The Acute Effect of Moderate Intensity Stair-Climbing on Postprandial Blood Glucose

NCT Number: Not assigned yet

February 24, 2016

BASIC STUDY INFORMATION

Background & Significance

* Discuss relevant background information and literature reviewed to provide the rationale for the proposed research.

Blood sugar (glucose) increase following meal consumption (i.e postprandial) is an independent predictor for developing cardiovascular disease and diabetes {{2485 Blaak, EE 2012;}}. In fact for people within a non-diabetic glucose range the association for postprandial glucose increase and CVD is even stronger than for the gold standard of glucose regulation (glycohemoglobin, HbA1c) and CVD risk {{2485 Blaak, EE 2012;}}. In addition intermittent glucose spikes elicit a greater inflammatory/oxidative stress response than consistently high glucose levels {{2485 Blaak, EE 2012;}}. Since in western societies most people spend the majority of their wake time in the non-fasted state (i.e. when metabolites from a previous meal are still being processed or distributed throughout the body) it is important to investigate how to mitigate the postprandial glucose spike as well as the concomitant rise in inflammatory and oxidative stress.

One of the most effective ways to improve the postprandial glucose response is exercise. Multiple studies have shown that even low-moderate intensity exercise of relatively short duration can attenuate postprandial glucose increases {{2486 Aadland, Eivind 2008; 2488 Lunde, Marianne SH 2012; 2487 Nygaard, Håvard 2009; 2485 Blaak, EE 2012;}}. The shortest single exercise bout that showed significant reductions in postprandial glucose for men with impaired glucose tolerance using moderate intensity stair climbing (21 up and down) for ~6 minutes {{2489 Takaishi , Tetsuo 2011;}}. Whether this can also be accomplished in healthy individuals or women is unknown. It is also unknown what the shortest bout of stair climbing is that still has a significant glucose lowering effect.

The purpose of this study is therefore to investigate whether low-moderate intensity stair climbing of short durations can result in significant lowering of postprandial blood glucose responses in healthy men and women. In addition, we aim to investigate how short such an effective stair climbing bout can possibly be.

We hypothesize that stair climbing will reduce postprandial blood glucose in a dose dependent manner at 10 and 3 minutes but will be an insufficient stimulus at 1 minute duration.

* Please provide a list of references to support the information found in the background and significance section.

Aadland, Eivind, and Arne T. Høstmark. "Very Light Physical Activity After a Meal Blunts the Rise in Blood Glucose and Insulin." Open Nutrition Journal 2 (2008): 94-9. Print.

Blaak, EE, et al. "Impact of Postprandial Glycaemia on Health and Prevention of Disease." obesity reviews 13.10 (2012): 923-84. Print.

Lunde, Marianne SH, Victoria Telle Hjellset, and Arne T. Høstmark. "Slow Post Meal Walking Reduces the Blood Glucose Response: An Exploratory Study in Female Pakistani Immigrants." Journal of Immigrant and Minority Health 14.5 (2012): 816-22. Print.

Nygaard, Håvard, Sissel Erland Tomten, and Arne Torbjørn Høstmark. "Slow Postmeal Walking Reduces Postprandial Glycemia in Middle-Aged Women." Applied Physiology, Nutrition, and Metabolism 34.6 (2009): 1087-92. Print.

Takaishi, Tetsuo, et al. "A Short Bout of Stair climbing–descending Exercise Attenuates Postprandial Hyperglycemia in Middle-Aged Males with Impaired Glucose Tolerance." Applied Physiology, Nutrition, and Metabolism 37.1 (2011): 193-6. Print.

Study Abstract

Briefly complete the following Study Abstract components:

* 1. Purpose/objective:

Blood sugar (glucose) increases after meal consumption (postprandial) and the larger this response the higher the risk of developing cardiovascular disease (CVD) and diabetes later in life. The rise in glucose and the concomitant rise in inflammatory/oxidative stress can be attenuated with relatively short and low-moderate intensity exercise. Particularly effective is stair climbing. A single bout of climbing 21 stairs (up and down) for ~6 min was effective in reducing postprandial glucose increases in men with impaired glucose tolerance. Whether this can be extended to healthy people, women or shorted bouts is currently unknown. We therefore propose to investigate moderate intensity stair climbing of various durations (i.e. 1, 3, and 10min) following ingestion of a standard 75 g glucose drink in a total of 30 healthy men and women. We will take standard finger stick blood glucose measurements every 15 minutes for one hour following drink consumption. We will also take two venipuncture blood draws, one at baseline and one 30 min after drink consumption (i.e. at the expected blood glucose peak). We hypothesize that stair climbing will reduce postprandial glucose rise in a dose dependent manner for 10 and 3 min bouts but not 1 min bouts. The risk is minimal (standard test such as venipuncture, finger stick and maximal exercise testing only). Direct benefits to participants are only the knowledge gained about blood glucose response and maximal exercise capacity.

* 2. Methods:

We therefore propose to investigate moderate intensity stair climbing of various durations (i.e. 1, 3, and 10min) following ingestion of a standard 75 g glucose drink in a total of 30 healthy men and women. We will take standard finger stick blood glucose measurements every 15 minutes for one hour following drink consumption. We will also take two venipuncture blood draws, one at baseline and one 30 min after drink consumption (i.e. at the expected blood glucose peak)

* 3. Subjects

a. This proof-of principle study will recruit 30 healthy adults (men and women) classified as low risk for exercise participation by the American college of sports medicine (ACSM 2014).

* 4. Planned analyses:
Oxygen consumption:
Maximal and stair climbing expired gases will be continuously collected through a softmask worn by the subject and analyzed by an open-circuit indirect calorimetry system (Vmax or Oxycon Mobile, CareFusion Corporation, CA, USA).

Blood Analysis:
Finger stick for blood glucose measurement will use standard over the counter diabetes analysis kits (Nova Max Plus, Nova Biomedical Corp.).
Blood will be collected in 5 mL EDTA tubes and centrifuged at 2,300 x g for 10 minutes at 4℃. Plasma will be extracted and stored for later analysis in at -80˚C.
Markers of glycemic and inflammatory/oxidative stress response will be assessed by standard methods. E.g. glucose by the glucose oxidase method, insulin by electro-chemi¬luminescence, tumor necrosis factor (TNF)-α by enzyme linked immunoassay (ELISA) and IL-6 by sandwich enzyme immunoassay as per manufacturer instructions and guidelines.

Statistical analysis:
Data will be analyzed with a 4 way repeated measures analysis of variance. The Level of significance will be set a priori at $\alpha \leq .05$.

* 5. Potential benefits:
a. This study will help to identify the shortest possible bout of exercise that is still effective in significantly reducing postprandial blood glucose using a simple, cheap and ubiquitously available exercise mode – stair climbing. Subjects will learn VO2max, which may be useful for assessing cardiovascular fitness and exercise prescription. In addition subject will be informed of their fasting and postprandial blood glucose, insulin and inflammatory response they so desire. At the end of the study, individuals that want their test results will be given a copy by the principle or co-investigator. However, we cannot guarantee the subjects will benefit from this information.

* 6. Potential risks:
a. During the testing participants may get light handedness, and fatigue. They may feel delayed muscle soreness (24-48 hours) after exercise. There is also a low risk of a cardiac event, such as a heart attack, cardiac arrest, or dangerous arrhythmia. This risk is less than 1 occurrence in 12,000 tests of healthy subjects. At least one person during testing will be certified in CPR and present for all exercise testing and an AED is located just outside of the lab. In addition, there is a telephone located in the laboratory should a medical emergency arise.
Whenever blood is drawn, there is a small risk of bruising. Although infection is a risk, this is minimized by use of alcohol to cleanse the area for the blood draw.
b. To decrease the anxiety of wearing the mask, for people doing it for the first time, they get to sit with it for 5 minutes before starting any testing, to get comfortable breathing through the mouthpiece.
Exercise termination for the maximal exercise test will be consistent with the ACSM Guidelines for Exercise Testing and Training. Indications for stopping the testing protocols in this research study include the following:
1) the onset of chest pain, or
2) a drop in systolic blood pressure (20 mm Hg), or
3) an absence of increased systolic blood pressure with increased intensity of exercise, or
4) a rise in blood pressure which is greater than 260 mm Hg for systolic pressure and greater than 115 mm Hg for diastolic pressure, or
5) if the participants experiences any combination of these signs and symptoms: lightheadedness, confusion, nausea, cold skin, clammy skin, pale skin, blue skin, lack of muscle coordination, or
6) an absence of increased heart rate with increased intensity of exercise, or
7) noticeable abnormal changes in heart rhythm, or
8) participant requests to stop the testing protocol, or
9) signs and symptoms of severe fatigue, or
10) failure of the testing equipment.
Participants will be continuously monitored (including assessment of blood pressure) by the research team for the presence of these termination points.
Whenever handling blood the investigators will wear gloves at all times, and all contaminated materials are deposited in a bio-hazard container, in accordance with the blood borne pathogens standard of OSHA.
c. N/A

* 7. Risk management procedures:
a. During the testing participants may get light handedness, and fatigue. They may feel delayed muscle soreness (24-48 hours) after exercise. There is also a low risk of a cardiac event, such as a heart attack, cardiac arrest, or dangerous arrhythmia. This risk is less than 1 occurrence in 12,000 tests of healthy subjects. At least one person during testing will be certified in CPR and present for all exercise testing and an AED is located just outside of the lab. In addition, there is a telephone located in the laboratory should a medical emergency arise.
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c. N/A

Research Design and Methods

* Specify aims of the research that include the hypotheses to be tested, research questions to answer, data to be gathered and tested.
a. 30 healthy men and women will report to the lab for the determination of maximal aerobic capacity (VO2max) using a standard incremental treadmill test to exhaustion (Bruce protocol, {{2397 Heyward, Vivian H 2010;}}. VO2max data will be used to describe the stair climbing bout in absolute (i.e. metabolic cost) and relative terms (i.e. relative to maximal capacity). For all testing participants will abstain from exercise for a period of 24 h prior to testing. Participants will also abstain from making any changes to their habitual diet during the duration of their study involvement.
At least 24 hours but no more than one week after the max test, participants will come in for an oral glucose tolerance test (OGTT). Participants will be instructed to stay fasted overnight (i.e 10 hours). For example, an 8 am test would mean no calorie consumption after 10 pm the night before. There will be no restriction of water consumption. Upon arrival at the lab, participants will sit quietly for 5 minutes and be fitted with a heart rate monitor strap around the chest. Participants will then consume 75 g glucose dissolved in 2 cups of water within 5 minutes. Finger-stick blood glucose sampling will be performed at baseline and every 15 minutes thereafter for 1 hour for a total of 5 samples. Finger-stick blood draws are easy, convenient and impose very little burden on subjects and are therefore suitable for frequent measurements; they are ill suited to obtain enough blood for more precise and additional measurements (described below). Therefore, two venipuncture blood samples will be obtained, one at baseline and one at 30 minutes (expected glucose peak) by a certified phlebotomist (Jochen Kressler, PhD) for a total amount of blood drawn at each visit of 10 mL. These blood draws will allow verification of the accuracy of the finger stick at the expected low point (i.e. baseline) and peak of the blood glucose response. It will also provide enough blood to investigate other key components of the postprandial response to glucose ingestion, namely insulin and inflammatory markers (described below). Participants will remain seated and calm throughout this hour of testing. Participants will be allowed to read or watch passive entertainment (e.g. videos). After one hour participants will be introduced to the (hand railed) stairwell that will be used for the stair climbing exercise. Participants will be asked to try out the stairs and self-determine the fastest stair stepping pace they would consider comfortable to maintain for 10 minutes. This pace will be recorded and employed for the other stair climbing bouts.
During the next three visits participants will go through the same overnight fast, OGTT and blood sampling procedures but will climb stairs (32 standard steps up and down) starting at 15, 22, or 24 minutes after finishing the glucose drink for 10, 3 and 1 min, respectively. This will ensure that everyone finish the stair climbing at the same time (i.e. start 15 min after ingestion --> climb for 10 min --> end at 25 min, start 22 min after ingestion --> climb for 3 min --> end at 25 min, start 24 min after ingestion --> climb for 1 min --> end at 25 min) five minutes before the expected peak. The order of trials will be randomized. All visits will be at least 24 hours but no more than 1 week apart and all visits will be at the same time of day. Participants will be encouraged to eat the same or similar dinner the night before each test.
During the stair climbing bouts respired gases will be measured via the ambulatory open-circuit method using the same type of softmask as was for the VO2 max test. The gas measurement will continue for 15 minutes after stair stepping is done.

Outcome Measures
Oxygen consumption:
Maximal and stair climbing expired gases will be continuously collected thr

* Describe procedures used to test the hypotheses or answer the research question.
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