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A comparison of the analgesic efficacy of medium-frequency alternating current and TENS

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Abstract

Objective To compare the analgesic efficacy of burst-modulated medium-frequency alternating current (BMAC) and transcutaneous electrical nerve stimulation (TENS) using an experimental cold pain model.
Design Within-group crossover study.
Setting A university research laboratory.
Participants Twenty healthy subjects.
Interventions BMAC (4-kHz AC applied in 4-millisecond bursts at 50 Hz) and TENS (125-microsecond phase duration applied at a frequency of 50 Hz) administered to each participant on separate occasions.
Main outcome measure Time to cold pain threshold.
Results The mean time to cold pain threshold with the BMAC intervention was no different than with TENS. Statistical analysis showed that both interventions elevated the cold pain threshold significantly [BMAC: increase = 15.2 seconds, 97.5% confidence interval (CI) 3.1 to 27.2, $P = 0.01$; TENS: increase = 15.4 seconds, 97.5%CI 2.5 to 28.4, $P = 0.02$], and the difference between interventions was not simply insignificant but the intervention effects were 'significantly the same' (mean difference = 0.3 seconds, 95%CI −15.3 to 15.9, $P = 0.97$).
Conclusions BMAC is as effective as TENS in increasing cold pain thresholds in healthy subjects. Since BMAC has been shown to be more comfortable than TENS in previous studies and is likely to be better accepted and tolerated by patients, clinical investigation is warranted.

Keywords: Transcutaneous nerve stimulation; Cold pain; Experimental pain; Hypoalgesia

Introduction

Electrical stimulation is a popular treatment used by physiotherapists for various purposes, including muscle strengthening, endurance, spasticity management, pain control, circulation promotion and oedema control [1–4]. Pain control is the most common use of electrical stimulation, and the two currents most often used to achieve this intention are pulsed current, usually referred to as transcutaneous electrical nerve stimulation (TENS), and burst-modulated, medium-frequency alternating current (BMAC) in the form of interferential current (IFC) [1,2].

A literature search was conducted in September 2008 to locate studies on the effectiveness of TENS and IFC/BMAC for pain relief. Electronic databases searched were Embase (1988 to mid-2008), Medline (1966 to mid-2008), Cinahl (1982 to mid-2008), Sports Discus (1975 to mid-2008), the Cochrane Library (1970 to mid-2008) and PubMed (1950 to mid 2008). The search involved four categories of keywords: 'transcutaneous electrical stimulation', 'interferential', 'burst-modulated alternating current' and 'pain'. Associated synonyms such as 'TENS', 'IFC', 'BMAC' and 'analgesic' were also included as keywords. 'Pain' or associated synonyms had to be included in the title or abstract, and the study had to be laboratory based using experimentally induced pain. Using these criteria, 18 relevant articles were identified. Six of the 18 studies only investigated the analgesic effect of TENS. Of these, five compared TENS with a placebo (sham) group [5–9], and one [6] compared the effects of several different TENS frequencies. Each study demonstrated at least one positive statistically significant ($P \leq 0.05$) outcome measure for the analgesic effectiveness of TENS, and in every study involving a sham group, there was at least

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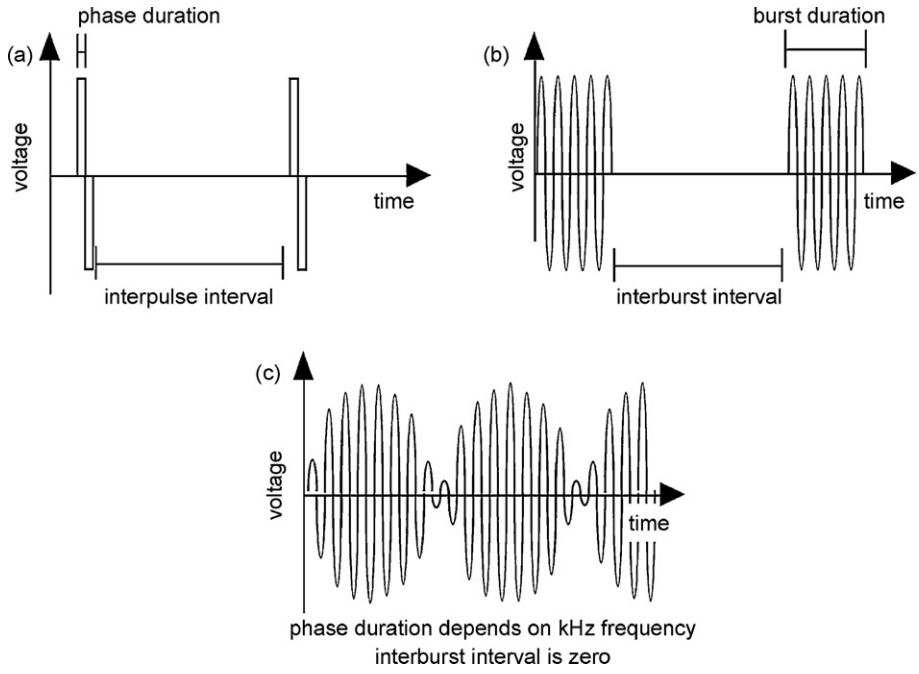

Fig. 1. (a) Biphasic pulsed current, (b) rectangular burst-modulated alternating current (BMAC), and (c) BMAC with sinusoidal modulation (interferential current).

one statistically significant outcome measure supporting an actual TENS effect rather than a placebo response. Thus, it appears probable that TENS is an effective electrotherapeutic treatment for pain management.

The analgesic effects of BMAC were examined in six of the 18 studies identified. These studies only examined one particular form of IFC/BMAC, namely IFC. Five of these studies compared IFC with sham, control and/or pre–post treatment baseline [10–14]. The remaining study compared different IFC burst ('beat') frequencies with one another [15]. Significant results ($P \leq 0.05$) confirming positive analgesic effects with the use of IFC were identified in three of the five studies [10,12,16]. Of the other two studies, Tabasam and Johnson reported that the comparative effect of BMAC versus sham during treatment cycles was not significant [11]. However, small subject numbers were used, raising the possibility of a type II statistical error as opposed to no true effect. Stephenson and Walker [14] found no significant differences when comparing BMAC with control and sham groups ($P = 0.49$). However, the study design and small number of subjects reduces confidence in these results. The balance of evidence suggests that IFC is also an effective electrotherapeutic treatment for pain management, but the evidence is less strong than that for TENS.

Only six of the 18 studies identified directly compared the effectiveness of TENS and BMAC [16–21]. Four of the studies compared TENS and IFC with either sham or control groups [16–19]. Three of these four studies found significant analgesic effects of both TENS and IFC [16,18,19], but none found any significant difference between the TENS and IFC interventions. Johnson and Tabasam [19] used 100-Hz stimulation and measured a greater effect with TENS than premodulated IFC. The measured difference was not statistically significant ($P = 0.09$), but the study only had seven participants in each group so the lack of significance could have been due to low statistical power. Shanahan *et al.* [21] reported a similar experimental study using a crossover design with larger participant numbers. They found that TENS at a frequency of 100 Hz had a greater analgesic effect than premodulated IFC at a beat frequency of 100 Hz ($P = 0.015$). The balance of evidence thus indicates that IFC is less effective than TENS. Ward and Oliver [20] surmised that the lesser analgesic effect of premodulated IFC might be due to the relatively long and unpredictable effective burst duration with IFC (Fig. 1c). They compared the analgesic effectiveness of 4-millisecond bursts of 1-kHz AC applied at a burst frequency of 50 Hz with 50-Hz pulsed current (TENS) of the same phase duration. The study found no significant difference between TENS and this particular form of BMAC, and little chance of a type II error ($P = 0.39$). The authors concluded that the lack of difference between the stimulus types was due to the short burst duration of the BMAC stimulus.

The published evidence thus suggests that both TENS and BMAC have a significant analgesic effect; however, there has been very little research into the comparative effectiveness of TENS and BMAC treatments and optimum analgesic parameters for both modalities. Of the few comparative studies, only one [21] reported a statistically significant result, with 100-Hz TENS being more effective than premodulated 100-Hz IFC. The lack of significant results in previous comparative

studies is possibly due to more stringent demands on statistical power and study design. If both TENS and IFC are effective in inducing hypoalgesia, it is much more demanding to evaluate whether one is better than the other than it is to evaluate whether each one alone is effective.

Stimulation parameters

The stimulation parameters for TENS and BMAC/IFC are different, but they have two important parameters in common: frequency and phase duration. Frequency is the number of pulses per second (TENS) or bursts per second (BMAC). Phase duration is the timed length of individual pulses for TENS or the duration of pulses within a burst for BMAC. Conventional TENS is low-frequency (usually less than 200 Hz) pulsed current with a duration in the range of 20–600 microseconds [4]. BMAC used for pain control is AC, usually with a frequency of 4–5 kHz, a low burst frequency of 50–200 Hz, and a phase duration of 100–125 microseconds [4].

With a frequency of 4–5 kHz, each phase of BMAC cannot elicit a nerve impulse due to the absolute refractory period (period of time following a nerve impulse whereby no stimulus can cause a subsequent action potential) [3,22]. Rather, successive subthreshold pulses in a burst can summate at kHz frequencies. Summation refers to successive subthreshold pulses of AC pushing a nerve fibre closer to threshold with each pulse in a burst. Membrane threshold is reached when successive pulses cause sufficient depolarisation to produce an action potential. Depolarisation due to summation occurs more readily at higher kHz frequencies because the membrane has less time to recover between successive pulses. Summation is responsible for the Gildemeister effect, which is a decrease in threshold intensity as the burst duration is increased [3,22].

TENS applied clinically is normally a low-frequency pulsed current applied for pain relief [3]. Sensory-level stimulation is referred to as 'conventional TENS', in which sensory fibres (Aβ fibres) are stimulated. As TENS involves single pulses applied repetitively, frequency and pulse duration can be altered without having an effect on one another (Fig. 1a). BMAC applied clinically consists of bursts of AC with a typical frequency of 1–10 kHz. The AC bursts are applied at low frequencies (less than 200 Hz), corresponding to the frequencies used for TENS stimulation. BMAC current can be delivered in rectangular bursts (Russian and Aussie current [23], Fig. 1b) or sinusoidally modulated (premodulated IFC, Fig. 1c).

The two types of BMAC that are in common clinical use are Russian current and premodulated IFC. Russian current is 2500-Hz AC delivered in a series of bursts (10-millisecond burst and a 10-millisecond interval, or 50% duty cycle). This is similar to Fig. 1b but with equal burst and interburst intervals [3]. Premodulated IFC is a series of sinusoidally modulated bursts (Fig. 1c).

A less commonly used form of BMAC is Aussie current [20]. Aussie current is similar to Russian current in being burst modulated; however, the bursts are of shorter duration. Aussie current has a lower burst duration than Russian current (2–4 milliseconds vs 10 milliseconds) (Fig. 1b). In contrast to premodulated IFC and Russian current, there is less possibility of multiple nerve firing during a burst with Aussie current [20,22].

The present study

A limitation of Ward and Oliver's study [20] was that 1-kHz AC was used and compared with pulsed current of the same phase duration (500 microseconds). The parameters chosen were based on conclusions made earlier [24] regarding torque rather than pain relief. Ward *et al.* [24] compared different duty cycles and frequencies of BMAC, and found that a short burst duration (a low duty cycle of 20–25%) was most effective for torque production and comfort, and that 1 kHz was the optimum AC frequency for torque production [24]. However, for pain control, higher AC frequencies (typically 4 kHz in the form of premodulated IFC) and TENS pulse durations of less than 500 microseconds are normally used clinically [3]. Furthermore, the earlier study [24] identified that 4 kHz, while not optimal for torque production, was best in terms of producing minimal discomfort. Accordingly, it was decided to compare the analgesic effectiveness of 50-Hz, 4-millisecond bursts of 4-kHz AC with 50-Hz pulsed current of the same phase duration (125 microseconds). 50 Hz was selected based on research by Johnson *et al.* [6] that compared the analgesic effects of TENS on cold-induced pain at different frequencies. Frequencies of 10, 20, 40, 80 and 160 Hz were compared. The study found that 40-Hz stimulation was more effective than the other frequencies. A plot of change in pain threshold versus stimulus frequency [6, Fig. 3] illustrated that maximum pain tolerance was achieved with frequencies in the range of 40–60 Hz, substantially lower than the common clinically used frequency of 100 Hz.

The present study utilised a single-blinded, within-group crossover design. Each subject experienced both TENS and BMAC on separate days in a randomly allocated predetermined order. A sham group was not included since the aim of the study was to compare the analgesic difference between the two modalities, rather than their individual effectiveness compared with sham stimulation. Pain threshold was the selected outcome measure since it obtained the most consistent results in previous research, most probably because the outcome is objective and quantifiable (time).

Method

Participants

Twenty subjects volunteered to participate in the research, 11 females and nine males aged between 19 and 25 years

(mean age 21 years, standard deviation ±1.7 years). Potential participants were excluded if their non-dominant arm was affected by any orthopaedic, neurological or circulatory pathology, or if the skin in the area under the electrodes was broken or irritated. Participants were instructed not to take any analgesic or anti-inflammatory medication (or apply them as creams or gels to their non-dominant forearm) in the 12 hours prior to each testing session. No volunteers were excluded when these criteria were applied.

Research design

The research design used in this study was based on that used by Shanahan *et al.* [21] and Ward and Oliver [20]. This design increased statistical power by allowing more subjects per group, since subjects participated in both TENS and BMAC trials. More importantly, the design eliminated any effect of between-subject variation on the outcome measures. Individual participant comparisons of the effectiveness of TENS and BMAC allowed for separation of between-subject effects and intervention effects. This would not have been possible had a traditional, independent-groups design been used. Power calculations were not used to establish the required number of participants; instead, the numbers used were the same as in previous studies which demonstrated adequate statistical power using the same experimental design [20,21].

Subjects received TENS and BMAC on two separate days, in a randomly allocated order to prevent an order bias effect. Random allocation was performed prior to testing via sealed gender-specific envelopes selected by the participant. The dependent variable was the time to pain threshold (seconds). This variable allowed comparison with previous research since it has been used commonly in similar studies. Previous studies [6,19–21,25] found that the subjective pain intensity and unpleasantness measures were poor indicators of hypoalgesic efficacy. These measures required that participants hold their hands in ice-cold water for a further 30 seconds after reaching their pain threshold, after which pain intensity and unpleasantness were rated by subjects on two, 10-cm visual analogue scales. Since these measures were such poor indicators of hypoalgesic efficacy, they were not included in the present study.

Electrical stimulation

Subjects received both TENS and BMAC from the same purpose-built electrical stimulator; thus, a potential source of bias was eliminated as participants had no indication of which intervention they were receiving. A BMAC frequency of 4 kHz was chosen for this study as this is the frequency commonly used for IFC stimulation [3,4]. At 4 kHz, one sinewave is 250 microseconds, so each phase (one positive, one negative) of a single cycle has a duration of 125 microseconds. Therefore, to keep parameters as constant as possible, the pulse width for the monophasic TENS current was set at 125 microseconds. Finally, a 4-millisecond burst duration (20% duty cycle) for BMAC was selected, since a previous study [24] found that a 20–25% duty cycle was most comfortable, and the study by Ward and Oliver [20], which used 1-kHz BMAC, found that a 4-millisecond burst duration was as effective as TENS for hypoalgesia.

Two rectangular 44 × 40 mm conductive rubber electrodes were applied to each subject's forearm using conductive, adhesive skin mounts (American Imex type 00200) and connected to the electrical stimulator via leads. The middle of the anterior electrode was positioned on the midpoint between the medial epicondyle and the radial styloid. The middle of the posterior electrode was positioned on the midpoint between the lateral epicondyle and the ulnar styloid. This procedure ensured accurate and standardised electrode placement between sessions and participants.

Procedure

On arrival, participants were invited to read and sign the informed consent form approved by the Faculty Human Ethics Committee. Subjects were then screened for exclusion criteria. Once eligibility had been confirmed and the informed consent form completed, participants were seated with their non-dominant arm closest to the water baths. The non-dominant arm was cleaned with an alcohol swab in order to remove any oil, dead skin cells or other barriers that may impede current flow through the skin. Electrodes were then positioned as described above.

Cold pain induction

Cold-induced pain was administered using two water baths of uniform size and shape, one maintained at 37 °C and the other at 0 °C (±0.2 °C). A Heidolph heater stirrer unit (Accurex Equipment, Brunswick, Victoria, Australia) was used in each bath to ensure that temperatures were kept constant. The temperature of each bath was checked routinely at 5-minute intervals with a thermometer. A digital stopwatch was used during the procedure to measure 5-minute increments and the time to pain threshold (seconds). The cold pain method was based on that used in previous research [6,10,19–21]. On the 'Start' command, the participant placed their hand into the 37 °C water bath down to the distal wrist crease. The participant's hand remained in the bath for 5 minutes in order to standardise the hand temperature between sessions and across participants. The subject was then instructed to move their hand into the 0 °C water bath, again down to the distal wrist crease. The participant was asked to concentrate on the sensations of the hand until they felt the onset of a deep, dull aching pain, at which time the subject was to state 'Pain' and withdraw their hand from the water. The time from hand immer-

sion to pain was recorded as the pain threshold (seconds). After removing their hand from the bath, it was placed on a table to rest at room temperature for the remainder of the 5 minutes since the beginning of the hand immersion in the 0 °C bath. At this point (completion of the 10-minute cycle), the next cycle was commenced, with hand immersion back into the 37 °C bath. In total, six cycles were performed per session.

Electrical stimulation

Electrical stimulation was applied via the electrodes attached to the participant's forearm. The electrical stimulation, either TENS or BMAC depending on random allocation, commenced at the beginning of Cycle 3 and continued uninterruptedly until the conclusion of Cycle 4, i.e. 20 minutes in total. The stimulation intensity was increased by the instructor until the participant felt the sensation was strong but comfortable, but never above the motor threshold. If a motor response was detected, the intensity was reduced to eliminate any muscle contraction. The subject was asked at 1-minute intervals whether the stimulation remained strong but comfortable, or whether it needed to be adjusted in order to fit this description. The stimulation was not adjusted at all during cold water immersion.

At the conclusion of the first session, the participants were advised against taking analgesics or anti-inflammatory medication, or applying anti-inflammatory cream to the non-dominant (tested) arm in the 12 hours prior to the following session.

The second session was conducted no earlier than 12 hours following the initial testing procedure in order to minimise the risk of a carry-over effect. The second session was identical to the first; however, the alternate modality was utilised. At the end of the second testing session, participants were asked two questions: 'Which of the two modalities, if either, seemed more effective?' and 'Which of the two modalities, if either, felt more comfortable?' The subjects were also given the opportunity to make any other comments.

Analysis

Pain threshold

Statistical analyses were performed using Statistical Package for the Social Sciences Version 14 (SPSS Inc., Chicago, IL, USA). Prior to analysis, participants were excluded if the pain threshold during one or more of the six cycles was 300 seconds or more. These results were excludable outliers, since 300 seconds was 4.2 standard deviations from the mean (69 seconds in the present study). Furthermore, immersion in cold water for a minimum of 300 seconds eliminated recovery time before the start of the following cycle, and thus unless eliminated may have confounded the results by producing a carry-over effect.

Pain threshold data for TENS and BMAC were first analysed separately. Since individual pain thresholds vary largely, as demonstrated previously [20,21], pain threshold changes in this study were analysed for each of TENS and BMAC using a two factor without replication analysis of variance (ANOVA) in order to separate between-subject and intervention effects. Post-hoc *t*-tests were then carried out and confidence intervals (CI) were calculated to establish whether the observed intervention effects were statistically significant. The pain threshold during each type of electrical stimulation (T3 and T4 averaged) was compared with the baseline pain threshold (T1 and T2 averaged) using a two-tailed paired *t*-test. Averaging of intervention data (T3 and T4) was performed since the aim of this study was to compare the intervention effect of two modalities, rather than the effect of time on the intervention. This method was also used to increase statistical power and avoid a large Bonferroni correction as a result of multiple comparisons. The same method was applied to the post-intervention data (T5 and T6 averaged) compared with the baseline threshold. Since two comparisons were made with baseline (T3 and T4 average, T5 and T6 average), a Bonferroni-corrected acceptable *P*-value of $0.05/2 = 0.025$ was used and 97.5%CI were calculated.

In order to establish whether there was a significant difference between the interventions and whether the effects of each modality were greater at T4 than T3, a two-way repeated-measures ANOVA (cycle × intervention type) was calculated. The pre-intervention data (T1 and T2 averaged) were subtracted from each of the with-intervention measures (T3 and T4) and the differences were used for the analysis.

Results

The outcome measures analysed were pain threshold (time to pain tolerance limit, measured in seconds) and subjective comments regarding effectiveness and comfort of each type of stimulation. These measures were used to test three hypotheses: (a) that both forms of electrical stimulation elevate pain threshold; (b) that TENS and BMAC are equally effective; and (c) that BMAC is more comfortable than TENS. When the exclusion criteria were applied, three of the 20 subjects were excluded from the study since they failed to reach their pain thresholds within 5 minutes of ice-cold immersion during one or more of the allocated measurement cycles. It is worth noting that two of the three excluded subjects only exceeded the 5-minute pain threshold whilst electrical stimulation was applied (one with TENS, one with BMAC). The data set therefore included 17 subjects for analysis.

Pain threshold

Pain threshold data were analysed in terms of change from baseline to the time of pain tolerance limit for each

Table 1
Group-averaged pain threshold changes from baseline for Cycles 3–6. Values shown are mean ± standard deviation.

Cycle	Threshold change TENS (seconds)	Threshold change BMAC (seconds)
T3	14.1 ± 23.8	14.7 ± 21.4
T4	16.8 ± 27.4	15.6 ± 24.8
T5	−6.0 ± 20.8	−3.5 ± 13.0
T6	−5.2 ± 25.6	5.3 ± 23.7

TENS, transcutaneous electrical nerve stimulation; BMAC, burst-modulated medium-frequency alternating current.

modality. Baseline was calculated as the average time (seconds) to pain threshold during Cycles 1 and 2 (T1 and T2). Change in pain threshold during Cycles 3–6 was calculated by subtracting the baseline value from the Cycle 3–6 pain threshold values (T3–T6). Table 1 shows the average change from baseline (mean ± standard deviation) for Cycles 3–6 for both interventions.

In Cycle 3, BMAC thresholds were increased, on average, by 14.7 seconds and TENS thresholds were increased by 14.1 seconds. Both the TENS and BMAC pain thresholds were greater during Cycle 4 than Cycle 3; TENS by a further 2.7 seconds and BMAC by 0.9 seconds. Although the Cycle 4 rise in pain threshold was not as great as that between baseline and Cycle 3, it does suggest that the longer the stimulation is applied, the greater the elevation in pain threshold. The pain threshold during stimulation (T3 and T4 averaged) was elevated by 15.2 seconds (22% increase) with TENS and 15.5 seconds (25% increase) with BMAC.

Once the electrical stimulation was switched off at the end of Cycle 4, thresholds returned close to baseline. Both TENS and BMAC pain threshold values fell below baseline at T5, suggesting no carry-over effect of TENS and BMAC immediately following stimulation. Pain threshold changes from baseline continued to remain low during the final cycle, with T6 for TENS averaging below baseline and T6 for BMAC averaging above baseline. The variation observed most likely represents the inherent experimental error.

Statistical analysis

Intervention effects

The hypotheses of this study were tested using a two factor (subject × intervention) without replication ANOVA for each modality to first determine whether an intervention effect was present by separating between-subject and between-intervention effects. The data were not normally distributed, and a Huynh-Feldt correction of 0.67 for TENS and 0.60 for BMAC was required. Both modalities produced statistically significant intervention effects (TENS: $F_{(5,16)} = 4.75$, $P = 0.004$; BMAC: $F_{(5,16)} = 4.28$, $P = 0.009$). Between-subject effects for both modalities were also found to be highly significant, presumably because pain thresholds vary greatly between individuals (TENS: $F_{(16,5)} = 22.52$, $P < 0.001$; BMAC: $F_{(16,5)} = 24.46$, $P < 0.001$). The lower P-values indicate that the large standard deviations of each mean (Table 1) were mainly due to between-subject effects. Post-hoc tests (paired t-tests) were conducted to answer two questions: is there a significant intervention effect and is there a significant carry-over (post-intervention) effect? To minimise the number of post hoc tests and thus avoid the need for a large Bonferroni correction, pre-intervention data (T1 and T2) were averaged, as were the during-intervention measures (T3 and T4) and post-intervention measures (T5 and T6). Two paired t-tests were then conducted using a Bonferroni-corrected acceptable P-value of 0.05/2 = 0.025 and 97.5%CI were calculated. Comparing the pre- and during-intervention averages, a significant intervention effect was found (TENS: 15.4 seconds, 97.5%CI 2.5 to 28.4, $P = 0.017$; BMAC: 15.2 seconds, 97.5%CI 3.1 to 27.2, $P = 0.012$). No significant difference was found between pre- and post-intervention measures (TENS: −5.6 seconds, 97.5%CI −18.0 to 6.8, $P = 0.324$; BMAC: 0.9 seconds, 97.5%CI −7.7 to 9.6, $P = 0.816$).

Data were analysed to establish whether either form of stimulation produced a greater intervention effect and whether the effects were greater at T4 than T3. Each participant's increase in pain threshold was calculated by averaging the pre-intervention baseline measures (T1 and T2) and subtracting this from each of the with-intervention measures (T3 and T4). The increases were used in a two-way repeated-measures ANOVA (cycle × intervention). Data for post-intervention measures (T5 and T6) were not used at this stage of the analysis, as there was no carry-over (pre- vs post-intervention) effect with either form of stimulation so any further comparison would be meaningless.

The ANOVA established that the between-cycle differences (T3 vs T4) were not statistically significant ($F_{(1,16)} = 0.094$, $P = 0.76$), and that between-intervention effects were not only not significantly different, but TENS and BMAC were 'significantly the same' ($F_{(1,16)} = 0.002$, $P = 0.97$, mean difference = 0.3 seconds, CI −15.3 to 15.9). When P-values are in the range 0.05–0.95, an acceptable conclusion is that there is no significant difference. It cannot, however, be concluded that the intervention effects are the same without risking making a type II error. When a P-value greater than 0.95 is obtained ($1 - \alpha < 0.05$), the equivalence of the interventions is considered to be statistically significant as the risk of a type II statistical error is acceptably minimised [26].

Comfort of stimulation

At the end of the second session, participants were asked which of the two types of intervention felt most comfortable. A majority preferring BMAC was evident. Twelve subjects

(71%) reported BMAC to be the most comfortable, and the remaining five (29%) felt that TENS was the most comfortable.

Effectiveness of stimulation

At the end of the second session, participants were also asked which modality felt more effective for pain relief. Ten subjects (58%) reported that BMAC was most effective, three (18%) felt that TENS was the most effective, and four (24%) reported that both interventions were equally effective.

Discussion

Hypoalgesic efficacy

The results clearly demonstrate a significant intervention effect for both TENS and BMAC with *P*-values of 0.017 and 0.012, respectively. These findings confirm the first hypothesis that both modalities elevate the cold pain threshold.

The main aim of this study, however, was to compare the analgesic effectiveness of one particular form of BMAC (4-kHz AC with a 4-millisecond burst duration) with TENS of the same phase duration (125 microseconds) and frequency (50 Hz). TENS and BMAC were found to be statistically equivalent in elevating the cold-induced pain threshold in healthy subjects. The *P*-value obtained ($P = 0.97$) allows the conclusion that TENS and BMAC are equally effective in pain modulation. With these results, one can be confident that a type II error has not occurred, i.e. a false-negative result, since the *P*-value falls outside the conventionally accepted questionable range (0.05–0.95).

These results provide an important contribution to the existing literature, since no previous research has compared the analgesic effectiveness of pulsed current (TENS) with that of 4-kHz AC with a 4-millisecond burst duration (BMAC) at the same frequency and using the same phase duration. The present results support the findings of Ward and Oliver [20] who used a different AC frequency (1 kHz) but the same 4-millisecond burst duration and 50-Hz burst/pulse frequency, and found that with short burst durations for BMAC, the modalities were equally effective in elevating pain threshold.

In contrast, Shanahan *et al.* [21] found that TENS (100-Hz pulsed current) was significantly more effective than premodulated interferential current (5-kHz AC, modulated at 100 Hz) in elevating pain threshold. 'Premodulated interferential current' as used in the study by Shanahan *et al.* [21] was sinusoidally modulated (Fig. 1c) so, strictly speaking, the duty cycle is effectively 100%, as the intensity only drops to zero instantaneously between each burst. The burst duration is maximum (20 milliseconds) and the effective burst duration (i.e. the time that the stimulus is above any effective threshold) is difficult to predict but, for most nerve fibres, it would be much larger than the 4-millisecond burst duration used in the present study and that of Ward and Oliver [20].

The difference between the present findings and those of Shanahan *et al.* [21] can be explained in terms of different nerve fibre firing rates produced by the two forms of electrical stimulation. The authors hypothesise that with long bursts of AC, as used with premodulated interferential currents, sensory nerve fibres fire multiple times during each burst, i.e. during a burst, sensory fibres undergo repeated cycles of firing, recovering and firing again. Hence the sensory nerve firing rate will be some multiple of the burst frequency. While stimulation at 50 or 100 Hz is beneficial for hypoalgesia, stimulation at higher multiples (150, 200, 250. . . Hz) might not be as effective. This seems to be a reasonable, physiologically based assumption, but only one study has actually tested this hypothesis and examined a wide range of TENS stimulation frequencies (10–160 Hz). Johnson *et al.* [6] found that higher frequencies of pulsed current (above 50 Hz) resulted in a lesser hypoalgesic effect. The between-frequencies differences in the study by Johnson *et al.* [6] were not statistically significant, possibly due to the small sample size, but a downward trend is clearly evident above 40 Hz. Since the present study and a previous study [20] have found that short-duration burst-modulated AC is as effective as pulsed current (TENS) in elevating pain threshold, the authors speculate that a short burst duration prevents or severely restricts multiple firing of sensory nerve fibres, and instead produces one action potential per burst. The hypoalgesic effects are thus equivalent to TENS.

Subjective comments

The majority of participants subjectively reported that BMAC was more effective and comfortable than TENS, thus supporting the original hypothesis. The results are in accordance with previous studies [20,21,23], which reported BMAC to be significantly more comfortable than TENS. The current results and previous TENS and BMAC comparative studies strengthen the conclusion drawn by Ward *et al.* [24] that low-duty-cycle, burst-modulated AC is more comfortable than conventional low-frequency pulsed current.

Clinical implications

The present research demonstrates that the particular forms of TENS and BMAC which were compared are equally effective, in fact 'statistically the same', at elevating the pain threshold in healthy subjects. Furthermore, since previous research by Shanahan *et al.* [21] found that TENS was significantly more effective than premodulated IFC, one can infer, with a degree of confidence, that this form of BMAC also has greater hypoalgesic effects than premodulated IFC.

However, whilst the objective effectiveness of a modality is an important component of the patient experience,

there are other factors that influence the efficacy of the treatment. Patient-perceived comfort and effectiveness are two other factors. There was a definite preference for BMAC in terms of both perceived comfort and effectiveness. This result combined with previous research [20,21,23] suggests the likelihood of greater patient acceptance and compliance with BMAC, since it is perceived to be more comfortable and effective. Therefore, it is concluded that BMAC utilising a 4-millisecond burst duration should be used clinically for the treatment of acute pain because it is as effective as TENS in hypoalgesic effects but is reportedly more comfortable, and thus provides an overall improved patient experience. A third factor is the expense of treating a patient with IFC in a clinic using a mains-powered, high-output machine compared with the home use of a portable TENS machine and the inconvenience of the patient travelling to a clinic for every treatment. In the case of low back or neck pain, the travelling runs the risk of undoing any gains made by the treatment. TENS-like, portable BMAC machines could provide the convenience of safe, home treatment between clinical consultations.

Conclusion

The major conclusion of the present study is that 50-Hz TENS with a 125-microsecond pulse duration and 4-kHz BMAC with a 4-millisecond burst duration (20% duty cycle) are equally effective in elevating cold-induced pain in healthy subjects. However, BMAC is subjectively reported to be more comfortable and effective. It is therefore recommended that BMAC in the form of 4-millisecond bursts should be trialled clinically since greater patient compliance and acceptance of the treatment is a likely consequence of the lesser discomfort.

TENS machines have long been established as a useful treatment tool since they are effective in elevating pain threshold and are a cheap and portable option for home use. The present findings suggest that 'take home' TENS units would be more successful if they delivered 4-kHz BMAC with a 4-millisecond burst duration rather than pulsed current.

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