

# DOUBLE-BLIND, PLACEBO-CONTROLLED, RANDOMIZED, CROSSOVER PILOT STUDY EVALUATING THE IMPACTS OF SODIUM BICARBONATE IN A TRANSDERMAL DELIVERY SYSTEM ON PHYSIOLOGICAL PARAMETERS AND EXERCISE PERFORMANCE

PERFORMANCE

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Lisa M. Misell<sup>1</sup>, Mark Kern<sup>2</sup>, Andrew Ordille<sup>2</sup>, Madeline Alm<sup>2</sup>, Brookell Salewske<sup>2</sup>

<sup>1</sup>Ampersand Biopharmaceuticals, LLC, Thousand Oaks, CA, <sup>2</sup>San Diego State University, San Diego, CA (Sponsor: Michael Buono, FACSM)

#### **ABSTRACT**

Oral sodium bicarbonate has been used for decades as an ergogenic aid by buffering muscle acid production during exercise and subsequently delaying the onset of fatigue in athletes. However, gastrointestinal side effects limit the use of sodium bicarbonate.

**PURPOSE**: This study evaluated the efficacy of a commercially available topical transdermal sodium bicarbonate (TSB) lotion (Amp Human Performance's PR Lotion) which is claimed to be delivered through the skin using a novel patent-pending transdermal delivery system for impacting exercise metabolism and performance.

METHODS: 20 trained cyclists (Category 1-3) and a professional triathlete participated in this randomized, cross-over, double-blinded, placebo-controlled study. After application of TSB or placebo lotions, subjects completed a variety of exercise and performance tests. On one day, subjects completed a high-intensity series of exercise tests which included a ramped protocol until reaching a rating of perceived exertion (RPE) of 17 out of 20, a 30-second sprint performance test, and a 5-minute time trial performance test, with 5 minutes of recovery between tests. On a separate day, subjects completed a 1-hour time trial. Heart rate, RPE, blood lactate and pH were assessed before, during, and after performance testing.

**RESULTS:** Heart rate and RPE were significantly (p<0.05) lower for TSB compared to placebo at the 15-min mark of the 1-hour time trial, but not at other time points. When TSB was applied, lactate was higher (p<0.05) after the high-intensity ramp, sprint and 5-min time trial series (10.8±3.2 mmol/L versus 9.7±3.1 mmol/L for TSB and placebo, respectively). Similar effects were not observed after the 1-hour time trial. Significance was not reached when examining performance differences (p>0.05).

**CONCLUSIONS:** Overall, the findings from this study provide evidence that TSB can significantly impact blood lactate, heart rate and RPE during performance tests of varying intensity/length. These significant findings support the ability of this lotion to transdermally deliver sodium bicarbonate, which could allow athletes to avoid the side-effects of oral bicarbonate use. Further research is warranted to substantiate these findings and determine the most effective use for this commercially available transdermal sodium bicarbonate lotion.

## INTRODUCTION

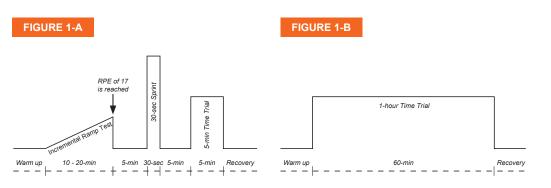
Muscle acidosis is a contributor to reduced exercise capacity by causing subsequent muscle fatigue. Oral sodium bicarbonate has been used for decades to buffer muscle acid production during exercise and subsequently delay the onset of fatigue in athletes. Several studies of cyclists have demonstrated the ergogenic effects of sodium bicarbonate. However, gastrointestinal side effects limit its use. A commercially available sports lotion has recently been developed using the manufacturer's patent-pending transdermal delivery technology to deliver sodium bicarbonate through the skin in order to impact performance and recovery without the limiting side-effects of oral use.

HYPOTHESIS: We hypothesized that the topical transdermal sodium bicarbonate (TSB) lotion (Amp Human Performance's PR Lotion) would increase pH and lactate levels, and would confer a performance benefit, similar to the effects observed when oral sodium bicarbonate is ingested, but without the gastric side-effects.

## **METHODS**

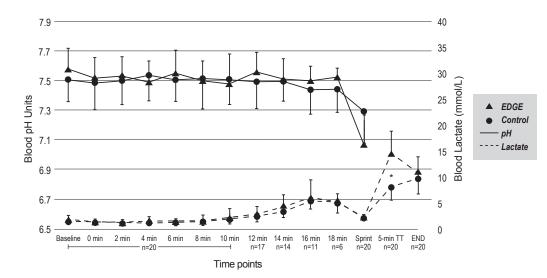
- 20 trained cyclists (Category 1-3) and a professional triathlete with an average VO2 Peak (VO2 mL/kg/min) of 58.9+/-7.2 participated in this randomized, cross-over, double-blinded, placebo-controlled study.
- After application of Transdermal Sodium Bicarbonate (TSB) or placebo lotions, subjects completed a variety of exercise and performance tests (Figure 1).
- Heart rate, RPE, blood lactate and pH were assessed before, during, and after performance testing.

**Figure 1.** Schematic of Study Protocol. Subjects completed both tests; A) High-intensity series of exercise tests, and B) 1 hour time trial, on separate days, and for each study product (placebo or active).



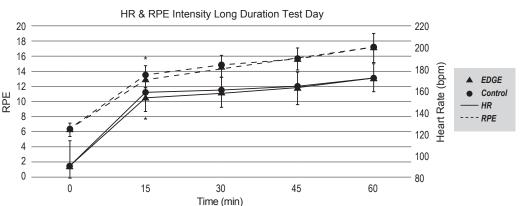
## **RESULTS**

• When TSB was applied, lactate was higher (p<0.05) after the high-intensity ramp, sprint and 5-min time trial series (10.8±3.2 mmol/L versus 9.7±3.1 mmol/L for TSB and placebo, respectively) (Figure 2).



**Figure 2.** Blood pH and Lactate. When the transdermal sodium bicarbonate lotion was applied, subjects had significantly higher lactate levels following the high-intensity series of tests compared to when applying placebo lotion. pH differences did not reach significance.

- Heart rate and RPE were significantly (p<0.05) lower for TSB compared to placebo at the 15-min mark of the 1-hour time trial, but not at other time points (Figure 3).
- Significance was not reached when examining other performance differences (p>0.05). This may potentially be due to inadequate dosing or inadequate time allowed for the lotion to penetrate prior to testing.



**Figure 3.** Heart Rate (HR) and Rate of Perceived Exertion (RPE). When the transdermal sodium bicarbonate lotion was applied, subjects had significantly lower HR and RPE at the 15 min. time point of the 1 hour time trial despite completing the same total work load.

### **CONCLUSIONS**

- Transdermal sodium bicarbonate significantly impacted blood lactate, heart rate and RPE during performance tests of varying intensity/length.
- Higher lactate levels and other significant effects support the ability of this lotion to transdermally deliver sodium bicarbonate.
- This route of bicarbonate delivery could allows athletes to avoid the side-effects of oral bicarbonate use.
- Although promising, further research is warranted to substantiate these findings and determine the most effective dosing and time of application for this commercially available transdermal sodium bicarbonate lotion.

#### **ACKNOWLEDGMENTS**

Ampersand Biopharmaceuticals, LLC (DBA Amp Human Performance), the manufacturers of PR Lotion sodium bicarbonate sports lotion, provided an unrestricted research grant and placebo and active products for testing.