain.

Objective: The objective of this study was to examine the effectiveness of therapeutic ultrasound with and without ketoprofen gel on pain and disability in patients with nonspecific low back pain.

Method: The study design was randomized clinical trial, conducted at MadinahTeaching Hospital and Sugraha trust hospital Faisalabad. This study included males and females between ages 20 to 35. A convenient sampling technique was applied, as patients who were visiting the physiotherapy department during months of February-June 2016 were considered. Signed consent forms and the privacy of patients was taken into consideration. Two groups were made; Group A received ultrasound with Ketoprofen gel and strengthening and stretching exercises whereas Group B received ultrasound with Aqua sonic gel and strengthening and stretching exercises. Total treatment sessions were over a period of 10 consecutive days. The pain intensity was measured by visual analogue scale (VAS) and functional level was measured by Oswestry Disability Questionnaire(ODQ) before, in the middle and at the end of the treatment.

Result: There was a significant difference before and after treatment in pain intensity between ketoprofen gel (3.07 ± 0.77 and $p=0.000$) and aqua sonic gel (5.08 ± 0.85 and $p=0.06$). There was a reduction in disability level after the treatment in both groups but greater improvement was achieved by Ketoprofen gel as compared to aqua sonic gel.

Conclusion: Therapeutic ultrasound with ketoprofen gel along with stretching and strengthening exercises is more effective than the aqua sonic gel ultrasound in the management of non-specific lower lumbar back pain.

KEYWORDS: ketoprofen, therapeutic ultrasound, nonspecific low back pain

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INTRODUCTION

Lower spinal back pain is a very common everyday problem which most people experience at some

point in their life¹. It can be specified and non-specified lumbar back pain. Most patients present without any specific underlying cause of back pain, but in about 10% of cases there is a specific known

cause of pain². Nonspecific low back pain constitutes about eighty five percent which are treated in primary care settings also a great number of backaches are managed by physical therapists³. Since, nonspecific low back pain varies with changes in posture and activity so it is also called mechanical low back pain⁴. Backache presented with spasm, tenderness and pain in lumbar back area which is not due to tumor, sepsis, fracture, ankylosing spondylitis or other inflammatory diseases is known as non-specific lumbar back pain³. Lower spinal back pain is very frequent in younger and middle aged individuals⁵.

According to⁶spinal muscle contraction and stability exercises are very useful for the avoidance and management of lower back pain. While according to Stevens et al., 2006, therapeutic exercises are beneficial for development of lumbar-pelvic stability and bridging exercises are especially used for this purpose. So clinician or physical therapists must educate the patients thoroughly about exercise and also explain those sets and repetitions⁷

Therapeutic ultrasound (US) is utilized in the management of damaged tissues but there is less evidence for the management of back pain with therapeutic ultrasound.⁸Phonophoresis is a procedure in which therapeutic ultrasound is used to administer pharmacological agents, mainly NSAIDs or analgesic medicines, over the unharmed skin to the subcutaneous tissues⁹. Ketoprofen, known as NSAID, is frequently prescribed simply as 'an anti-inflammatory', or as an 'NSAID'. It acts by inhibiting the synthesis of chemicals inducing pain and tenderness in the body. When ketoprofen is used topically on the skin as a gel, it produces localized instead of a generalized effect. It penetrates deeper into areas of the skin which are inflamed¹⁰. So efficacy of this drug has remained ambiguous via phonophoresis.

Analgesic or anti-inflammatory drugs could be added into ultrasound gel for improving treatment efficacy.¹¹Ultrasound waves cause temporary skin changes, causing drug molecules to be absorbed through the skin, when directed towards inflammatory area, the muscle pain is relieved. Drugs added in ultrasound gel must not block the intensity or power density of the ultrasound wave¹² Diclofenac emulgel has been studied for combination usage with ultrasound therapy. In order to reduce treatment cost for patients, some herbal medicines such as plailemulgel might be substituted for diclofenac emulgel in ultrasound therapy¹³The optimization of drug absorption through skin is of great value in modern therapy. Phonophoresis is the use of therapeutic ultrasound to increase percutaneous drug absorption. However, few studies have compared pulsed and continuous modes of therapeutic ultrasound.¹⁴

During the absorption of ultrasonic waves in tissues and their reflection among the surfaces, heat energy is produced and provides deep heating. At the same time, ultrasound therapy has analgesic effects, increases nutrition, and also speeds up blood circulation.¹⁵ Phonophoresis is noninvasive and has potential benefits over oral administration and injection of pharmaceutical agents, including eliminating both injection site morbidity and first-pass metabolism in the gastrointestinal tract.¹⁶According to theoretical models of phonophoresis, US acts at the skin surface, resulting in cavitation of the micro channels within the stratum corneum, the most protective and outermost layer of the skin.¹⁷

Pulsed mode US is preferred for the treatment of acute and subacute cases.¹⁸ Therapeutic pulsed ultrasound (TPU) is a form of mechanical energy that is transmitted through and into living tissue as acoustic pressure waves. It has been theorized that the micromechanical strains produced by these pressure waves in biological tissues may trigger biochemical events that accelerate tissue repair¹⁹ Ketoprofen were effective at controlling pain, swelling, and trismus after the surgical removal of third molars²⁰ ketoprofen at therapeutic doses is more efficacious than ibuprofen in pain management of rheumatoid arthritis, supporting its use in clinical practice.²¹ Oral ketoprofen is superior in efficacy than diclofenac/ibuprofen in relieving moderate-severe rheumatic pain and in improving functional status and general conditions, with an overall good safety profile, comparable to ibuprofen and diclofenac.²² This study was conducted to examine the effectiveness of therapeutic ultrasound with ketoprofen gel and aqua sonic gel in the reduction of pain and disability level in non-specific low back pain.

METHODS

This research design was Randomized Clinical Trial. Convenient sample of selected patients was between ages 20-35 years both male and female visiting physical therapy center of Madinah Teaching Hospital, and SugrahTrust Hospital Faisalabad during the period of February to June, 2016. Patients not included in this study were presented with mild pain according to VAS < 3 and having inflammatory disease, disc herniation, radiculopathy, vertebral fracture, spinal degenerative changes and pregnant women.

Before collecting the data, all information about the study was provided to the patients and they were required to sign consent forms. Privacy of patients was taken into consideration. There were 30 males and 30 females which were randomly allotted into two treatment groups. Total sample size was 120. In group A, Therapeutic Ultrasound with ketoprofen along with routine physical therapy

(stretching and strengthening exercises) was applied while in group B, Therapeutic Ultrasound with aqua sonic gel along with routine physical therapy (stretching and strengthening exercises) was applied.

Participants in each group received 10 sessions of treatment on consecutive days within two weeks. The pain intensity level was recorded by visual analogue scale (VAS) and daily life activities were recorded by Oswestry Disability Questionnaire (ODQ). Pain intensity and Functional level were measured before the treatment and after 5 sessions then at the end of 10 sessions of treatment. (treatment was discontinued if pain increased then other modalities were used).

Ultrasound application: Each group received; continuous US that applied on the paravertebral region of lumbar spine at 1 MHz frequency while intensity was 1.5W/cm² with continuous mode for ten minutes as described by Ebadi et al.⁸

Patients were instructed to perform stretching exercises prone on elbow; rise on elbows as much as possible while keeping hips on the floor and strengthening exercise bridging; Supine lying flat on the back with bent knees while feet should be flattened on the floor, then squeeze abdominal and buttock muscles and lift buttocks off the floor. Patients were asked to perform 2 sets with 10 repetitions during each treatment session, depending on the ability of each patient.

Outcome measures: Both primary and secondary-outcomes were measured. Primary outcome was reduction in pain measured through the visual analogue scale (VAS) with readings measuring from 0-10, 0 means no pain while 10 means maximum pain. Pain is also divided into three levels mild, moderate and severe. If a respondent scores within 0-3

range it indicates mild pain while 3-7 and 7-10 is moderate and severe respectively. Respondents marked the pain level corresponding to the degree of pain they feel and were also provided freedom to express their exact pain intensity²³

The secondary outcome was reduction in disability which is measured by modified Oswestry scale. Modified Oswestry low back pain disability index questionnaire was used for assessment of low back pain during activities of daily living before and after this study. This questionnaire has two sections, one is personal data information name, age, sex, and other section include ten daily life activities such as pain intensity, sitting, standing, walking, washing, sleeping, social life, travelling, personal care, and employment/homemaking. In ODI each section has six points from 0-5. ODI score > 60% indicates severe disability while ≤ 20% indicates minimal disability.

Data analysis: The acquired data was entered in to SPSS version 20. Paired sample t- test were applied to compare the VAS. Frequency was used to determine the functional disability for both groups before, during and after treatment. The data was subjected to further analysis using 5% level of significance. The data was then presented in the form of charts and graphs.

RESULTS

Figure 1 shows the participants recruitment in this study, total participants were 120. In group A total drop outs were 10 while in group B they were 13. The age ranged from 20 to 35 years. The overall mean age was 29.51 ± 4.95 years. The VAS before treatment was 5 to 7 in both groups with a mean of 5.65 ± 0.58 in Ketoprofen gel group and 5.70 ± 0.79 in aqua sonic gel group

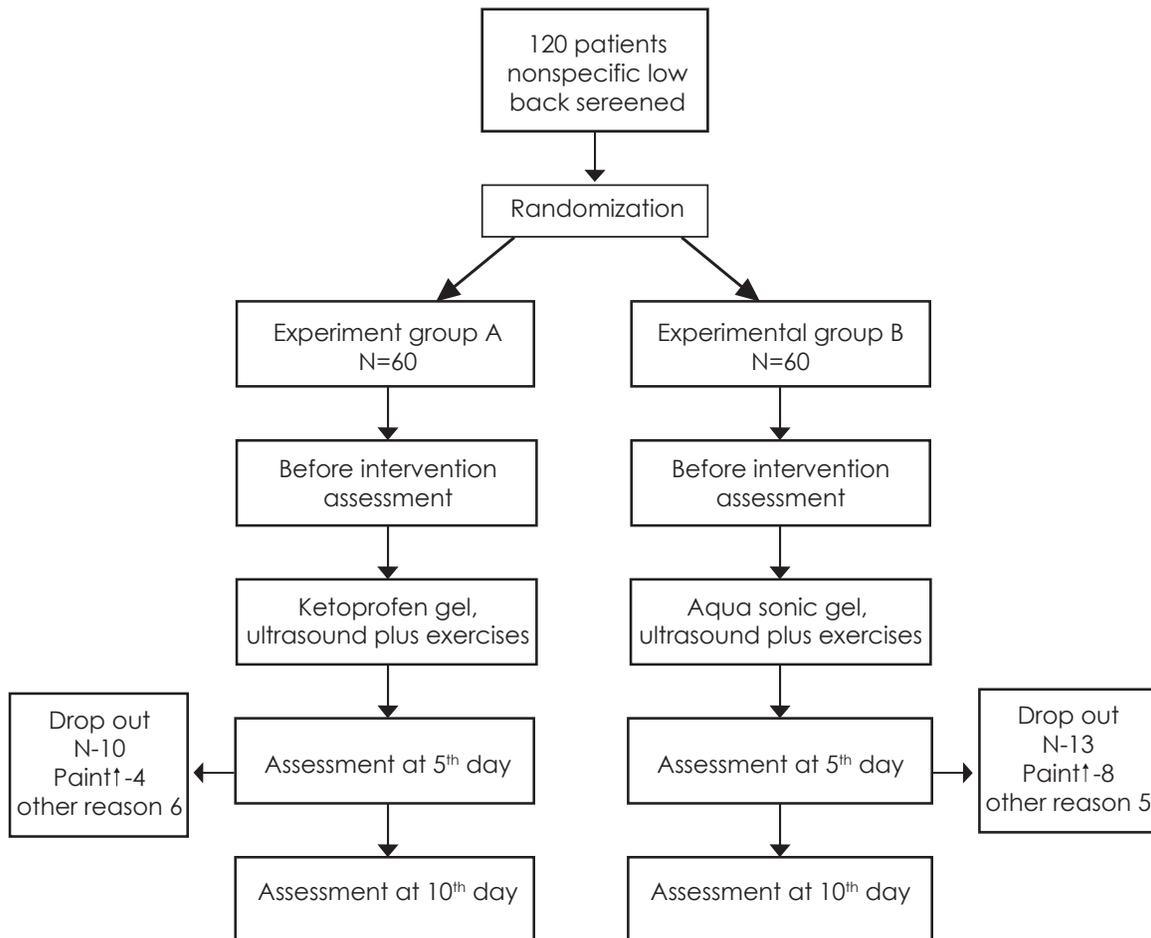


Figure 1: Flow chart of experimental trail

Table 1: Mean, std. deviation and within group association for both the groups

Group	Mean±Std. Deviation	P-value
Group A VAS1-VAS2	3.07±0.77	0.000
Group B VAS1-VAS2	5.08±0.85	0.06

VAS noted after completion of treatment, is shown in table 1. There was significant difference before and after treatment in pain intensity between group A (Mean±SD 3.07±0.77 and p=0.000) and group B (Mean±SD 5.08±0.85 and p=0.06). This shows that decrease in pain of group A (Ketoprofen gel) was significantly lower than group B (Aqua sonic

gel). While disability level was measured by ODI which shows improvement in disability level after the treatment in both groups but greater improvement was achieved in group A as compared to group B. Table 2 shows group A and table 3 shows group B, ODI score interpretation.

Table 2: Frequency of ODI at before, during and after treatment sessions for Group A

Score of interpretation	Frequency Before	Frequency Mid	Frequency After
0-20% Minimal disability	6	20	34
20-40% Moderate disability	40	28	16
40-60% Severe disability	12	2	0
60-80% Crippled	2	0	0
Total	60	50	50

Table 3: Frequency of ODI at before, during and after treatment sessions for Group B

Score of interpretation	Frequency Before	Frequency Mid	Frequency After
0-20% Minimal disability	6	20	34
20-40% Moderate disability	40	28	16
40-60% Severe disability	12	2	0
60-80% Crippled	2	0	0
Total	60	50	50

DISCUSSION

A Study conducted by Crichton, 2001 indicated that ultrasound with aqua sonic gel and therapeutic ultrasound with olive oil both have equal effects in treatment of low back pain and show improvement in activities²³. Another study conducted by Stevens et al, 2006 investigates that methyl salicylate phonophoresis in combination with cryotherapy more effective in pain reduction and patients recovered faster than alone cryotherapy or phonophoresis.²⁴

In a study by Krismer and Van Tulder, 2007 pain intensity was between 5-7 before treatment in both groups but after treatment, pain intensity was below 3 in more patients in the ketoprofen gel group. Therefore, ketoprofen acted as pain killer, suggesting that this gel is used as the nearby treatment of musculoskeletal problems and irritation in muscles and joints (injuries, twists, strains, firm neck). The topical application of the dynamic molecules is locally successful, and due to low systemic bioavailability, it is connected with less unfavorable occasions than with systemic effects of oral ketoprofen. Patient's pain intensity reduced faster than simple ultrasound.²

Savigny et al., 2009 stated that there was no significant difference between pre and mid-session in both groups but in the pre and post treatment effects of aqua sonic gel, there was a minor decrease in pain compared to ketoprofen group. Ultrasound has therapeutic effects and also acts as a heating modality to produce heat by sound waves via motion of the transducer head on the affected area, increasing tissue temperature. Similarly, many researchers who investigated the effects of ultrasound versus placebo ultrasound found that ultrasound is effective in management of backache but suggested that ultrasound provided only short term effects.²⁵

In the study by Ebadi et al., 2012, continuous ultrasound was applied in both groups at a frequency of 1MHz and 1.5 W/cm² for 10 minutes on lumbar paravertebral region to attain effective results of therapeutic ultrasound. Other studies also used the same parameters in their studies because deep tissues required 1MHz frequency at this frequency penetration is more with intensity 1.5 W/cm² due to the larger area and delivery of drugs through these parameters is effective which increased the circulation and enhanced the waste products removal. There are two modes of ultrasound, continuous and

pulsed. In this study, continuous mode is used because it reduces the thickness of fluid molecules and pain sensitivity by slowing nerve transmission velocity and boosts metabolic rate. Ebadi et al., 2012

The present study is on the comparison of effectiveness of therapeutic ultrasound with therapeutic ultrasound and aqua sonic gel in the management of nonspecific low back pain. The main aim of this study was to find out a more effective treatment for reduction in pain and improvement of daily life activities in patients with nonspecific lower back pain.

Limitations: limiting factors were shortage of time and large sample size, better and in depth research could be done if finance was not limited, inadequacy of direct access of complete text related to researches, unlimited researches.

CONCLUSION

It can be concluded that reduction in pain intensity and disability level with strengthening and stretching exercises in ketoprofen gel group greater compared to the aqua sonic gel group after the ten consecutive treatment sessions. Therefore, ketoprofen gel with exercises is more helpful in reduction of pain and functional disability level in non-specific low back pain.

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