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Research Article

Effects of Pulse Ultrasound and Kneading Massage Using Lofnac Gel in the Management of Chronic Non-Specific Low Back Pain: A Randomized Control Study

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Abstract

Background: Continuous Therapeutic Ultrasound (CTUS) has been investigated in patients with low back pain but effect of pulse therapeutic ultrasound (PTUS) has not been thoroughly investigated.

Objectives: The study examined the effect of PTUS in the management of patients with non-specific low back pain (CNSCLBP) in comparison with kneading massage.

Methods: Fifty CNSLBP recruited purposively were randomly assigned into ultrasound group and kneading massage group equally. Subjects received stabilization exercise as baseline treatment. Ultrasound group (USG) received pulse mode of ultrasound (PUS) with Lofnac gel while kneading massage group (KMG) was treated using kneading massage (KM) with Lofnac gel. The treatments were administered twice in a week for six weeks. Pain intensity (PI) and disability index (DI) were assessed at baseline, third week and sixth week of treatment. Descriptive and inferential statics were used to summarise the data.

Result: There was a significant difference in pre- and post-treatment PI ($F=32.6$, $P < 0.001$) and DI ($F=2.5$, $P < 0.021$) in USG. In KMG, there was a significant difference in the pre and post treatment DI ($F= 4.1$, $P < 0.05$) but not in PI ($F =2.9$, $P < 0.086$). In the sixth week, there was a significant reduction of PIin the USG relative to PI in the KMG ($F=11.98$, $P < 0.001$), and a significant improvement in the DI in the KMG relative to that in the USG ($F= 2.58$ $P=0.05$).

Conclusion: Pulse ultrasound may be better than KM in management of PI but KM is better than PUS in DI of patients with low back pain.

Keywords: Ultrasound; Kneading Massage; Low Back Pain; Pain Intensity; Disability

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Background

Low back pain (LBP) is a prevalent global disorder, being one of most frequent complaints affecting nine of ten adults at some points in their lives and five of ten working adults, per year [1]. In Africa, Louw et al. reported a prevalence of 12% among adolescents and another of 32% among adults [2]. These findings are in tandem with the global burden of diseases of low back pain suggesting that there is an increase in incidence of LBP in Africa, a challenge which should spur members of health profession into action Louw et al [2]. A study in southwestern Nigeria by Omokhoidon concluded that 40 % of the study population had low back pain in the last 12 months and 33 % percent had LBP at the time of their study [3].

The goals of treatment of patients with LBP are that the patients return to their desired level of activities and participation, and to prevent chronic complaints and recurrences [4]. In the management of NSLBP with non-pharmacological methods, there are many instruments and techniques within the physiotherapeutic armamentarium, of which therapeutic ultrasound (TUS) is among those commonly used [5]. The use of TUS can be in two modes: continuous and pulse. Continuous TUS entails delivering the TUS wave steadily, without any interruption; while pulse is TUS is intermittent in nature in the course of the treatment [6]. In the application of TUS, sound waves convert minute gas-pockets in the tissues into cavities and bubbles, which results in stable acoustic cavitation causing the micro bubbles to pulsate without imploding which leads to micro streaming of fluid around the pulsating bubbles [7]. Due to processes called non-thermal changes, the cell membrane activity improves the vascular wall permeability and enhances soft tissues healing [8]. Systematic review by Kumar et al., documented that, in the management of NSLBP, especially for the short term, massage may be considered as a treatment option in comparison with placebo and some active treatment options [9]. Their study also reported that there are conflicting and contradictory findings for the effectiveness of massage therapy when compared with other manual therapies, standard medical care, and acupuncture.

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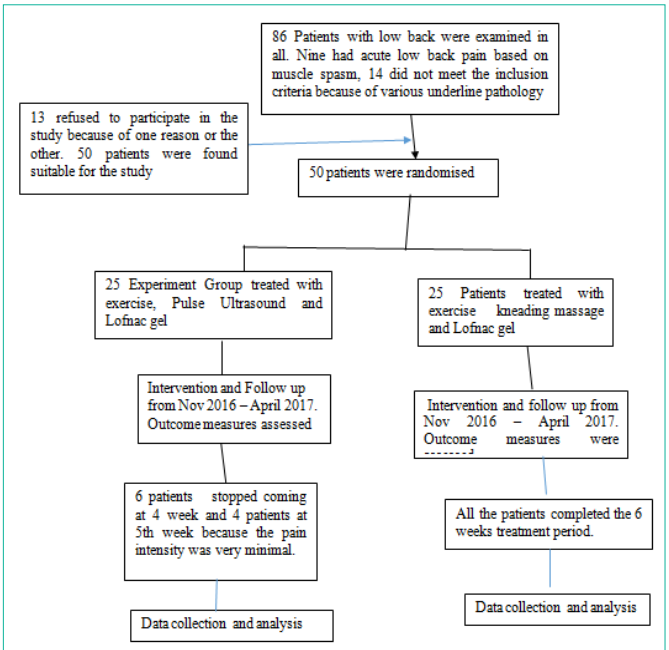

Figure 1: Consort diagram of random allocation of subjects in to 2 groups.

Continuous TUS have been investigated in patients with NSLBP [9,10]. Pulse TUS has been reported to be useful and effective in transdermal absorption in Wistar rats using indomethacin, gold nanoparticles and dimethyl sulfoxide [11-13]. More importantly, researches have shown comparison of massage with each of self-care, acupuncture, exercise and education, and muscle relaxation [14]. In addition, TUS requires the use of electricity which is not at regular supply in many health facilities in Nigeria, but kneading massage does not require electric power or equipment. The question is, will kneading massage produce a similar effect with pulse ultrasound in patients with CNSLBP? The purposes of this study were to examine the effects of pulse TUS and kneading massage and to compare their effects on the pain and disability of patient with NSLBP. The main hypothesis is that there will be no significant difference in the post treatment values of PI and DI in patients with CNSLPB using PUS and KM.

Subjects and Methods

The subjects for the study were patients with chronic non-specific low back pain (CNSLBP) receiving treatment at Physiotherapy Department, Osun State Specialist Hospital, Oshogbo, Nigeria. The inclusion criteria for the patients were patients with non-specific low back pain with symptom of pain lasting more than three months. Patients with nerve roots symptoms, underlying systemic or visceral disease, and specific conditions such as neoplasms, fracture, ankylosing spondylitis, previous low back surgery, and pregnancy were excluded from the study. The design of the study was quasi-experimental design.

Among other screening procedures, spinal movements that provoked pain were noted because spinal pain of mechanical origin may be reproduced by movement which induces tension and neural sliding [15]. Straight leg raising and Ely's test were carried out according to Nwuga [16] and were found to elicit pain at the lower back. X- Ray report of each patient was also reviewed and none of the reports indicated osteoporosis, carcinoma, or pot disease.

Table 1: Summary of Repeated Measure ANOVA Comparing the mean value of pain intensity, disability index, pre-treatments, 3rd week and 6th week of treatment in PUS group N= 25.

VARIABLES	MEAN ± SD	F	P
PI			
PRE	5.2 ± 0.45	32.6	0
3RD	3.0 ± 0.71		
6TH	2.4 ± 0.54		
DI			
PRE	65.3 ± 24.3	2.5	0.021
3RD	49.4 ± 17.1		
6TH	37.5 ± 16.4		

Key: ** Significant at p < 0.01, * Significant at P < 0.05. PI=Pain Intensity, DI=Disability Index.

In order to determine the number of subjects to be involved, a sample size equation to compare two means according to Eng, [17] was used:

$$N = 4\delta^2(Z_{crit} + Z_{power})^2/D^2$$

Where N is the sample size (the sum of sizes of both comparison group). Where δ is the standard deviation of each group (assumed to have a value of six and to be equal for both groups). Z_{crit} is the standard normal deviation corresponding to the selective significant criterion [i.e. 0.05 (95% =1.960)].

Z_{power} is the standard deviation corresponding to the selective statistical power (i.e 0.80=0.842).

D is the minimum expected difference between the two mean values, to be significant the value should be 2, therefore D = 5 are chosen.

$$N=4*6^2(1.96 + 0.842)^2/5^2$$

$$=45.22= 45$$

Therefore, the total numbers of 50 subjects were enrolled for the study: 25 subjects for the PUS group and 25 subjects for the KM group in order to give room for attrition. The patient flow chat was shown in Figure 1.

For the purpose of the study the following instruments were used: verbal-rating scale, Roland-Morris disability questionnaire, and an ultrasound machine.

The verbal rating scale (VRS) is a 10-point scale with 1 and 10 indicating the extremes used to assess pain. The VRS was validated with the visual analogue scale by Williamson and Hoggart who concluded that VRS provides a useful alternative to the visual analogue scale scores in the assessment of chronic pain. VRS was used to measure present pain, i.e., pain at the time of study [18].

Roland Morris Disability Questionnaire (RMDQ): This is a commonly utilized instrument for measuring spinal disability as an outcome measure [19]. It is a 24-item questionnaire that is relevant to low back pain disability. RMDQ is easy to score by totalling the

Table 2: Summary of Repeated Measure ANOVA comparing the mean values of pain intensity and disability index, Pre-treatment, 3rd week and 6th week in KM group N= 25.

VARIABLES	MEAN ± SD	F	P
PI			
PRE	5.7 ± 1.3		
3RD	5.2 ± 1.2	2.9	0.086
6TH	4.0 ± 0.7		
DI			
PRE	60.7 ± 12.7	4.1	0.038
3RD	47.1 ± 13.4		
6TH	41.7 ± 10.5		

Key: * significant at P < 0.05. PI = Pain Intensity, DI = Disability index.

sum of circled items (maximum is 24) which represent the final score. The Roland Morris study was referred to as the best single study of assessing short-term outcome of primary care patients with low back pain [20].

Ultrasound machine (with pulse and continuous mode; Sonopuls 490, Enraf-Nonius B.V, Rotterdam and The Netherlands): This was used to produce the ultrasonic wave for phonophoresis. Subjects were randomized into the two groups as follows: Envelopes which contained alphabets A and B were made. Subjects were asked to pick from the envelopes. All subjects who picked A were assigned to ultrasound (PUS) group, whereas subjects who picked B were assigned to kneading massage (KM) group. Ethical approval was obtained (HREC No: IPHOAU/12/784) from the Health Research and Ethics Committee, Institute of Public Health, Obafemi Awolowo University, Ile-Ife, Nigeria, and informed consent of the participant was obtained.

Subjects in each group received 12 sessions of treatment within a period of six weeks of treatments. Subjects in each group were placed on stabilization exercise for 20 minutes. Pulse ultrasound was administered for the subjects in pulse ultrasound group and kneading massage for the control group. Lofnac gel was used as topical gel for the subjects in the two groups. Treatment was administered twice (Monday and Fridays of every week for six weeks). Assessment was done before the treatment began and every Mondays of the week of the treatment.

The PUS group received pulse mode of ultrasound (sonoplus 490s), with frequency of 1MHZ and intensity of 1.5w/cm according to Ebadi et al [10]. Grey's formula was used to estimate the duration of ultrasound (US) for each patient [21]. The average local exposure time was one minute and the effective radiating area of the transducer head was 5 cm^2. For a patient with an area of low back pain of 40 cm^2, the required total treatment time was: 1 min × (40 cm^2/5 cm^2) = 8 minutes. US was applied using slow circular movements, with the transducer head placed over the painful paravertebral low back region and Lofnac gel used as coupling medium.

Kneading massage was done with the two hands maintaining a slow circular compression of soft tissues against underlying bone. Pressure was applied as the hands moved proximally, continuously maintaining a contact with the skin, according to Goat [22]. Lofnac gel was used as a coupling medium for the massage. This was done for an approximately ten and 12 minutes.

For stabilization exercise, a supervised exercise program was employed for each patient. The exercises included posterior pelvic tilts, sit-ups, bridging, quadruped exercises, and posterior hip and knee muscles stretching [23]. Not all patients could do all the exercise at a stretch; exercises were done according to the levels of tolerance and endurance of each patient. Patients were instructed to perform two to three stretches (of all muscles) per treatment and hold the stretch for 20 seconds unless it hurts. Strengthening exercises started with five repetitions and progressed according to each patient's improvement, to three sets of 10 repetitions [10].

In order to avoid co-interaction, subjects were informed not to participate in any other exercise or treatment program until the end of the follow-up period. Also they were informed not to take any analgesic drug during the period of this treatment without the consent of the researchers. However, no patients requested for additional medication apart from the treatment in the department. The primary measure was pain intensity and the secondary outcome measure was disability index. They were measured by a separate physiotherapist who was independent of the study every week of the treatment. Data for pre-treatment, third week, and six week of treatment were used for data analysis.

The data was analyzed using Statistical Package for Social Sciences (SPSS 17). Descriptive statistics and inferential statistics were used to summarize the data. Independent-t-test was used to compare the anthropometric indices of subjects in each group. Repeated measure analysis of variance (ANOVA) was used to compare the mean values of pre-treatment, third-week and sixth-week pain intensity and physical function within the group and across the group. Post hoc analyses were carried out when necessary. An alpha level of < 0.05 is set as significant level.

Results

Revealed in Table 1 is the summary of the Repeated Measure ANOVA comparing the pain intensity and disability index of subjects in PUS group pre-treatment, third, and sixth week of treatment session. There was significant reduction in pain intensity (F=32.6, P=0.00) and disability (F=2.5, P= 0.021) between pre-treatment and sixth week of treatment in the ultrasound group. Shown in Table 2 is the summary of the repeated measure ANOVA comparing the pain intensity, and disability index of subjects in KM group, pre-treatment, third, and sixth week of treatment. There was no significant reduction (F=2.9, P=0.086) in pain intensity between pre-treatment and sixth week of treatment in ultrasound group but there was significant reduction in disability index between pre-treatment and sixth week of treatment in group B.

Analysis of variance with the post hoc analysis that assessed the direction of significance was reported in Table 3. There was no significant difference (P> 0.05) between PUS and KM group in the pre-treatment PI and DI but PI of PUS group was significantly lower (F = 11.98, P<0.000) than that of KM group at sixth week. Similarly, the disability in the KM group was significantly (F=4.1 P=0.038) lower at sixth week compared to PUS group. The magnitude of the effect size of comparing the third and sixth weeks of PUS group and KM group of pain intensity and disability index was shown in Table

Table 3: Comparison of the outcome measure across the two groups' pre-treatment, 3rd week and 6th week N=50.

VARIABLES	GROUP A	GROUP B	F	P
	MEAN ± SD n=25	MEAN ± SD n=25		
PI PRE	5.2 ± 0.45^{a**}	5.7 ± 1.3^{a}		
3rd	3.0 ± 0.71^{b**}	5.2 ± 1.2^{a}	11.98	0
6th	2.4 ± 0.54^{c**}	4.0 ± 0.7^{d}		
DI PRE	65.3 ± 24.3^{a}	60.7 ± 12.7^{a}		
3rd	49.4 ± 17.1^{b*}	47.1 ± 13.4^{c}	2.58	0.05
6th	37.5 ± 16.4^{d*}	41.7 ± 10.5^{e}		

Keys: Post-hocs least significant difference; Superscript abcde-mean mode with the same superscript indicates no significant difference between mean. Mean mode with different superscript indicates significant difference.

Table 4: Magnitude of Effect Size Using Partial Eta Square for Pain Intensity and Disability between the two Groups for 3rd and 6th Week N=50.

Variables	M1	M2	ΔM	SD1	SD2	SD1+SD2	PETA (Π^2_p)
Pain Intensity							
PUS & KM 3rd WK	3	5.2	2.2	0.71	1.2	1.91	1.15**
PUS&KM 6rd WK	2.4	4	1.6	0.54	0.7	1.24	1.29**
Disability Index							
PUS & KM 3rd WK	49.4	47.1	2.3	17.1	13.4	30.5	0.07
PUS & KM 6th WK	37.5	41.7	4.2	16.4	10.5	26.9	0.15*

Key: PUS = Pulse Ultrasound group, KM = Kneading massage group; WK = Week, M1 = mean values for PUS group; M2 = Mean value for KM group; = Change in means, SD = standard deviation. PETA = Partial Eta square **Significant at P< 0.01, * Significant at P<0.05.

4. The pain intensity at third week is significantly (F=2.710, P = 0.000) reduced in PUS group than in KM group, with the mean difference of 2.2 and the effect size being significant with η^2_p of 1.15. However, there was a significant (F= 9.810, P= 0.039) increase (4.2) in the improvement of the disability in KM group at sixth week compared with PUS group with significant effect size ($\eta^2_p = 0.15$).

Discussion

The purpose of this study was to examine the effect of pulsed ultrasound therapy (PUS) and to compare it with kneading massage (KM) on pain intensity and disability in the treatment of chronic non-specific low back pain.

The study observed that there was no significant difference in the physical characteristics of the subjects in the two groups. This can be interpreted to mean that the subjects in the two groups were comparable, an indication that the difference observed from the study was due to the intervention, not to the variation in the physical characteristics. The study revealed that there was a significant reduction in pain intensity of the subjects in PUS group when the baseline values were compared to the third and sixth week. It has to be noted that there was no significant difference from the pain intensity in the kneading massage (KM) group comparing the pre-treatment, baseline and sixth week. The present study revealed that pulsed mode of ultrasound has a significant effect in driving the active ingredient of Lofnac (methyl salicylate and diclophenac) gel into the tissues in the low back more than kneading massage, hence the reduction in pain intensity in the PUS group. Ojoawo et al [11] in their study though using continuous form of ultrasound for phonophoresis of Lofnac gel reported a significant improvement in pain intensity compared with ultrasound without Lofnac gel. This is a confirmation that Lofnac gel is effective in the management of chronic low back pain, which is in tandem with our study. The enhancement of taking in of drug by the skin using therapeutic ultrasound wave is called phonophoresis [12]. Phonophoresis involves the use of ultrasound energy for transdermal delivery of low-molecular-weight drugs [24].

Therapeutic pulse US creates a combination of acoustic, streaming, and cavitation, very difficult to delineate 25. Acoustic is defined as the physical forces of the sound waves that provide a driving force capable of displacing ions and small molecules [26]. This is the principle of phonophoresis. At the cellular level, organelles and molecules of different molecular weight exist; some of these structures are stationary, while many are free-floating and may be driven to move around more stationary structures. The mechanical pressure applied by the wave produces unidirectional movement of fluid along and around cell membranes, a phenomenon called streaming [26]. Another effect of pulse ultrasound is cavitation, which could be explained as the physical forces of the sound waves on micro-environmental gases within a fluid 27. As the sound waves propagate through the medium, the characteristic compression and rarefaction causes microscopic gas bubbles in the tissue fluid to contract and expand; the rapid changes in pressure caused by the leading and lagging edges of the sound wave both in and around the cell, may cause damage to the cell [27]. The process of cavitation, may be used to explain how pulsed ultrasound wave can drive in active ingredients of Lofnac gel (methyl salicylate and diclofenac) into the deeper tissues and vertebrae of the low back, the site of the pain.

Ojoawo et al., in their research, documented that Lofnac gel and exercise were effective in the management of pain intensity of patients with non-specific low back pain [11]. It will be recalled that there was no significant difference between the baseline, the third and sixth week of pain intensity in kneading massage group. In addition, PUS group was found to have a significant reduction of pain intensity in the sixth week of treatment session compared with KM group with a significant effect size using partial eta square. This could be interpreted that the absorption of lofnac gel through kneading massage is not deep enough to reach the level of pain in patients with low back pain. Therefore this study affirmed that therapeutic exercise with kneading massage using non-steroidal anti-inflammatory drugs (NSAID) as a coupling medium may not produce a significant reduction in the pain intensity of patient with non-specific low back pain.

The study observed further that there was a significant difference in disability, in the third and sixth week of treatment in the KM group as well as ultrasound group. However, the effect size was not significant at the third week when the two groups were compared but the sixth week of KM was better than that of PUS with a significant effect size. The significant effect of kneading massage supported the work of Pyrede [28] and Brosseau [29] who revealed that massage significantly improved both the short and long term function well than some inert treatment would. The significant increase between in the sixth week of KM than the PUS group implied that kneading massage has more effect on the musculature of the low back than the pulse ultrasound.

Kneading massage promotes the flow of tissue fluid and causes

reflex vasodilation, it decreases muscle spasm and can stretch tissues shortened by injury [29]. In the process of kneading massage which involves application of alternate pressure and mobilization, muscle tension is relieved, fibres are manipulated and muscle flexibility is increased. Massage including kneading has been reported to have the potential of providing several benefits to the body which includes increased blood flow, reduced muscle tension and neurological excitability, and an increased sense of well-being [28]. The inference from this is that after a period of massage, some features characterizing low back pain may be affected such as increase in the range of motion and active stiffness while the tension of such patient reduces. This buttresses the point that KM reduces the disability of patients with non-specific low back pain better than pulse ultrasound therapy.

The study did not follow up the improvement on the patients, owing to logistic problems within the environment of the study. Most of the patients called for the follow up could not be reached because of poor telephone service; and appointments given to them could not be honored because of the financial plight of the patients.

Conclusion

The study has established that pulse ultrasound reduces pain intensity and disability of patients with non specific low back pain significantly. However kneading massage can reduce disability in the patients with non specific low back pain more when compared to pulsed ultrasound. Therefore in clinical practice, a combination of pulsed ultrasound, stabilization exercises, and kneading massage can be helpful will be helpful in ameliorating the pain intensity and disability of patient with non-specific low back pain.

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