



# Comparison of the Therapeutic Efficacy of Double-Modality Therapy, Phonophoresis and Cryotherapy in the Management of Musculoskeletal Injuries in Adult Nigerian Subjects

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**Summary:** This study was designed to compare the efficacy of double-modality therapy, phonophoresis and cryotherapy in the management of pain among subjects who suffered from musculoskeletal injuries (MSIs). Sixty (60) subjects were assigned randomly to one of three groups: DMT group (n=20) received cryotherapy and 15% methyl salicylate phonophoresis, PHONO group (n=20) received 15% methyl salicylate phonophoresis and CRYO group (n=20) received cryotherapy and 'sham' phonophoresis. Ultrasound at an intensity of 1.5 W/cm<sup>2</sup> and frequency of 1MHz was used to apply methyl salicylate while intermittent cryotherapy was the mode of application. Subjects' pre- and post-treatment pain perception scores (PPS) using visual analogue scale (VAS) were assessed and the sessions of treatment in all groups were recorded. Treatment was administered on alternate days and discharges were made in all groups when subjects were pain free. A total of 275 treatment sessions was recorded – 72 (26.2%) in DMT, 105 (38.2%) in PHONO and 98 (35.6%) in CRYO group respectively which indicated no significant difference (P>0.05). Nineteen (19), thirteen (13) and twelve (12) subjects were pain free in DMT, CRYO or PHONO groups respectively after 1 to 5 treatments. The difference in the severity of pain was significant (P<0.05) in each group post-treatment which suggests that DMT, phonophoresis and cryotherapy were equally effective. The study has demonstrated therapeutic efficacy of DMT, but it was not superior to the single treatment protocol of phonophoresis or cryotherapy. However, it might take fewer sessions in the DMT group to treat and make more than 90% of the subjects pain free and fit to return to active performance.

**Keywords:** Cryotherapy, Double-modality therapy, Musculoskeletal injury, Phonophoresis, Ultrasound

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## INTRODUCTION

Musculoskeletal injuries (MSIs) which are usually due to strenuous activity (Hootman et al, 2002) account for roughly 25% of patient complaints in the primary health care settings (Childs et al, 2005) and are a leading cause of work absenteeism worldwide (Beeb et al, 2005). Musculoskeletal problems constitute the largest proportion of injuries among athletes (Reilly and Hardiker, 1983). Report has indicated that more than 60% of men and women who work on the computer have complained of pain resulting from various MSIs (Idowu et al, 2005). Low back pain (LBP) is not only one of the most common MSIs in industrialised societies (Sanya and Ogwumike, 2005; Saidu et al, 2011), but it is the most costly, and it is the primary cause of disability in persons under age 45 years (DeRosa and

Porterfield, 1992). In the United States more than 25,000 ankle sprains occur each day and the concomitant symptoms (pains and swelling) leave the individuals with some functional disability (Man et al, 2007).

Physical treatments (i.e phonophoresis, cryotherapy, etc.) have been used for many years and are currently being used to reduce pain, control swelling or inflammation and improve or restore function in the management of MSIs (Bolin, 2003; Kozanoglu et al, 2003). Phonophoresis which is the use of ultrasound (US) to enhance percutaneous absorption of topical drugs in the management of MSIs (Machet and Boucuad, 2002; Kuntz et al, 2006) and dermatological conditions (Kozanoglu et al, 2003) has been a widely applied clinical therapeutic procedure (Byl, 1995; Kozanoglu et al, 2003) since the first time it was used in 1954 by Fellingner and

Schmid to treat polyarthritis of the hand (Byl, 1995). It is believed to accelerate functional recovery by decreasing pain and promoting healing (Cagnie et al, 2003). In a comparative study involving iodex phonophoresis (n = 15), iodex iontophoresis (n = 15) and a placebo (n = 15) in the management of shoulder peri-arthritis, Bumin and Can (2004) did observe that iodex phonophoresis and iodex iontophoresis were significantly effective in decreasing pain as compared to the placebo. The application of cold (otherwise known as cryotherapy) for the treatment of injury or disease, particularly for increasing pain threshold, decreasing inflammatory reaction and spasm following MSIs (Swenson et al, 1996; Yagiz, 2006) has been advocated by some researchers as the sole treatment to be used during all phases of soft tissue injury (Cote et al, 1988; Swenson et al, 1996). In a systematic review of some randomised controlled trials (RCTs) to identify the efficacy of ice in the management of pain and swelling resulting from soft tissue injury, it is reported that cryotherapy seems to be effective in decreasing pain and speeds return to full activity (MacAuley, 2001; Hubbard and Denagar, 2004).

Phonophoresis or Cryotherapy in isolation or in combination with other therapies has become widely used regimen for reducing pain, inflammation and improving or restoring function in managing MSIs (Kellet, 1986; Palmer and Toombs, 2004; Wilson and Best, 2005). Davis (1991) has recommended the application of cryotherapy as a single treatment protocol for hours (i.e 72 hours) when there is trauma (i.e rotator cuff syndrome) before resorting to phonophoresis for the remaining period of treatment. Literature has indicated that cold application prior to phonophoresis produces an intense hyperemia which may improve the absorption and distribution of the medication to effect pain relief and resolution of inflammation (Santiesteban, 1983). The recognition of the importance of pain control in the recovery from MSIs to enable the injured persons return to participation (athletes) or return to work (typical population) has prompted clinicians to continue to explore more aggressive pain management strategies (Brolinson and Sampson, 2003; Hubbard et al, 2004). Some reports (Santiesteban, 1983; Balogun, 1990) suggested that phonophoresis and cryotherapy can be combined (double-modality therapy - DMT) in the management of MSIs for better outcome. Sequel to this, pain clinics and sport centres have adopted as a tradition the treatment protocol of combining phonophoresis and cryotherapy (DMT) in the management of MSIs worldwide. Despite the general acceptance and the frequency at which this treatment approach (DMT) is being practiced, there is dearth in the literature to support the practice or demonstrate its efficacy or superiority over the single treatment

protocol (Balogun, 1990; Ball, 2002). The practice is probably or largely based on anecdotal evidence rather than on empirical data. Clinical opinion just isn't good enough anymore. Hence, it is incumbent upon the clinician or the therapist to collect information or data to support clinical decision making with something more than physiologic philosophy based on opinion. Randomised clinical trials are required therefore, to support clinical decision making on the use of phonophoresis and cryotherapy as combined treatment (DMT) protocol for optimal outcome or response following MSI management.

## **MATERIALS AND METHODS**

### **Subjects**

Sixty (60) subjects (43 males, 17 females; mean 34 years; range 18 to 77 years) who sustained musculoskeletal injuries were all recruited as they presented before the physician for treatment at the Jos University Teaching Hospital, Primary Health Centres and Sports Council Clinic; all located within Jos, Plateau State in Nigeria. Only subjects who sustained not more than one musculoskeletal injury (i.e subjects with multiple injuries were not eligible) with acute onset of symptoms or occurring as an acute exacerbation of chronic lesion were included in the study. Subjects who were on any form of analgesics (steroids and non-steroidal anti-inflammatory drugs – NSAIDs), muscle relaxants and any form of physiotherapy treatments were all excluded from the study. Subjects with open wounds over the injury sites, pregnancy, disease conditions (e.g thrombophlebitis, cardiac disease patient with pacemaker, tumour, etc) and those allergic to topical methyl salicylate or cold which contra-indicate the treatment protocols used in this study were all excluded. The use of NSAIDs or analgesics and any other form of treatment was not permitted or allowed throughout the study period. Before entry into the study all subjects voluntarily signed the informed consent forms after the protocol for the trial was explained to them. All procedures involving the subjects met criteria established by the University of Jos Teaching Hospital Health Research Ethics Committee (JUTH/DCS/ADM/127/XXVI/1800).

### **Procedure**

On completion of history, careful clinical and radiographic examination the sixty (60) subjects whose injuries were classified as follows :- rotator cuff syndrome (n=15), ankle sprain (n=8), knee sprain (n=4), patellar bursitis (n=5), low back pain (n=12), muscle strain (n=10), tennis elbow (n=3), hamstring tendinitis (n=2), De Quervain tenosynovitis (n = 1) were randomly assigned to one of three treatment groups:

- (i) Double-modality Therapy (“Live” phonophoresis and cryotherapy combined) –DMT (n = 20)
- (ii) “Live”phonophoresis–PHONO (n = 20)
- (iii) Cryotherapy and “sham” phonophoresis–CRYO (n = 20)

An independent researcher generated the randomisation sequence by writing the treatment groups and placed in sequentially numbered opaque sealed envelopes which were used to assign the subjects to their respective groups. Neither the primary researchers nor any other person that was involved in treatment allocation were aware of the randomisation schedules (Brolinson and Sampson, 2003). The ultrasound machine (EMS Therasonic MK IV) and the transducer (5cm<sup>2</sup>, 1MHz and 3MHz treatment head) were all tested and certified functional. Subjects pain perception was subjectively assessed or measured and recorded using a 10cm visual analogue scale (VAS) marked “ no pain” at one end and “worst pain ever” at the other (Klaiman et al, 1998; Hoppenrath and Ciccone, 2006) after the subjects were carefully educated on the use of VAS and it was observed that subjects could identify their pain levels or scores on the scale without any difficulties. This form of assessment was considered most appropriate because of its high level of repeatability when used serially on the same patient (Bleakley et al, 2006). Sensory test was conducted among the subjects to ascertain that there was no sensory loss (Oakley, 1978). Subjects were instructed and made to understand that at no time during insonation (phonophoresis) should they suffer discomfort. There might be a sensation of very mild warmth, but other than that only the pressure and the movement of the transducer should be felt. Any other sensation should be reported at once. All subjects assigned to cryotherapy were made to understand that sensation like cold, burning, aching and numb (Kellett, 1986) would be felt during the treatment procedure which causes no harm. Finally, subjects were comfortably supported and positioned to maximise circulation to the area being treated (Byl, 1995) when they were ready for treatment.

The subjects in DMT group (n = 20) received cryotherapy and “live” phonophoresis as combined therapy (DMT). Intermittent cryotherapy (MacAuley, 2001; Bleakley et al, 2006) using ice pack (16cm x 12cm) was applied directly over the subjects conditions for 10 minutes. The ice pack was then removed after the initial 10 minutes application and allowed the treatment part to rest at room temperature for 10 minutes. The ice pack was reapplied immediately following the expiration of the rest period for another 10 minutes (total cryotherapy period = 20 minutes). At the expiration of the second ice pack application the treatment part was cleansed with a towel and continuous ultrasound at an intensity

of 1.5W/cm<sup>2</sup> and frequency of 1MHz (Byl, 1995; Klaiman et al, 1998) was used to apply 1.5g of 15% methyl salicylate cream thoroughly mixed with 1.5g of aquasonic gel (Aallen, 2005) as coupling medium for 8 minutes. The ultrasound head was moved over the part under treatment about one-half (1½) the width of the transducer at approximately 2 to 4 cm/sec; using small, continuous and overlapping circular movements (Oakley, 1978; Cagnie et al, 2003; Kuntz et al, 2006) to avoid or prevent periosteal pain (Santiesteban, 1983). These treatment values or settings were selected to capture both the thermal and nonthermal effects of ultrasound in other to optimize transdermal methyl salicylate 15% delivery (Byl, 1995; Cagnie et al, 2003). The subjects in PHONO group (n = 20) received a “live” phonophoresis as a single treatment protocol. The treatment procedure (phonophoresis) was exactly the same as applied in DMT group. All subjects in CRYO group (n = 20) received cryotherapy and “sham” phonophoresis with placebo coupling medium. Intermittent cryotherapy was applied directly over the subjects’ conditions with the same procedure described in DMT group. At the expiration of cryotherapy application, the treatment part was cleansed with a towel and continuous ultrasound at zero (0) intensity and frequency settings (no US transmission) was applied with 1.5g of placebo aquasonic gel (devoid of methyl salicylate 15% cream) as coupling medium (Ciccone et al, 1991; McElnay et al, 2004) for 8 minutes

Treatments were administered on alternate days in each group until subjects were fit for discharge. At the end of weeks 1, 2, 3 and 4 after treatment in each group, subjects post-treatment pain perception scores (PPS) were assessed and recorded. Assessment and recording of pre-and post-treatment pain perception scores (PPS) were blinded from the researchers to reduce or eliminate bias (assessment by neutral assessors). Treatments were terminated and subjects discharged in all groups when subjects felt pain was sufficiently relieved and no longer needed treatment.

### **Statistical analysis**

Descriptive and inferential statistics using the Statistical Packages for the Social Sciences (SPSS) was used for data analysis. Independent and paired mean difference tests (t – test) were used to compute subjects repeated measures within all groups while a one – way ANOVA (Klaiman et al, 1998) was used to compute measures across the groups with the level of significance for all tests set at 0.05.

### **RESULTS**

Two hundred and seventy-five (275) treatment sessions were recorded in all the groups – 72 (26.2%)

was recorded in the DMT group, 105 (38.2%) recorded in the PHONO group while the CRYO group recorded 98 (35.6%) respectively. The result indicates no statistical significant ( $P > 0.05$ ) difference in the mean treatment sessions between the three groups. The number of subjects discharged on or before completion of treatment term in all the three groups is presented in Table 1. While all subjects were fit for discharge without necessarily completing the 12 sessions of treatment (initially designed for the study) in DMT group, 5% (1) of the subjects in CRYO and PHONO groups received the full term treatment (i.e. 12 sessions of treatment) respectively. Nineteen (95%) subjects in the DMT group were fit for discharge after receiving treatment for 1 to 5 sessions. Only 12 (60%) and 13 (65%) subjects in PHONO and CRYO groups respectively were fit for discharge after the same duration of treatment. While no subjects were fit for discharge in the PHONO group after receiving 1 to 2 treatment sessions, the DMT and CRYO groups recorded 6 (30%) discharges respectively. Furthermore, at the completion of 10 sessions of treatment, DMT group had discharged all subjects (100%) pain free while PHONO and CRYO group recorded 95% discharges respectively.

**Table 1: Subject Discharge Pattern**

Number of sessions on discharge	Number of discharged subject/group		
	DMT	PHONO	CRYO
1-2	6(30%)	0	6(30%)
3-5	13(65%)	12(60%)	7(35%)
6-10	1(5%)	7(35%)	6(30%)
12	0	1(5%)	1(5%)

DMT=Double-Modality Therapy (Phonophoresis+Cryotherapy), PHONO = Phonophoresis, CRYO = Cryotherapy

**Table 2. Comparison of Pain Perception Scores**

GROUP	PAIN PERCEPTION SCORES	
	Pre – Treatment Mean ± SD	Post Treatment Mean ± SD
DMT (n = 20)	5.50 ± 0.89	1.95 ± 0.76*
PHONO(n = 20)	5.05 ± 0.69	1.85 ± 0.81*
CRYO (n = 20)	5.20 ± 1.24	2.50 ± 1.15*

DMT=Double-Modality Therapy (Phonophoresis+Cryotherapy), PHONO = Phonophoresis, CRYO = Cryotherapy \* =  $P < 0.05$

Table 2 shows that the three modalities (DMT, PHONO and CRYO) were equally and significantly ( $P < 0.05$ ) effective in producing optimal pain relief among the subjects and no group was superior to the other. No subject complained of any discomfort or adverse effect; such as periosteal pain, skin allergy, frostbite or nerve palsy; instead the subjects reported treatments were effective, tolerable and pleasant. All subjects felt satisfied with their level of pain relief and requested for discharge accordingly.

## DISCUSSION

The use of phonophoresis and cryotherapy in isolation or in combination with other therapies in the management of MSIs has been widely reported. They are widely used regimen for reducing pain, inflammation and improving function (Palmer and Toombs, 2004; Wilson and Best, 2005). On the contrary, the use of phonophoresis and cryotherapy as combine therapy (DMT) protocol has gained general acceptance and popularity in the clinical setting, but there is no existing clinical trial in the literature to suggest or indicate its efficacy (Ball, 2002). This study is the first that has reported with empirical data the efficacy of DMT. The study has further indicated that DMT was not superior to the single treatment protocol of phonophoresis or cryotherapy which has debunked the belief that has been probably or largely based on anecdotal evidence (Santesteban, 1983; Balogun, 1990).

The groups did not show significant difference in the overall discharge pattern. The DMT group discharged all subjects (100%) after 10 sessions of treatment while PHONO and CRYO group discharged 95% of their subjects who were pain free. However, the discharge pattern in the DMT group suggests it might take fewer sessions (about 5 sessions) to treat and make more than 90% of the subjects with the type of musculoskeletal injuries (MSIs) included in this study pain free, side effect free and fit to return to active performance. The fewer treatment sessions may be an advantage for the subjects (patients), the employer and the clinician. On the part of the subjects, absenteeism from work to keep hospital treatment appointments and subsequent loss of work hours is minimized; while the workload usually experienced by the clinician may be reduced. On the other hand, with the pressure to treat athletes who sustained MSIs safely and efficiently in order to get them back to effective performance as quickly as possible (Hubbard et al, 2004), DMT protocol may have an edge or advantage over other modalities.

Phonophoresis and cryotherapy have demonstrated significant pain relief among the subjects in this study which has corroborated the works of Klaiman et al (1998), Kozanoglu et al (2003), and Hubbard and Denegar (2004). This has further reduced the inconsistency or controversies associated with the level of efficacy of the modalities. Phonophoresis simply produces thermal effect from

the ultrasound which increases kinetic energy of molecules in the drug and in the cell membrane, dilates points of entry such as hair follicles and the sweat glands, and increases the circulation to the treated area (Byl, 1995; Cagnie et al, 2003). These physiological changes enhance the opportunity for drug molecules (e.g methyl salicylate 15%) to diffuse through the stratum corneum (SC) and be collected by the capillary network in the dermis (Byl, 1995), thereby initiating pain relief. The mechanism by which cryotherapy decreases pain after injury is however a contentious issue (Bleakly et al, 2006). Pain relief with cold application could be due to altered nerve conduction velocity (NCV), inhibition of nociceptors, etc. (Algaflly and George, 2007; Herrera et al, 2010). Intermittent cryotherapy application helps sustain reduced muscle temperature without compromising the skin and allows the superficial skin temperature to return to normal while the deeper muscle temperature remains low (MacAuley, 2001).

The current study has indicated significant therapeutic efficacy of DMT, but it was not superior to the single treatment protocol of phonophoresis or cryotherapy. However, the discharge pattern in the DMT group suggests it might take fewer sessions (about 5 sessions) to treat and make more than 90% of the subjects with the type of musculoskeletal injuries (MSIs) included in this study pain free, side effect free and fit to return to active performance.

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