Original Article

COMPARISION OF THE EFFICACY OF KETOPROFEN AND AQUASONIC GEL IN THE MANAGEMENT OF NON-SPECIFIC LOW BACK PAIN

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Abstract

Objective: The objective of this study was to examine the efficacy of Aquasonic gel and ketoprofen gel on pain and disability in the patients with nonspecific low back pain.

Study design: The study design was experimental randomized trial,conducted at MadinahTeaching Hospital and Sugraha trust hospital Faisalabad .

Method : In this study included 20 to 35 years age group both male and female. A convienient sampling technique of patients used visiting in physiotherapy department during months of Febraury-June 2016. Signed the informed consent forms and the privacy of patients will be taken into consideration. Two groups were made Group A was received ultrasound with Ketoprofen gel with strengthening and stretching exercises. Whereas Group B was received ultrasound with Aquasonic gel with strengthening and stretching exercises. Total treatment sessions were 10 consecutive days. The pain intensity was measured by visual analogue scale (VAS) and functional level was measured by Oswestry Disability Questionnaire (ODQ) before , mid and at the end of the treatment.

Result: Pain mean was before treatment 5.65±0.58 in ketoprofen gel group and 5.70±0.79 in aquasonic gel group but after treatment mean reduced to 3.07± 0.77 in ketoprofen gel group and 5.08± 0.85 in aquasonic gel group. While functional level also improved in ketoprofen gel group after treatment as compared to aquasonic gel group.

Conclusion: It could be 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.

Key words: ketoprofen gel, aquasonic gel, non-specific low back pain

INTRODUCTION:

Lower spinal back pain is a very common everyday problem which mostly people experienced in their life at some points (Hoy et al., 2010). It can be specified and non-specified lumbar back pain. Most of patients presented without causes they have no specific underlying cause of back pain, but in about 10% of cases there is a specific known cause of pain (Krismer and van Tulder, 2007). Non specific low back pain constitutes about eighty five percent which are treated in primary care settings as well as a great amount of backache also manage by physical therapists (Wand and O'Connell, 2008). Non specific low back pain varies with the change in posture and activity so it is also called mechanical low back pain (Kenny, 2013). Backache presented with the spasm, tenderness and pain in lumbar back area that is not due to tumor, sepsis, fracture, ankylosing spondylitis or other inflammatory diseases is known non-specific lumbar back pain (Savigny, Watson and Underwood, 2009). Lower spine back pain is very frequent in the younger and middle aged individuals (TAGUCHI, 2003).

According to Lehman, et al., 2005 for the avoidance and management of lower back pain spinal muscle contraction and stability exercises are very useful. While according to Stevens et al., 2006 therapeutic exercises are beneficial for development of lumbar-pelvic stability especially bridging exercise used for this purpose. So clinician or physical therapists must educate the patients thoroughly about the exercise and also explain those sets and repetitions (Dickerman, 2005).

Therapeutic ultrasound (US) is utilized in the management of damaged tissues but still there is less evidences for the management of back pain in patients with therapeutic ultrasound(Ebadi etal.,2012). Phonophoresis is a procedure by which

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therapeutic ultrasound is used to administrating pharmacological agents, mainly NSAIDs or analgesic medicines, over the unharmed skin to the subcutaneous tissues (Saliba et al., 2007). Ketoprofen is a drug known as NSAID. It is frequently prescribed simply as 'an anti-inflammatory', or as a 'NSAID'. It acts by inhibiting the synthesis of some chemicals in body which results in pain and tenderness. When ketoprofen is used topically on the skin as a gel, it will produce localized effect instead of generalized effect. It is immersed into skin and then penetrates deeper into areas of body which are inflamed (Allen, 2013). So efficacy of this drug was remained ambiguous via phonophoresis. This study was conducted to examine the efficacy of ketoprofen gel phonophoresis in the reduction of pain and disability level in the non-specific low back pain.

SUBJECT AND METHOD:

STUDY DESIGN: This research design was (experimental) Randomized trial.

PARTICIPANTS:

RECRUITMENT PROCEDURE:

Convenient sample of patients was between ages 20-35 years both male and female visiting physical therapy centre of Madinah Teaching Hospital, and Sugrah Trust Hospital Faisalabad during the period of February to June, 2016. Patients not involved 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.

DATA COLLECTION PROCEDURE:

Before collecting the data, all information about the study was provided to the patients then they were signed the consent forms. Privacy of patients was taken into consideration. There were 30 males and 30 females which were randomly allotted to two treatment groups. Total sample size was 120. Two treatment groups were made, in group A applied ketoprofen phonophoresis with stretching and strengthening exercises, While in group B applied Aquasonic gel through Ultrasound with stretching and strengthening exercises.

Participants in each group were received 10 sessions of treatment at 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.(Discontinued the treatment if pain increased then other modalities was used).

ULTRASOUND APPLICATION:

Each group was received; continuous US that applied on the paravertebral region of lumbar spine at 1 MHz frequency while intensity was $1.5W/cm_2$ with continouous mode for ten minutes according to Ojoawo et al., 2015, Onuwe, Amadi plus Odeh, 2013, Durmus et al., 2009, Ebadi et.al, .2013

Patients instructed to perform stretching exercises prone on elbow; rise on elbows as possible, keeping hips on floor and strengthening exercise bridging; Supine lying flat back with bent knees feet should be flatted 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, it also depend on the ability of each patient.

OUTCOME MEASURES:

Primary and secondary both outcomes measured. Primary outcome was reduction in pain measured through the visual analogue scale (VAS) which measure reading form 0-10, 0 means no pain while 10 mean maximum pain and also pain is divided in to three levels mild, moderate, severe. If a respondent within 0-3 range it indicates mild pain while 3-7 and 7-10 is moderate and severe respectively. Respondents mark the pain level corresponding degree of pain they feel and also provide freedom to express their exact pain intensity (CRICHTON, 2001).

The secondary outcome was reduction in disability which is measured by modified oswetery scale. Modified Oswestery low back pain disability index questionnaire was used for assessment of low back pain during activities of daily living before and after in 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 (JM and JJ, 2001).

DATA ANALYSIS:

The acquired data was entered in to SPSS version 20. Paired sample t- test were applied to compare the VAS. The data was subjected to further analysis for test of significance using 5% level of significance .Then data was 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 out was 10 while in group B drop out was 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 aquasonic gel group.

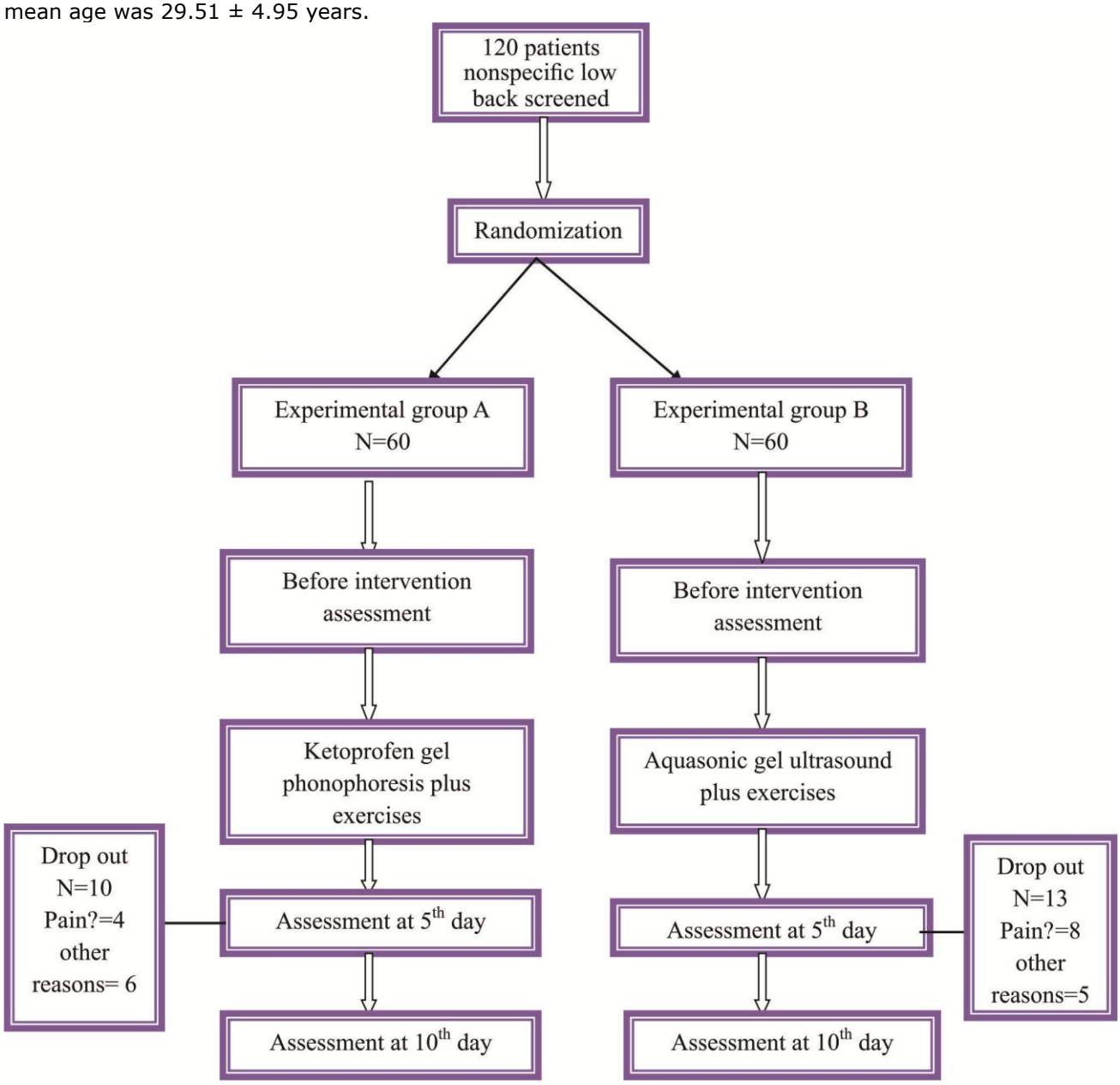

Figure 1. Flow chart of experimental trail

Table .1 paired sample t-test

Score of interpretation	Frequency Before	Frequency Mid	Frequency After
0-20% Minimal disability	6	22	24
20-40% Moderate disability	30	14	20
40-60% Severe disability	20	9	3
60-80% Crippled	4	2	0
80-100%	0	0	0
Total	60	47	47

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). Which shows that pain decreases in group A (Ketoprofen gel) was significantly lower than group B (Aquasonic 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 the group A as compared to group B. The table 2 shows group A and table 3 shows group B, ODI score interpretation.

Table 2. Group A ODI score interpretation

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
80-100%	0	0	0
Total	60	50	50

Table 3. Group B ODI score interpretation

	Paired sample difference					
	Mean	**Std. Deviation**	**Std. Error Mean**	**t**	**df**	**Sig.2-tailed**
Group A VAS1-VAS2	3.07	0.77	.087	11.4	54	.000
Group B VAS1-VAS2	5.08	0.85	.213	16.4	56	0.06

DISCUSSION:

The present study is on the comparison the efficacy of ketoprofen and aquasonic gel in the management of nonspecific low back pain. The main aim of this study was to find out the more effective treatment for reduction in pain and improvement of daily life activities in nonspecific low back pain patients.

This study shows significant difference in pre and post treatment in pain intensity and disability in the ketoprofen gel group. While Ojoawo et al., 2015 also found improvement in pain and disability in experimental group as compared to the control group. Similarly Nakhostin-Roohi and Bohlooli, 2014 study indicated that ultrasound with aquasonic gel and phonophoresis with olive oil both have equal effects in treatment of low back pain and show improvement in activities. Onuwe, Amadi and Odeh, 2013 methyl salicylate phonophoresis in combination with cryotherapy more effective in pain reduction and patients recovered faster than alone cryotherapy or phonopheresis.

In the present study pain intensity was between 5-7 before treatment in both groups but after the treatment pain intensity was below 3 in more patients in the ketoprofen gel group because ketoprofen act as pain killer, Stafeno, 2011 suggested 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 arrival of the dynamic molecules is locally successful, and due to the low systemic bioavailability is connected with less unfavorable occasions than with systemic effects of oral ketoprofen, so patient's pain intensity reduced faster than simple ultrasound.

In the present study there was no significant difference between pre and mid-session in the both groups but in the pre and post treatment effects of aquasonic gel shows minor pain decrease as compared to ketoprofen group because ultrasound has therapeutic effects and act as a heating modality to produce heat by sound waves via motion of the transducer head on the affected area which increase the tissue temperature, similarly, many researchers Ebadi et.al, 2013, Durmus et al., 2009 investigated the effects of ultrasound versus placebo ultrasound they found that ultrasound is effective in management of backache. But Boyraz et al., 2015 suggested that ultrasound provide short term effects.

In this study continuous ultrasound applied in both groups at frequency 1 MHz and intensity 1.5 W/cm2 for 10 minutes on lumbar paravertebral region to attain effective results of therapeutic ultrasound. Onuwe, Amadi plus Odeh, 2013, Ebadi et.al, 2013, Ojoawo et al., 2015, Nakhostin-Roohi and Bohlooli, 2014 and Durmus et al., 2009 were also used same parameters in their studies because deep tissues required 1 MHz 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 used because it reduced the thickness of fluid molecules and pain sensitivity by slowing nerve transmission velocity and boost metabolic rate.

LIMITATIONS:

Following were the limiting factors.

- 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.
- Limited researches.

CONCLUSION:

It could be concluded that reduction in pain intensity and disability level with strengthening and stretching exercise in ketoprofen group is more as compared to aquasonic gel group after the ten consecutive treatment sessions. So ketoprofen gel with exercises is more helpful in reduction of pain

and functional disability level in the non-specific low back pain.

REFERENCES:

1. CRICHTON, N. (2001). Visual analogue scale. Blackwell Science Ltd, Journal of Clinical Nursing, 10:697-706
2. Dickerman, R. (2005). Specific Low Back Pain Exercises. [online] Spine-health. Available at: http://www.spine-health.com/treatment/physical-therapy/specific-low-back-pain-exercises [Accessed 16 Jul. 2016].
3. Ebadi, S., Ansari, N., Naghdi, S., Jalaei, S., Sadat, M., Bagheri, H., vanTulder, M., Henschke, N. and Fallah, E. (2012). The effect of continuous ultrasound on chronic non-specific low back pain: a single blind placebo-controlled randomized trial. BMC Musculoskeletal Disorders, 13(1):192
4. Hoy, D., Brooks, P., Blyth, F. and Buchbinder, R. (2010). The Epidemiology of low back pain. Best Practice & Research Clinical Rheumatology, 24(6):769-781.
5. JM, F. and JJ, I. (2001). A comparison of a modified Oswestry Low Back Pain Disability Questionnaire and the Quebec Back Pain Disability Scale. Functional fitness and physical therapy, 81:776-788.
6. Kenny, D. (2013). Non-specific low back pain in adults. [Online] patient trusted medical information and support. Available at: http://patient.info/health/nonspecific-lower-back-pain-in-adults.
7. Krismer, M. and van Tulder, M. (2007). Low back pain (non-specific). Best Practice & Research Clinical Rheumatology, 21(1):77-91
8. Lehman, G., Hoda, W. and Oliver, S. (2005). Trunk muscle activity during bridging exercises on and off a Swissball. Chiropractic & Osteopathy, 13(1):14.
9. Saliba, S., J mistry, D., H perrin, D., Gieck, J. and Weltman, A. (2007). Phonophoresis and the Absorption of Dexamethasone in the Presence of an Occlusive Dressing. J Athl Train, [online] 42(3)(PMC1978471):349–354. Available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1978471/
10. Savigny, P., Watson, P. and Underwood, M. (2009). Early management of persistent non-specific low back pain: summary of NICE guidance. BMJ, 338(jun043):b1805-b1805.
11. Stevens, V., Bouche, K., Mahieu, N., Coorevits, P., Vanderstraeten, G. and Danneels, L. (2006). Trunk muscle activity in healthy subjects during bridging stabilization exercises. BMC Musculoskeletal Disorders, 7(1):75.
12. TAGUCHI, T. (2003). Low Back Pain in Young and Middle-Aged People. the Journal of the Japan Medical Associatio, 46(10):417–423
13. Wand, B. and O'Connell, N. (2008). Chronic non-specific low back pain – sub-groups or a single mechanism? BMC Musculoskeletal Disorders, 9(1):11

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