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Traditional Cryotherapy Treatments are More Effective than Game Ready® on Medium Setting at Decreasing Sinus Tarsi Tissue Temperatures in Uninjured Subjects

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Abstract

Background: Treating residual pain is a common clinical practice. The cooling potential, a determiner of residual pain relief, of Game Ready® has not been compared with standard cryotherapy treatments.

Hypothesis: Our purpose was to compare the cooling potential of Game Ready® with ice with compression and a slush bucket, at comparable pressures. We believed that ice with compression would cool the tissue the most, followed by the slush bucket, and Game Ready®.

Study design: Cross-sectional group comparison.

Methods: We compared sinus tarsi tissue and skin interface cooling of ice with compression, a slush bucket, and Game Ready® during a 20 minute treatment in 20 healthy college-aged subjects (10 males and 10 females: age=23 years, ht=174.1 ± 13.3 cm, mass=75.9 ± 15.3 kg). All participants had a thermocouple inserted 2 mm into their sinus tarsi and an additional thermocouple taped to the skin within 5 mm of the same location. We recorded temperature 10 minutes after insertion (baseline), 20 minutes after the treatments were applied (treatment), and 20 minutes after the treatments were removed (post treatment); measurements served as the dependent variable.

Results: There was no difference in tissue (Tukey-Kramer P=0.80) and skin (Tukey-Kramer P=0.69) temperatures at the end of baseline. Following the 20-minute treatment, tissue and skin temperatures for the ice with compression and slush bucket treatments were colder than the Game Ready treatment (Tukey-Kramer P<0.001), but did not differ from one another (Tukey-Kramer P=0.48 and 0.49 respectively). Temperatures for all three modalities differed (Tukey-Kramer P<0.001) both in the tissue and on the skin following the post treatment period, Game Ready® > ice with compression > slush bucket.

Conclusions: After a 20 minute treatment at the sinus tarsi (surface and 2 mm), Game Ready on the medium setting and with a large sleeve did not cool as well as ice with compression or a slush bucket.

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Clinical relevance: When treating residual pain, traditional treatments may be a better option than Game Ready® using the parameters studied.

Keywords: Acute care; Cryotherapy; Intermittent compression; Rehabilitation

Introduction

The daily application of cryotherapy for orthopedic injury pain management is a common practice in clinical settings. McCaffery reported in 1979 that cryotherapy was the most effective, yet underutilized modality for pain [1]. This underutilization of cryotherapy for pain management may be in part due to unclear relationship between cryotherapy application and orthopedic injury pain [2].

According to Knight and Draper, "understanding the relationship between cryotherapy and pain begins with the recognition that pain from three origins is involved [2]". First, there is cold pain, or pain associated with the application of cryotherapy [2]. This pain is most commonly associated with cold immersion, but as the application time of cryotherapy increases, and with each subsequent application, the pain response diminishes. Second is the residual pain associated with the injury [2]. Until the tissue is healed, and as long as there is an accumulation of swelling, residual pain can be present. During post-immediate care cryotherapy, eliminating residual pain is top priority. Doing so allows for earlier motion and exercise, both of which help the athlete recover more quickly. Reinjury pain is the third source of pain [2]. Reinjury pain serves as a protective mechanism and will be present even if the patient is numb from cryotherapy application. Reinjury pain needs to be assessed and activity adjusted accordingly.

Due to the priority residual pain commands, clinicians have a variety of cryotherapy options to consider. Options include crushed ice, gel, artificial ice, or crushable chemical packs. Each of these options can be applied either alone or be held in place by plastic or elastic wraps. Care must be taken as to whether packs are applied directly to the skin or not-only crushed ice packs should be applied without a barrier between the modality and the skin [2]. In addition to the various cryotherapy packs, other options include ice massage, cold whirlpool, or slush (ice and water) buckets. In recent years, the use of intermittent compression devices with cooling capabilities have also gained prominence. Examples of these devices include the Game Ready® Injury Treatment System, BioCryo Compression System, and the AIRCAST® Cryo/Cuff.

With all of these options for decreasing residual pain available to a clinician, which option is best? Merrick, et al. and Tomchuk, et al. demonstrated that adding a compression wrap to an ice bag treatment is more effective than an ice bag alone at decreasing tissue temperature [3,4]. Although pain was not measured in either study, a decrease in tissue temperature correlates with a decrease in pain. Jutte et al. demonstrated that immersing the ankle in colder water (1°C) was more effective at inducing numbness than warmer water (4°C or 10°C) [5]. Additionally, the numbness corresponded with a greater decrease in skin temperature. Even though immersion tends to be unpleasant for the patient [2] due to cold pain, the resultant

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numbness from circumferential cooling can facilitate exercise, potentially expediting return to activity. In considering a third option, intermittent compression devices, the Game Ready® system claims to be "the only product on the market that provides [rhythmic] cyclical compression and controllable cold therapy," the combination of which "helps bodies heal faster [Game Ready Advanced Cooling System User's Manual]." Game Ready® purports to provide circumferential cooling like a slush bucket with the compression obtained from an ice bag with compression, while avoiding cold pain. These claims have not been substantiated in the research, however.

The purpose of this study was to compare the cooling abilities of the Game Ready® Injury Treatment System, ice with compression, and a slush bucket. Cooling ability, as measured by skin and sinus tarsi tissue temperature, was selected as the dependent variable due to the relationship between tissue cooling and pain relief [5]. Since we conducted this study in a healthy population, we did not measure pain itself. Based upon limited previous research [6-9] and clinical experience, we hypothesized that ice with compression would cool the tissue the most, followed by the slush bucket, with Game Ready® cooling the least.

Materials and Methods

Study design

This controlled cohort, laboratory study followed a 3×3 crossover repeated measures design. The independent variables were treatment (ice with compression, slush bucket, Game Ready®), and time (temperature reading after 10 minute baseline, 20 minute treatment, and 20 minute post treatment re-warming).

Subjects

Twenty healthy, uninjured college-aged students (10 females: age=22.0 ± 1.6 years, ht=164.6 ± 8.7 cm, mass=67.7 ± 10.5 kg and 10 males: age=22.9 ± 2.4 yrs, ht=183.6 ± 9.8 cm, mass=84.0 ± 15.5 kg) volunteered to participate in this study. Each gave written informed consent approved by the institutional review board and reported prior cryotherapy use, without complications, prior to inclusion.

Instruments

Temperature measurement occurred via three PT-6 Kapton-insulated and one IT-18 (implantable) thermocouples (Physitemp Instruments Inc., Clifton, NJ) connected to a 16-channel Iso-Thermex electro thermometer (Columbus Instruments, Columbus, OH). We used a 20-gauge×2.5 cm intravenous catheter needle (BD Insyte Autoguard, Franklin Lakes, NJ) to insert the IT-18 thermocouple. Both thermocouple types were secured using transpore tape (3M Corporation, St. Paul, MN). Sterilization of the thermocouples occurred by immersion in Cidex Plus (Advanced Sterilization Products, Irvine, CA) between uses, for no less than 24 hours. A 53 cm tall, 34 cm diameter, 45.4 kg capacity calcium hypochlorite bucket served as the slush bucket. One Game Ready® control unit (Cool Systems Inc., Alameda, CA, model # 500055) with a large ankle sleeve was used for all Game Ready® treatments.

Procedures

Subjects reported to the therapeutic modalities laboratory dressed in shorts at the same time of day on 3 occasions, each occasion separated by no more than 1 week. We inserted one IT-18 thermocouple into the sinus tarsi of the right ankle at a depth of 2 mm. We selected this depth because it was just greater than ½ of the skinfold of the area [10], and we desired to be near the depth of the anterior talofibular ligament, but not in it. We ensured consistent depth via markings on the thermocouple.

The insertion site was shaved if necessary and cleaned with a povidone iodine swab prior to thermocouple insertion. We inserted a 2.5 cm catheter into the site and thread the thermocouple through the catheter (Figure 1). After inserted of the thermocouple, we removed the catheter and secured the thermocouple to the skin with tape. We also taped one PT-6 thermocouple to the skin within 5 mm of the insertion site to measure ice/skin interface temperature (Figure 2). We taped the second PT-6 thermocouple near the treatment table to measure ambient temperature and the third thermocouple either inside the ice water container or ice bag to measure water/ice temperatures. We interfaced all thermocouples with a 16-channel Iso-Thermex electro thermometer, connected to a personal computer.

Following thermocouple insertion, we established a baseline by measuring tissue temperature for 10 minutes. During pilot work all temperature readings stabilized, meaning we observed less than a 0.1°C fluctuation in temperature for 3 consecutive readings, within 10 minutes. Thus, a 10-minute baseline was selected for this study. Following the baseline period, we applied 1 of 3 cryotherapy treatments at a comparable pressure, following a Latin square design: a 1 kg crushed ice bag with a compression wrap, a slush bucket, or a Game Ready® treatment. In accordance with the Latin square design, treatment order was randomized.

We prepared the ice bag by putting 1 kg of ice in to an ice bag, as measured by a digital scale. The subject lay supine on a treatment table with the right foot elevated approximately 6 inches. We applied the ice bag to the treatment area and secured it with a double length 6" ace bandage, wrapped at 35-40 mm Hg. We practiced wrapping to this pressure during pilot work by placing a slightly inflated sphygmomanometer between the wrap and the skin on the medial

Figure 1: Threading the thermocouple through the inserted catheter.

Figure 2: Insertion site with both thermocouples present. Care was taken to ensure neither sensing tip was covered with tape.

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side of the ankle (Figure 3). We did not continue this practice during the study so as to remove the potential of any insulatory effect of the sphygmomanometer. We shook the ice bag every 5 minutes to remove any thermal gradients between the skin and the ice bag.

We prepared the slush bucket by filling a large bucket with half ice and half water [11] to a depth of 51 cm. This depth served to approximate the pressure provided by the 2 other treatments-1 mm Hg per 1.4 cm of water depth—producing approximately 36 mm Hg of pressure at the bottom of the bucket [12]. While seated in a chair, each subject placed their right foot into the water to the bottom of the bucket (Figure 4). We stirred the water in the slush bucket every 5 minutes to remove any thermal gradients between the skin and the ice water.

We filled and operated the Game Ready® according to the directions in the user's manual. We ran the machine on its coldest setting with the compression turned off during the 10-minute baseline period so that the boot would be cold upon application. The subject lay supine on a treatment table with the right foot elevated approximately 6 inches. We applied the sleeve to the right foot, covering the treatment area (Figure 5). The pressure on the machine was placed on the medium setting (5–50 mmHg).

Figure 3: Ice with compression treatment set up with sphygmomanometer in place to measure pressure.

Figure 4: Slush bucket treatment set up.

Figure 5: Game Ready® treatment set up

All treatments were administered for 20 minutes. Following the 20-minute treatment, the modalities were removed and we continued to record temperature an additional 20 minutes, the post treatment re-warming period. During the post treatment period, those who had been in the slush bucket assumed the same position as the other groups. After the 20-minute post treatment, we removed the thermocouple from the subject and detached it from the Iso-Thermex. We cleaned the treatment area with a sterile wipe, applied an adhesive bandage with anti-biotic ointment over the insertion site, and instructed subjects on how to properly care for the wound.

Statistical analysis

We recorded temperature measurements at 10, 30, and 50 minutes (end of baseline, treatment, post treatment re-warming) to use for statistical analysis. We also calculated the means and standard deviations for the ice bag, slush bucket, Game Ready® water reservoir, and ambient air temperatures. Two (sinus tarsi tissue and skin) repeated measure ANOVA's with treatment as the between-subjects factor were run, followed by a Tukey HSD for multiple comparisons post-hoc test. We considered results statistically significant at an alpha level of $P<0.05$. Data were analyzed using SPSS version 18.0 (SPSS Inc., Chicago, IL).

Results

Sinus tarsi tissue temperatures did not differ between the three treatments after baseline, but did following the 20-minute treatment and 20-minute post treatment re-warming periods (Table 1). The ice bag with compression and the slush bucket resulted in greater cooling than the Game Ready® at both time points, but did not differ from one another. Similar results were observed with the ice/skin interface temperatures (Table 1).

The intra-ice bag, slush bucket, Game Ready® reservoir, and ambient temperatures remained stable (within 1.5°C) on each day of testing (Table 2).

Discussion

Intermittent compression devices, such as the Game Ready® Injury Treatment System, are thought to provide a beneficial alternative to more traditional cryotherapy approaches. Proposed benefits include controlled cooling and rhythmic cyclical compression, the combination of which, according to Game Ready, expedites healing. A comparison of these three approaches at equivalent pressures had not been performed previously. Using tissue and skin temperatures of the sinus tarsi as dependent variables during a 20-minute treatment with a 20-minute post treatment re-warming period, we observed both traditional treatments cooled more and maintained cooling longer than the Game Ready® on the medium setting.

The greatest decrease in tissue temperature was observed in the ice with compression treatment, followed by the slush bucket treatment (Table 1). This is consistent with previous research where constant compression increased the effectiveness of an ice application [3,4]. The intermittent compression of the Game Ready® sleeve, as applied in this study, may not be sufficient to promote the same decrease in temperatures. One potential reason for this is that on the medium setting the sleeve progressively inflates and deflates between 5 and 50 mmHg over a 3-minute cycle. Although not explicitly stated in the user's manual, the premise behind this cyclical compression is to mimic muscle contraction, not facilitate temperature decrease.

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Table 1: Average sinus tarsi tissue and skin temperatures (mean ± SD°C) at the end of baseline, treatment (Tx), and post treatment re-warming (Post Tx) for the ice with compression, slush bucket, and Game Ready® treatments. Within subject differences were observed at all time points (sinus tarsi: $F_{1.4,77.9}$=1593.3, P<0.001; skin: $F_{1.4,78.9}$ = 2140.0, P<0.001).

	Sinus Tarsi Tissue Temperatures			Sinus Tarsi Skin Temperatures		
	Baseline	Tx [a]	Post Tx [a]	Baseline	Tx [b]	Post Tx [b]
Ice with compression	30.5 ± 1.4	7.4 ± 3.2	19.0 ± 2.0	28.9 ± 1.6	4.8 ± 3.0	19.2 ± 1.8
Slush bucket	30.7 ± 1.7	8.5 ± 3.4	16.7 ± 1.6	29.2 ± 1.6	3.7 ± 2.1	16.6 ± 1.9
Game Ready®	30.3 ± 2.0	18.6 ± 2.8	22.5 ± 1.6	28.8 ± 1.9	13.9 ± 3.4	22.2 ± 1.4

[a] Ice with compression and the Slush bucket differed from the Game Ready® ($F_{2,57}$ = 56.4, P<0.001; Tukey<0.001) after the treatment and the post treatment re-warming periods, but not from each other (Tukey=0.85)

[b] Ice with compression and the slush bucket differed from the Game Ready® ($F_{2,57}$=56.4, P 0.001; Tukey 0.001) after the treatment and the post treatment re-warming periods, but not from each other (Tukey=0.08)

Table 2: Average Game Ready® reservoir, intra-ice bag, slush bucket, and ambient temperatures on each day used in the study (mean ± SD°C).

Day	Game Ready®	Ice Bag	Slush Bucket	Ambient
1	0.4 ± 0.5	0.4 ± 0.3	1.0 ± 0.6	21.7 ± 0.9
2	0.6 ± 0.5	0.5 ± 1.2	0.7 ± 0.4	21.6 ± 0.8
3	0.3 ± 0.5	0.5 ± 0.6	1.2 ± 1.6	21.5 ± 0.7
Day Average	0.5 ± 0.5	0.5 ± 0.8	1.0 ± 1.0	21.6 ± 0.8

In contrast to our observations, both Trowbridge et al. [7] and Womochel, et al. [9] observed that the Game Ready® operated on the medium setting did not differ from ice with compression - they observed similar decreases in temperature between the two approaches. Both used the same pressure settings as we did, but ran the treatment for longer (30 minutes). There is the potential that if we ran the Game Ready for an additional 10 minutes we may have seen similar results, but we question if that would be the case due to differences in our procedures. Both Trowbridge et al. and Womochel, et al. measured temperature in the thigh 1.5 cm below subject's subcutaneous adipose tissue. Similar procedures are not practical in the ankle. Due to the relatively shallow placement of our thermocouple, the sinus tarsi tissue responded very similar to the skin (Table 1). Temperatures of deeper tissue see a more gradual decrease in temperature and to a lesser magnitude than subcutaneous tissue like the sinus tarsi [2]. A more plausible reason for the differences observed may lie in the sleeve itself.

We believe that our results differed due to the moldability of the modalities. The ice in the ice bag and within the slush bucket was closer to the tissue. In our opinion, the Game Ready® did not do well across all subjects in this regard because of the poor fit of the sleeve. We used the large ankle sleeve, one of two ankle sleeve sizes sold by Game Ready® (the other being an extra-large). This sleeve was too large for the majority of our female participants, as well as some of the males, a definite limitation of this product. Since the water/ice mixture in all three modalities was nearly the same temperature (Table 2), the poor fit of the sleeve may have contributed to the Game Ready® being less effective at decreasing temperature. This theory seems to be supported by the Trowbridge et al. and Womochel et al. studies. Both collected data in the distal thigh, using a straight knee sleeve [7,9]. Because there is less variation in the contour of the distal thigh as compared to the ankle, the straight knee sleeve most likely had much better contact in their studies than in ours. One could propose that if the ankle sleeve fit as well as the straight knee sleeve does, similar results in temperature decrease would be observed. Further research is needed to determine if this is the case.

It is important to point out that because attempts were made to compare these three modalities with equivalent pressures, they were not applied as they most likely would have been clinically. For example, the slush bucket was filled much higher than it would normally be for someone suffering from an ankle sprain—a slush bucket is typically used to cool the body part to facilitate a cryokinetic treatment, not to provide compression. The depth of the water did allow for comparable pressures, but it also increased the cooling capacity of the slush bucket. We believe this increased cooling capacity accounts for the least re-warming and lowest skin temperatures of the three modalities (Table 1). Also, in clinical practice we would have operated the Game Ready® on the high setting if we were truly treating an injured ankle. Due to the poor fit of the ankle sleeve across subjects, we do not believe the high setting would have changed our results though. However, we do see the depth of the water and the settings on the Game Ready® as limitations to the clinical applicability of this study.

Conclusions and Clinical Implications

The Game Ready®, operated on the medium setting with a large ankle sleeve, did not cool the tissues of the sinus tarsi as well as the traditional applications of ice with compression or a slush bucket. Due to this observation, we question the choice to use the Game Ready® Injury Management System instead of the more traditional approaches of ice with compression or a slush bucket for residual pain management. Further research using the Game Ready® machine is warranted to determine if adjustments in the amount of compression, time of application, or a better fitting sleeve, may increase the cooling ability of the machine, aiding in residual pain control.

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