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Effect of Bacrobial® Skin Cleanser on the Prevention of Muscle Cramps

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Abstract: Anecdotal evidence supports the use of Bacrobial® skin cleanser for preventing muscle cramps; however, empirical evidence is lacking. OBJECTIVE: To examine whether Bacrobial® prevents muscle cramping in the triceps surae. DESIGN: Randomized, double-blind, placebo-controlled, crossover study. SETTINGS/LOCATION: Laboratory. SUBJECTS: Seventeen cramp-prone participants (11 male, 6 female; age 21 ± 2 yrs; 79.72 ± 19.75 kg; 175.86 ± 11.76 cm) volunteered. INTERVENTION: Participants completed two trials, at least one week apart. On the first trial, Bacrobial® was liberally applied to the skin over the triceps surae musculature of one leg, while placebo was applied to the other leg. At 1, 5, 10, and 20 min after application, participants were instructed to induce a cramp in the triceps surae via maximal voluntary contraction. For the second trial, treatments were applied to the opposite leg as in trial one and the cramping procedure was repeated. OUTCOME MEASURES: Incidence of cramping was the main outcome measure and event-odds tables, risk reduction and NNT (numbers needed to treat) or NNH (numbers needed to harm) were calculated at the time intervals of 1, 5, 10 and 20 minutes. RESULTS: No significant differences between treatments were found in cramping incidences at all time intervals. Bacrobial® decreased the risk of cramping by 12.5% at one minute (NNT = 8), while causing a 5.3% increased risk at five minutes (NNH = 5.3). CONCLUSIONS: Our findings indicate Bacrobial® skin cleanser is not an overall effective treatment for muscle cramp prevention. However, the observed results at one minute may be useful to clinicians who treat cramp-prone patients.

Key words: Cramping frequency, cramping incidence, alternative therapy, topical treatment.

1. Introduction

Muscle cramping is a common condition seen by health care professionals, and EAMC (exercise-associated muscle cramping) is commonly treated by sports medicine professionals [1]. However, despite extensive research, the etiology of muscle cramping and best practice for treatment remains unknown. Several therapies have been used to prevent and treat muscle cramping, yet research on the efficacy of these therapies remains inconsistent [2].

Recently, growing anecdotal evidence has emerged for the use of a topical skin cleanser called Bacrobial® (iFan Health Products, Inc., Black Mountain, NC) as an alternative therapy for preventing and treating muscle cramps, especially EAMC. However, no empirical studies have been published on the efficacy of this product. Therefore, the purpose of this study was to empirically examine the effect Bacrobial® has on the prevention of cramping in the triceps surae musculature.

2. Materials and Methods

Seventeen participants (11 male, 6 female; age 21 ± 2 yrs; 79.72 ± 19.75 kg; 175.86 ± 11.76 cm) volunteered for this IRB approved study. All participants completed a demographic and cramping history questionnaire and provided written informed consent prior to participation.

A randomized, double-blind, placebo-controlled, crossover design was utilized. Unmarked 8oz spray bottles were filled with Bacrobial® or placebo (purified water with Bacrobial® fragrance). Bacrobial® topical solution contains purified water, aloe, citrus based preservatives, tego betaine, allantoin, colloidal silver,

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lauryl glucoside, beta glucan, abil B, methylparaben propylparaben, EDTA (ethylenediaminetetraacetic acid), fragrance and vitamin E (US patent 6,358,516). A person unaffiliated with the study filled and marked the bottles with "A" and "B." Identification was kept in a sealed envelope and not opened until the study was completed.

A voluntary maximum contraction cramping protocol [3] was utilized to induce muscle cramping. Participants reported for three separate visits: a cramp induction screening visit and two intervention trial visits. Each visit was completed one week apart.

2.1 Cramping Intervention Procedure: Trial One

All participants were asked to report hydrated. Hydration status was verified by measuring urine specific gravity with a handheld refractometer (Model URC-Ne; ATAGO, USA; Bellevue, WA); if urine specific gravity was > 1.020, participants were required to reschedule on a different day. Participants were randomized to begin with either bottle-A or bottle-B on the right leg. The skin overlying the participant's right triceps surae was liberally sprayed (~15 sprays) and lightly rubbed in by a researcher wearing non-latex gloves for approximately five seconds. After one minute, the participant performed the cramping protocol. If a cramp occurred within the 60-second time frame, the incidence (yes) was recorded and the cramp was relieved via stretching. If a cramp did not occur within 60 seconds, the attempt was stopped and incidence (no) was recorded. The protocol was repeated at 5, 10 and 20 minutes from application. After completion on the right leg, the opposite spray and cramping procedure was performed on the left leg.

2.2 Cramping Intervention Procedure: Trial Two

Participants returned one week later and the same protocol from trial one was repeated. However, the solutions were crossed over (i.e., if the participant had bottle-A sprayed on the right leg in trial one, bottle-B was sprayed on the right leg in trial two).

2.3 Statistical Analyses

Event-odds tables were calculated based on the outcome variable of cramping across Bacrobial® and placebo groups at time intervals of 1, 5, 10, and 20 minutes from initial application. Our data did not meet assumptions for chi-squared analysis (expected values < 5). Therefore, differences between groups were calculated using a two-way Fisher's exact test. An *a priori* level of significance was set a 0.05. Additionally, risk reduction and NNT (numbers needed to treat) or NNH (numbers needed to harm) were also calculated from event odds tables.

3. Results

Cramping incidences are displayed in Table 1. No significant differences were observed in cramping incidence between Bacrobial® and placebo groups at 1 minute (P = 0.484), 5 minutes (P = 0.333), 10 minutes (P = 1.000), or 20 minutes (P = 1.000). Bacrobial® decreased the risk of cramping by 12.5% at 1 minute (NNT = 8); while causing a 5.3% increased risk at 5 minutes (NNH = 5.3). At 10 and 20 minutes, there were no changes in risk reduction between groups.

4. Discussion

Despite an abundance of anecdotal evidence, our findings suggest that Bacrobial® is not an overall

Table 1 Cramping incidences and Fisher exact significance.

Group	Cramp?	1 min	5 min	10 min	20 min
Treatment	Yes	14	15	14	14
	No	2	1	2	2
Placebo	Yes	16	12	14	14
	No	0	4	2	2
Fisher exact significance		0.484	0.333	1.000	1.000

effective alternative treatment for preventing muscle cramps. The most clinically significant finding of this study was that Bacrobial® made participants 12.5% less likely to cramp one minute post-application. This information could be useful to clinicians working with cramp-prone individuals.

Many different therapies have been studied for the prevention and treatment of muscle cramps. Hydration and electrolyte replacement have long been promoted to reduce EAMC, yet little evidence supports these interventions [1]. Results remain mixed on the use of stretching [1] and ingestion of pickle juice [4] as a prevention therapy. One well-studied pharmacological treatment that is highly effective in reducing muscle cramps is quinine sulfate [5]; however, the side effects associated with quinine sulfate ingestion suggest caution of its use as a long-term treatment. Calcium channel blockers, Verapamil [6] and Diltiazem [7], have proven effective in treating nocturnal muscle cramps, but with many pharmaceuticals there are risks of adverse side effects.

Non-prescription treatment of muscle cramps has shown promise. In a small study, ingestion of vitamin B complex reduced the frequency, duration and intensity of cramps [8]. Vitamin E has also been used to successfully alleviate muscle cramps in hemodialysis patients, but not for nocturnal muscle cramps [9, 10]; however, the mechanism by which vitamin E functions to relieve muscle cramps is unknown. The limited effectiveness of Bacrobial® may be explained by the presence of EDTA. This chemical possesses calcium-chelating properties and may function to sequester calcium ions in the muscle fiber after rapid transdermal absorption. This may also help explain why we observed a reduced risk of cramping at one minute post-application, but an increased risk at five minutes.

5. Conclusions

Although Bacrobial® skin cleanser does not appear, overall, to be an effective treatment for the prevention of muscle cramps, the observed results at one minute may be useful to clinicians who frequently treat patients who are prone to cramping. It is unknown whether Bacrobial® works to treat (relieve) muscle cramps once a cramp has occurred, thus future research should investigate whether Bacrobial® is effective to treat muscle cramps, as well as whether re-application works to reduce subsequent cramping.

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