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PHYS THER. 2007; 87:1056-1063.
Originally published online June 19, 2007

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Comparison of the Hypoalgesic Efficacy of Low-Frequency and Burst-Modulated Kilohertz Frequency Currents

Alex R Ward, Warwick G Oliver

Background and Purpose
A within-subject randomized controlled trial was conducted to compare monophasic pulsed current (PC) with a frequency of 50 Hz and a phase duration of 500 microseconds with burst-modulated alternating current (BMAC) (1-kHz alternating current, burst modulated at a frequency of 50 Hz with a 20% duty cycle) to establish whether there were differences in hypoalgesic efficacy as assessed by cold pain threshold measurements.

Subjects
Twenty-two young adults who were healthy and drawn from a population of students of La Trobe University volunteered to participate in the study. Nineteen subjects (7 male, 12 female) met the inclusion criteria.

Method
Each participant experienced monophasic PC and BMAC. Time to cold pain threshold was measured before, during, and after the electrical stimulation intervention.

Results
Both PC and BMAC currents were effective at elevating the cold pain threshold, although there was no statistically significant difference between the 2 currents during stimulation.

Discussion and Conclusion
Pulsed current and BMAC appear to be equally effective at elevating the cold pain threshold. Analysis indicated that if any real difference exists, it would only be apparent with large (100) subject numbers. Any differences in hypoalgesic efficacy thus are not likely to be clinically important.
Electrical stimulation of nerve and muscle has a long history of use by physical therapists. The stimulators used clinically include large, mains-powered devices, commonly interferential current (IFC) or “Russian current” stimulators. Portable, battery-operated transcutaneous electrical nerve stimulation (TENS) units also are a treatment option. They produce pulsed current (PC), are low power and relatively safe, and can be used at home without direct clinical supervision.

Stimulators that produce kilohertz-frequency alternating current (AC), such as Russian current and IFC stimulators, generally are unsuitable for take-home use because the units are expensive and, more importantly, their output power is too high to be safe for unsupervised use. Their benefit is claimed to derive from kilohertz-frequency AC stimulation being more comfortable and “effective” than PC stimulation, but the claims are anecdotal.1–3 The relative efficacy of kilohertz-frequency AC is something that has only recently been called into question and tested, in terms of muscle torque production and hypoalgesia, in laboratory studies using subjects who are healthy.4–6 The discomfort of PC relative to kilohertz-frequency AC has only more recently been quantitatively assessed.7,8

One study7 compared 2 forms of kilohertz-frequency AC with PC of 2 different pulse durations. Participants were asked to identify whether any stimulus type was more uncomfortable than the others. Both forms of kilohertz-frequency AC (Russian and “Aussie”) were identified as less uncomfortable than PC (P = .005). That study also showed that Aussie current, identical to the burst-modulated alternating current (BMAC) used in the present study (ie, 1 kHz AC bursts with a 20% duty cycle) while being more comfortable than PC, elicited as least as much muscle torque at the highest tolerable intensity. By contrast, Russian current (2.5 kHz AC bursts with a 50% duty cycle) at the highest tolerable intensity elicited significantly less torque than the other stimulus types (P = .004). These findings suggest that, although kilohertz-frequency AC may be more comfortable than PC, the frequency and duty cycle of the AC are important factors determining relative discomfort and torque production.

The importance of frequency and duty cycle has been reported previously. Ward et al9 stimulated the wrist extensors using a range of frequencies (0.5–20 kHz) and duty cycles (10%–100%) and found that kilohertz-frequency AC applied in bursts was identified by participants as least uncomfortable when the bursts had a 20% duty cycle. Greatest discomfort was reported with continuous AC. These findings are consistent with those of Ozcan et al,10 who reported that, when used for maximum electrically induced torque of the quadriceps femoris muscle, continuous AC at a frequency of 4 kHz (IFC) was significantly more uncomfortable than burst-modulated AC (premodulated IFC) with a duty cycle of 50% and produced less muscle torque. The balance of evidence thus suggests that, although kilohertz-frequency AC stimulation is more comfortable than PC, the duty cycle and frequency of the AC are important factors determining comfort and torque production.

Both PC and kilohertz-frequency AC are used for the relief of pain.1–6,8,11 Kilohertz-frequency AC is commonly applied in the form of IFC, where continuous AC with 2 different frequencies is superimposed so as to “interfere,” theoretically producing burst-modulated AC, with the bursts being sinusoidal in shape.1–3 The evidence for hypoalgesic efficacy of PC has been reviewed previously.1–5,12 Far fewer studies have assessed the efficacy of IFC for pain relief, and it is generally assumed that the effects are similar when the interferential burst (beat) frequency and the PC frequency are the same.1–3 Only 5 studies1–6,8,11 have questioned this assumption and directly compared TENS and IFC. Four of the 5 studies showed no difference in pain relief associated with TENS and IFC, but the findings could be challenged due to their low statistical power.4–6,11

Shanahan et al8 used what was arguably a more robust experimental design (in that it was a repeated-measures design that allowed between-subject effects to be separated from between-intervention effects) to compare the effects of IFC and PC on pain. These authors8 found that PC stimulation was significantly more effective than premodulated IFC stimulation (P = .015) at relieving cold-induced pain in subjects who were healthy. Paradoxically, when asked to rate the stimuli in terms of comfort and hypoalgesic efficacy, the majority of the subjects who perceived a difference (12 of 16) reported that IFC was more comfortable and that they thought it was more effective. Premodulated IFC thus appears to have an advantage over PC in that it is perceived as more comfortable and is likely to be better accepted and tolerated by the patient. Nonetheless, it appears that IFC is less effective in terms of actual pain relief when assessed by the quantitative measure of time to onset of cold-induced pain.

The finding that a shorter kilohertz-frequency AC burst duration results in stimulation that is perceived as more comfortable—and more effective in terms of torque production when stimulating the wrist extensors9 or the quadriceps femoris muscle10 at maximum tolerable intensity—
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raised the question whether a short burst duration (low duty cycle) also might be more effective for pain control. Could it be that the reason pre-modulated IFC is less effective than PC for pain control is that the duty cycle of IFC is simply too high? Would shorter-duration bursts (a lower duty cycle) be equally or more effective than PC, as has been found for force production and comfort?7,9

To answer these questions, we decided to compare the hypoalgesic efficacy of BMAC with a 4-millisecond burst duration (20% duty cycle) and PC with pulses of the same phase duration. Two questions, however, remained: (1) what burst or pulse frequency to use and (2) how to induce pain in a standardized way so that pain reduction can be quantified.

Testing of hypoalgesia in a laboratory setting requires a reliable method of pain induction. The cold-induced pain model, first described in 1941,13 is well established and has been used in a number of more recent studies4,8,14,15 to assess the hypoalgesic efficacy of different forms of electrical stimulation. In the present study, BMAC was compared with PC using a protocol similar to those used previously.4,8,14,15 A difference was that only pain thresholds were measured rather than pain threshold, intensity, and unpleasantness. The previous studies4,8,14,15 demonstrated that pain intensity and unpleasantness are insensitive indicators of electroanalgesia and subjected the participants to greater discomfort. For these reasons, these extra measures were not used.

The stimulus frequency normally used for electroanalgesia is approximately 100 Hz (typically in the range of 80–120 Hz).1–3,16,17 Although this frequency range is commonly used, a literature search revealed no substantive evidence in support of this particular range. The argument for these higher-than-physiological frequencies seems to be that gating of pain signals is achieved by activation of sensory (A-β) fibers, so bombardment with higher-frequency stimulation will produce more A-β activation and consequently a better pain-blocking effect. This “more is better” argument is simplistic and does not appear to have any scientific basis in clinical or laboratory studies. It is possible that other factors associated with high-frequency stimulation, such as neurotransmitter depletion or insufficient recovery time due to the relative refractory period of the nerve fibers, might result in the opposite effect at higher frequencies.

A literature search identified only 2 studies that evaluated the efficacy of different TENS stimulus frequencies for hypoalgesia. Sjölund19 applied 7 different TENS stimulation frequencies (10, 40, 60, 80, 100, 120, and 160 Hz) to a dissected skin nerve in lightly anesthetized rats and reported that a stimulation frequency of 80 Hz resulted in the greatest inhibition of the C-fiber–evoked flexion reflex. This finding cannot be directly extrapolated to electroanalgesia induced clinically, not only because the subjects were rats but also because the inhibition of the flexion reflex was measured after cessation of application of the stimulus and it is not known whether the effect would be sustained if the stimulation period was longer or whether the effect is greater while the stimulus is being applied. A longer stimulation period might result in “sensory fatigue” if neurotransmitter depletion was an issue, in which case a lower stimulus frequency could be more effective for pain control because there would be proportionally less depletion.

Johnson et al15 performed a more clinically relevant study when they compared the effects of frequencies of 10, 20, 40, 80, and 160 Hz on perception and tolerance of cold-induced pain in subjects who were healthy. They found that 40-Hz stimulation was more effective than stimulation at the other frequencies. A plot of the change in pain threshold versus frequency (see Fig. 3 in Johnson et al15) indicates that maximum efficacy is achieved with frequencies in the approximate range of 40 to 60 Hz—appreciably lower than the frequencies of 100 Hz or so that are commonly used clinically. For this reason, a stimulus frequency of 50 Hz was chosen for the present study.

For the reasons discussed, the purpose of this study was to compare BMAC (1-kHz AC, burst modulated at a frequency of 50 Hz with a 4-millisecond burst duration) with PC (ie, single pulses of the same phase duration [500 microseconds] and frequency [50 Hz]) for altering the threshold of cold-induced pain.

Method
Subjects
Twenty-two individuals volunteered to participate in the study. Of these volunteers, 19 subjects (7 male and 12 female) met the inclusion criteria. Subjects were recruited from students of the School of Physiotherapy, La Trobe University. The ages of the subjects ranged from 19 to 27 years (X=21.0, SD=1.9). Inclusion criteria required that a subject have no pathology affecting the left forearm, no pacemaker, and no damage to the skin overlying the wrist extensor muscles.

Procedure
A randomized controlled trial with a within-subject, repeated-measures design was used. The design was based on the method used in previous research,8 with modifications made to minimize unnecessary discomfort to the participants and to increase statistical power by having a
practice or learning session prior to the 2 test sessions. The independent variable was the type of stimulation administered (BMAC or PC). The dependent variable was the time to pain threshold (in seconds). Pain threshold time was measured by immersing the hand in water at 0°C and measuring the time when the subject reported the onset of a “deep, dull, achling pain.” Previous studies also required that participants hold their hands in ice-cold water for a further 30 seconds, after which pain intensity and unpleasantness were rated by subjects on two 10-cm visual analog scales. These studies demonstrated that the self-rated pain intensity and unpleasantness measures were poor indicators of hypoalgesic efficacy. We decided, therefore, that these measures would not be used in the present study, so as to minimize the participants’ discomfort without compromising statistical power.

Cold pain induction required 2 water baths of uniform size and shape (one maintained at 37°C and the other at 0°C containing ice and water). A Heidolph heater stirrer unit* was used in each bath to mix the water and ensure that the water temperatures (monitored with a thermometer in each bath) remained constant (±0.2°C).

Each participant completed three 1-hour test sessions. Each session consisted of 6 cold pain cycles, each of 10 minutes’ duration, applied sequentially. The first test session was only for the purpose of familiarization and training, as a marked training effect was found in a previous study. Participants were randomly allocated into 1 of 2 groups. The first group had interventions in the order of PC, BMAC, and PC over the 3 sessions. The second group had interventions in the order BMAC, PC, and BMAC.

The procedure for each session is depicted in Figure 1. Each cycle commenced as the subjects placed their hand in a warm water bath (up to the distal wrist crease). After 5 minutes, the subjects transferred their hand to a cold water bath. The subjects were instructed to focus on the sensations in their immersed hand until they felt the onset of deep, dull, aching pain and then to make the statement “Pain.” The time from immersion in cold water to this point was recorded as the pain threshold (in seconds). The subjects then rested until 10 minutes had elapsed since the beginning of the cycle, at which time the next cycle was commenced with reimmersion of the hand in warm water. The cold immersion times for each of the 6 test cycles were recorded as T1 to T6, respectively.

As in previous studies, participants were excluded if they did not report pain within 5 minutes (300 seconds) of immersion in ice-cold water. An immersion time of 300 seconds was 3.6 standard deviations from the mean (90 seconds in the present study), so these results were considered to be excludable outliers. Another, more practical, reason for their exclusion was that extended immersion would not allow a 5-minute recovery time before the start of the next cycle and so would be likely to confound the results by increasing the likelihood of a carryover effect.

During the intervention (cycles 3 and 4), current was applied via 2 Stimtrode 50-× 90-mm rectangular

* Accurex Equipment, 19 Weston St, Brunswick, Victoria 3056, Australia.
self-adhesive electrodes. The electrodes were positioned on the forearm, one anterior and one posterior, with the center point of the electrode lying equidistant to the lateral humeral epicondyle and the head of the ulna when the forearm was pronated. The electrodes were connected to a purpose-built stimulator, designed to produce either rectangular, monophasic pulses or a burst of sine waves with operator-controlled selection of the pulse width (PC) or burst frequency and number of sine waves per burst (AC). The BMAC (1-kHz AC with a 4-millisecond burst duration) was applied at a burst frequency of 50 Hz. The PC stimulus was rectangular, monophasic PC of the same frequency with a pulse (ie, phase) duration of 500 microseconds—the same duration as each phase of 1-kHz AC. The purpose-built stimulator allowed pulse widths and frequencies to be set to an accuracy of ±3%.

At the start of cycle 3 (ie, 20 minutes into the session), the allocated electrical stimulator was turned on. The investigator (WGO) increased the current intensity, as directed by the participants, until the participants experienced a “strong but comfortable” level of stimulation, just below the motor threshold. The current intensity was adjusted upon request to maintain this level, except when the participants’ hand was in the cold water bath. Participants were asked once during the warm water phase whether any increase was necessary and once during the recovery phase following withdrawal from the ice water bath. Stimulation continued uninterrupted for 20 minutes, which constituted 2 complete pain cycles (cycles 3 and 4). Two further pain cycles (cycles 5 and 6) were completed once the stimulation was turned off. The procedure was identical for PC and BMAC delivery, which were tested on separate occasions, at least 4 hours apart. Consistent electrode placement was ensured by marking the electrode outlines on the skin with indelible ink so that the electrodes could be correctly repositioned at the second and third test sessions.

**Data Analysis**

The specific hypotheses tested were: (1) that both forms of electrical stimulation (PC and BMAC) would increase the pain threshold and (2) that PC and BMAC would increase the pain threshold to different extents. To test the first hypothesis, each form of electrical stimulation was tested separately. For each form of stimulation, pain thresholds were analyzed using 2-factor, without-replication analyses of variance (ANOVAs) to separate between-subject effects and intervention effects. The ANOVAs showed very large and highly significant between-subject effects for BMAC (F=33.4; df=16.5; Fc=1.77; P<.000) and PC (F=42.4; df=16.5; Fc=1.77; P<.000). The intervention effect was also significant for BMAC (F=3.41 df=16.5; Fc=2.33; P=.008) and PC (F=7.49; df=16.5; Fc=2.33; P=.000). These findings indicate that the large error bars in Figure 2 (the standard deviations) were due mainly to large between-subject variation, and, when this was taken into account, intervention effects were found to be significant for both stimulus types.

Post hoc comparisons then were made. The effect of electrical stimulation was assessed, for each stimulus type, by comparing thresholds with intervention (T3 and T4 averaged) to a pre-intervention baseline (T1 and T2 averaged) using a 2-tailed paired t test. Averaging was used to increase the statistical power while avoiding the need for multiple com-
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comparisons, which would have required a large Bonferroni correction to the acceptable $P$ value and so would have decreased power and increased the risk of a type II statistical error. Both BMAC ($P=.001$) and PC ($P=.002$) intervention produced significant increases (ie, they both demonstrated an appreciable hypoalgesic effect). Mean increases in time to pain threshold were 18.5 seconds (97.5% confidence interval = 7.4 - 29.6) for BMAC and 24.2 seconds (97.5% confidence interval = 10.6 - 37.8) for PC.

Increases in pain threshold with PC and BMAC intervention (during cycles 3 and 4) were compared using a 2-tailed paired $t$ test. The differences were not statistically significant ($P=.51$ for cycle 3 and $P=.47$ for cycle 4). Despite the enhanced statistical power when using a paired comparison, the differences did not approach significance. When the T3 and T4 increases were averaged (to increase statistical power) and compared between stimulus types, the difference between PC and BMAC still was not statistically significant ($P=.39$).

**Results**

When the exclusion criteria were applied, 3 of the 22 participants were excluded because their pain threshold was not reached after 300 seconds of ice-water immersion. It is noteworthy that 2 of the 3 excluded participants only exceeded the 300-second tolerance limit when electrical stimulation was applied (their baseline and post-intervention measurements were less than 300 seconds).

The Table shows the average time to pain threshold averaged over all included subjects. An intervention effect is clearly evident with both forms of stimulation (times T3 and T4). The mean times to pain threshold during cycles 3 and 4 were about 20% higher than baseline values.

Cycles 1 and 2 of cold pain induction were used to establish a baseline that was the average time to pain threshold over the 2 cycles (T1 and T2). The change in pain threshold for cycles 3 to 6 was calculated by subtracting the baseline value from the cycle 1 and 2 average time to threshold. Figure 2 shows the mean change in pain threshold for cycles 3 to 6 (T3–T6) together with their standard deviations. The standard deviations were large, but they were due to both between-subject and between-condition effects.

**Table.**

<table>
<thead>
<tr>
<th></th>
<th>T1</th>
<th>T2</th>
<th>T3</th>
<th>T4</th>
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<tr>
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<td>65.5</td>
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</tbody>
</table>

* T1 and T2 are initial, pre-intervention values. T3 and T4 are during intervention (pulsed current [PC] or burst-modulated alternating current [BMAC]). T5 and T6 are the 2 post-intervention measures.

It could be argued, simply on the basis of the present study, that the intervention effect was due to a placebo response or “Hawthorne effect,” where the participants’ responses are influenced by their beliefs about the effectiveness of the intervention. The lack of any significant difference between the 2 interventions certainly is consistent with this explanation. However, the placebo response or Hawthorne effect explanation has been refuted by previous studies. Johnson et al compared the hypoalgesic efficacy of different TENS frequencies (using the same cold-induced pain model), and a large and systematic variation was found. The subjects perceived the electrical intervention in each instance, yet the outcome varied with TENS frequency. This would not happen if the effect was simply a placebo response or Hawthorne effect. Perhaps more telling is the study by Shanahan et al, which compared IFC and TENS (again using the same cold-induced pain model). In that study, TENS was quantitatively found to be more effective than IFC in terms of an increased time to pain threshold. Paradoxically, participants reported that they believed IFC was both more comfortable and more effective than TENS at alleviating cold-induced pain. This is the opposite to what would be expected if...
a placebo response or Hawthorne effect was responsible.

A second explanation for finding a lack of difference between the 2 interventions is that the small number of subjects compromised the statistical power. “What if” calculations were made to assess the possibility of a type 2 error (ie, concluding that there was no difference between the interventions when, in fact, there was one). A type 2 error could result if there really was a difference but there were insufficient subject numbers to show it. If the same distribution of results is assumed (ie, the same means and standard deviations at T4), the calculated P value would be .05 if we had about 130 subjects rather than the 19 subjects who were included. With the T3 results, the required number of subjects is estimated to be about 150. Using averaged results, the required number of subjects is 95. Thus, the difference, if any exists, would only be evident with very large numbers of subjects. A conclusion is that the differences observed between PC and BMAC (Fig. 2), although possibly real, were both statistically insignificant.

Previous studies7,10 have shown that kilohertz-frequency AC stimulation, applied in bursts, is perceived as more comfortable than PC stimulation. Another form of burst-modulated current, “premodulated IFC” (sinusoidally modulated bursts of AC), also is perceived as more comfortable than PC stimulation.8 Shanahan et al8 found that premodulated IFC (4-kHz AC, sinusoidally modulated at 100 Hz), despite being perceived by the participants as more comfortable and more effective in terms of suppressing cold-induced pain, had a significantly lesser hypoalgesic effect than PC stimulation. This finding raised the question of whether kilohertz-frequency AC stimulation generally is less effective than PC stimulation for electroanalgesia. The present study used 4-millisecond bursts of 1-kHz AC, modulated at 50 Hz, and found it to be as effective in elevating the pain threshold as PC stimulation of the same phase duration and frequency. This finding suggests that kilohertz-frequency AC can be as effective as PC, while still being more comfortable, provided that the burst duration is sufficiently short.

It should be noted that the PC used in the present study has a longer phase duration (500 microseconds) than that normally used clinically for pain control, where a pulse duration in the range of 50 to 200 microseconds might be chosen.1-3 so the results do not show that BMAC and TENS as conventionally applied are equally efficacious. A direct comparison of TENS and BMAC remains to be made.

We speculate that the findings of the present study explain why premodulated IFC and, indeed, any stimulus that uses long-duration bursts of AC is less efficacious than PC for hypoalgesia.4,8 We hypothesize that the lesser efficacy is due to the long burst duration allowing nerve fibers to fire at multiples of the burst frequency.8,9 During a burst, nerve fibers could fire, recover, and fire again if the burst is long enough or the recovery time sufficiently short, so the nerve fiber firing rate would be some multiple of the burst frequency.3,5,9,20 As the study by Johnson et al19 indicates, if the sensory nerve fiber firing rates are higher, this will likely result in a lesser hypoalgesic effect.

The main finding of this study was that short-duration bursts of lower kilohertz-frequency AC (4-millisecond bursts of 1-kHz AC) are as efficacious as PC of the same phase duration for hypoalgesia, as assessed using the cold pain model and subjects who were healthy. This finding is consistent with the explanation that short-duration bursts do not allow, or severely restrict, multiple firing of sensory nerve fibers.

Clinical Implications

The findings of the present study support the notion that 1-kHz AC, delivered in 4-millisecond bursts (BMAC), is as effective as PC stimulation and, therefore, more effective than premodulated IFC stimulation for electrically induced hypoalgesia.8 This hypothesis is based on laboratory studies using cold-induced pain and subjects who were healthy. The greater comfort of BMAC stimulation,7,8 because of the short burst duration,9 suggests the likelihood of greater patient acceptance and adherence when BMAC stimulation is used. This suggests that BMAC may be more clinically effective than PC or IFC for management of acute pain and potentially more effective for management of chronic pain. Further studies are needed to compare the relative hypoalgesic effectiveness of PC, IFC, and BMAC in a clinical context.

A frequency of 50 Hz was used in the present study, lower than commonly used clinically for electroanalgesia. The choice of frequency was based on relevant scientific evidence rather than common clinical practices. The evidence, although scant, suggests that this lower frequency might be more clinically effective for mitigation of pain during the intervention. There is clearly a need for more studies to confirm or refute the suggested optimum frequency.

Conclusion

The major conclusion of the present study is that BMAC, as applied in this study, is as efficacious as PC in ameliorating cold-induced pain in people who are healthy. An implication is that the lesser discomfort of BMAC7,8 may make it more clinically useful.
than PC due to a greater likelihood of patient tolerance and acceptance. This study and previous studies\(^4\)–\(^6\),\(^9\) indicate the need for clinical trials comparing the effectiveness of PC, IFC, and BMAC for pain relief.

Both authors provided concept/idea/research design, writing, data collection and analysis, and consultation (including review of manuscript before submission). Dr Ward provided project management, fund procurement, and facilities/equipment. Mr Oliver provided subjects.

Ethics approval was obtained from the Human Research Ethics Committee of the Faculty of Health Sciences, La Trobe University.

This article was received July 14, 2006, and was accepted April 6, 2007.


References

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Originally published online June 19, 2007