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Pilot Safety Study: The Use of Vasper™, A Novel Blood Flow Restriction Exercise In Healthy Adults

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ABSTRACT

Gladden J, Wernecke C, Rector S, Tecson K, McCullough P. Pilot Safety Study: The Use of Vasper™, A Novel Blood Flow Restriction Exercise In Healthy Adults. **JEPonline** 2016;19(2):99-105. The purpose of this study was to examine the effects of a Vasper™ workout on healthy adults. The use of the Vasper™ machine in current clinical settings is similar to blood flow restriction (BFR) exercise in safety profile and in benefits. The Vasper™ machine delivers blood flow restriction through the use of cool water pressure and delivers a 20-min high intensity interval training (HIIT) program. The study outcome measure, safety, is established by successful subject completion of the program with no associated adverse events in measured parameters. The tested null hypothesis is that there is no adverse response in measured parameters associated with increasing cuff pressure (40 to 85 mmHg) as compared to control (no pressure). We conclude that Vasper™ HIIT BFR exercise, with concomitant cooling, is safe in a cross section of the general population of regular exercises. An IRB approved trial appears to be warranted to evaluate if Vasper™ is safe and offers enhanced benefits to a cardiac rehab population in a conventional rehab program.

Key Words: High Intensity Interval Training, Vasper, Blood Flow Restriction, Exercise, Kaatsu

INTRODUCTION

Blood flow restriction (BFR) exercise targets hypertrophy efficiency by partially occluding limbs and thus, decreasing oxygen delivery and increasing concentration of metabolites in the working tissue. While conventional resistance exercise requires loads exceeding 70% of maximal strength to induce muscle hypertrophy, increasing evidence suggests that hypertrophy can be achieved using low-intensity exercise in combination with blood flow restriction (1,5,9,10,12).

Blood flow restriction has been studied in comparison to conventional exercise methods. Takarada and colleagues (12) studied a 16-wk program of low-intensity resistance training with BFR and found it significantly improved muscle mass and voluntary strength in comparison to both a high-intensity training program (80% 1RM) without BFR and an identical low-intensity training program without BFR (12). Madarame et al. (8) studied BFR exercise in a 10-wk training program and similarly found that cross-sectional area and isometric torque significantly increased in comparison to baseline and to the non-BFR control group. Another 7-wk exercise program studied by Luebbers et al. (7) again supported significant increases of muscle strength (1RM squat performance) compared to control exercisers. Furthermore, Wilson et al. (14) demonstrated that during a single blood-flow restriction workout (30-15-15-15, 30% 1RM), the BFR group had significantly greater muscle activation and muscle thickness without increasing indices of muscle damage.

This study does not evaluate the use of simple blood flow restriction, however, the use of the Vasper™ machine in current clinical settings is similar, both in safety profile and in benefits of the use of BFR. The Vasper™ machine delivers blood flow restriction through the use of cool water pressure and also includes a cooling mat for use during the 20-min high intensity interval training program. The Vasper™ machine is a new exercise technology that has already been used to improve efficiency and effectiveness of sports medicine training programs for both competitive athletes and individuals with impairments (2,13). Additional research is required to establish the effectiveness and safety of the new technology for rehabilitation as well as fitness, and to determine how to optimally deliver these services to a target population.

METHODS

Materials

The Vasper™ cooling and compression unit in this study is combined with the NuStep™ T5XR recumbent cross trainer. Liquid-cooled compression cuffs are applied to the upper thighs with adjustable pressures that were pre-determined for this study. Feet are placed on cool pedals and the subjects wear a liquid-cooled vest during the workout. Vasper™ provides a high-intensity workout through a computer tablet that directs the subjects to warm up at a jogging pace and, then alternate between sprints of maximal effort and interval periods of walking pace.

Subjects

Twenty subjects participated in this study. *Inclusion criteria:* subjects may be either gender, must be of age greater than 16 yrs, and of the mental capacity to consent. *Exclusion criteria:* subjects that have physical limitations, which prevent the use of exercise equipment, lack mental capacity to consent, and/or are unable to complete the study protocol. Recruitment

and selection of subjects is equitable within the confines of the study. Researchers did not exclude subjects on the basis of gender, race, national origin, religion, creed, education, or socioeconomic status. All eligible subjects were staff or members of the Wise Regional Medical Fitness Center. A diverse study population was sought – gender, age, and exercise capacity was varied. The age range was16 to 78 with 12 female and 8 male subjects, and the racial demographics included 1 philipino and 19 caucasian participants. The subjects' exercise capacity ranged from non-exerciser to professional athlete. Subjects did not alter their exercise routines (or lack thereof) during the course of the study.

Procedures

The study outcome measure, safety, was established by successful subject completion of the program with no associated adverse events in measured parameters. The tested null hypothesis is that there is no adverse response in measured parameters associated with increasing cuff pressure. The study design consists of the Vasper™ 20-min exercise program on the NuStep^{TM} T5XR recumbent cross trainer and 10-min supine cooling bed with leg elevation twice weekly for seven sessions. The initial session was performed without pressure cuffs. Then, each subsequent session increased the pressure setting for the cuffs to 40 mmHg, 50 mmHg, 60 mmHg, 70 mmHg, 80 mmHg, and 85 mmHg. Subjects selected an interval exercise program from the Vasper™ tablet to match their fitness level and stayed with the same program for all sessions.

The subjects were evaluated for resting heart rate and blood pressure before the session started while sitting on the NuStep^{TM} recumbent cross trainer. During the intervention, maximum heart rate (HR_{MAX}) was recorded through continuous recording with polar monitors and exercise blood pressure (EXBP) was taken halfway through the protocol. At the end of the session while still sitting on the NuStep^{TM}, the subjects rated their perceived exertion on the Borg RPE scale, a linear scale of rating from 6 to 20 that is a valid indication of physical exertion and correlates linearly with heart rate, oxygen consumption, and lactate levels. At the same time, the subjects rated their perceived thigh burn on a 0 to 10 scale (0 being no burn at all and 10 being so severe they could not continue). Before leaving the NuStep^{TM}, immediate post-exercise blood pressure (IPBP) was also taken. While the subjects were completing their 10-min rest while lying supine on the cooling bed with legs elevated, cooling heart rate (HR_C) and cooling blood pressure (CBP) were taken.

Statistical Analyses

The dependent variable in our analysis was the cuff pressure, set to pre-determined levels (0 mmHg, 40 mmHg, 50 mmHg, 60 mmHg, 70 mmHg, 80 mmHg, and 85 mmHg). To test for differences in average heart rate and blood pressure across the seven cuff pressures, we used multiple analysis of variance (MANOVA) at a p-value of 0.05 and repeated measures analysis of variance (ANOVA) with a p-value of 0.05, respectively. We also used contrasts to determine if there was a difference in heart rate or blood pressure at the baseline cuff pressure to those of the other cuff pressures.

RESULTS

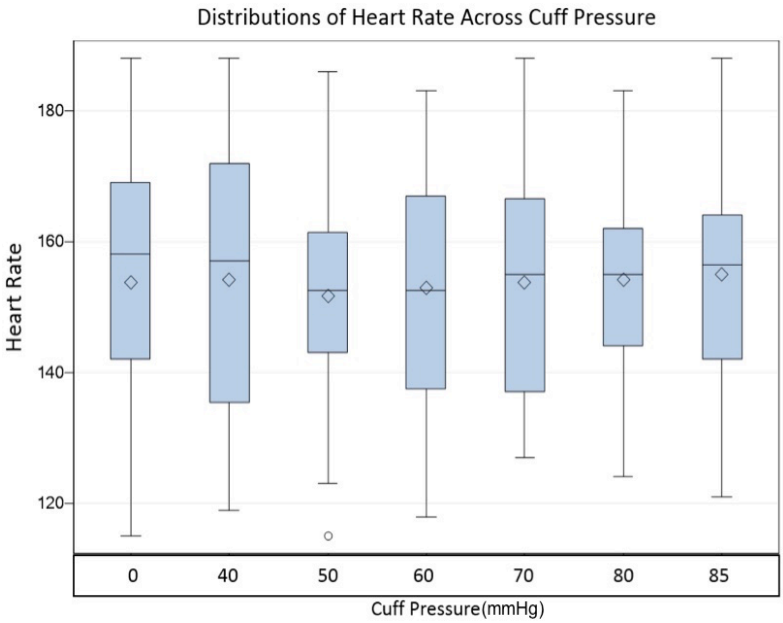
First, the maximum exercise heart rate (HR_{MAX}) was compared across cuff pressures. Using the Kolmogorov-Smirnoff test for normality, all p-values were greater than 0.05, indicating the normality assumption for repeated measures ANOVA was met.

Mauchley's test for spericity yielded a p-value <0.0001, which indicated the sphericity assumption was not met. For this reason, we could not use repeated measures ANOVA, and we proceeded with MANOVA. The p-value for the MANOVA using Wilks' Lambda was 0.8068, which indicated that average heart rate did not vary significantly across the different cuff pressures (Table 1 and Figure 1, Maximum Heart Rate).

Table 1. Maximum Heart Rate

Cuff Pressure	Heart Rate (Mean±SD)
0 mmHg	153.8 ± 21.8 BPM
40 mmHg	154.2 ± 20.9 BPM
50 mmHg	151.7 ± 17.6 BPM
60 mmHg	152.95 ± 19.4 BPM
70 mmHg	153.8 ± 18.8 BPM
80 mmHg	154.3 ± 15.9 BPM
85 mmHg	155.0 ± 16.7 BPM

Figure 1. Maximum Heart Rate



The exercise blood pressure was also compared across cuff pressures. Using the Kolmogorov-Smirnoff test for normality, all p-values were greater than 0.05, indicating the normality assumption for repeated measures ANOVA was met. Mauchley's test for spericity yielded a p-value of 0.1488, which indicated the sphericity assumption was met. The p-value for the repeated measures ANOVA was 0.0015, which was less than 0.05. This indicated that the average exercise blood pressure was significantly different across the seven cuff pressures. Further, using contrasts, we determined that the average exercise blood pressure at baseline (cuff pressure = 0 mmHg) was significantly different than at cuff pressures 60 mmHg, 70 mmHg, 80 mmHg, and 85 mmHg (Figures 2 and 3 Exercise Systolic and Diastolic BP, Table 2 Exercise Blood Pressure).

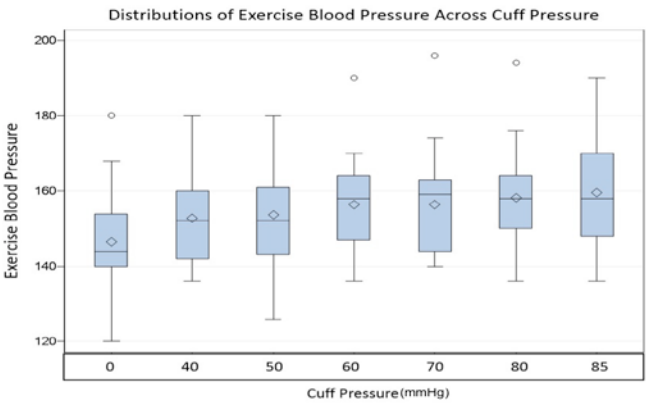


Figure 2. Exercise Systolic BP

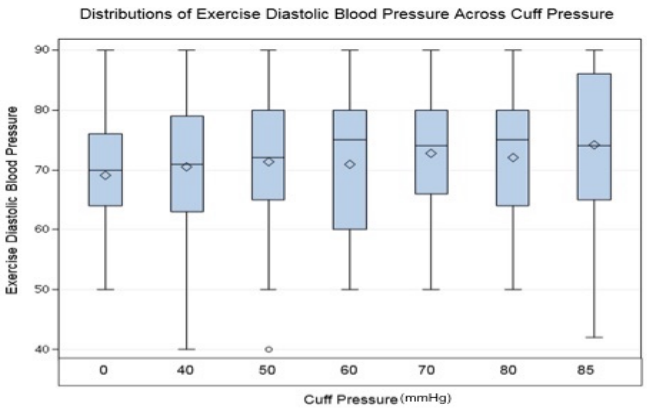


Figure 3. Exercise Diastolic BP

Table 2. Exercise Blood Pressure

Cuff Pressure	Systolic Blood Pressure Mean ± SD	Diastolic Blood Pressure Mean ± SD
0 mmHg	146 ± 14.6 mmHg	69.16 ± 9.12 mmHg
40 mmHg	152.8 ± 12.6 mmHg	70.50 ± 13.34 mmHg
50 mmHg	153.6 ± 16.0 mmHg	71.40 ± 12.19 mmHg
60 mmHg	156.4 ± 12.2 mmHg	71.00 ± 11.99 mmHg
70 mmHg	156.5 ± 13.8 mmHg	72.80 ± 10.02 mmHg
80 mmHg	158.1 ± 13.8 mmHg	72.00 ± 11.19 mmHg
85 mmHg	159.5 ± 15.0 mmHg	74.20 ± 12.80 mmHg

DISCUSSION

Blood flow restriction (BFR) has been studied for many years. Kaatsu has been the primary form of BFR reported. Kaatsu consists of constriction bands applied to the thighs and/or arms. The compression pressures are typically reported to be from 160 mmHg to 230 mmHg. The level of exercise that is performed is low intensity and many times at a walking pace or at 20 to 30% of maximal exertion. Hemodynamic studies looking at heart rate and blood pressure responses to BFR exercise are few. Available data suggests that in response to BFR exercise there is an increase in pulmonary ventilation and a decrease in end tidal CO_2. Heart rates are reported to be blunted in some BFR exercise reports and increased in others (1). Blood pressure was increased in a study that pneumatically compressed the legs at 50 mmHg coupled with maximal supine exercise (3).

The intent of the present study was to look at the safety of Vasper™ in a cross section of a normal exercising population at a community gym. The subjects volunteered to perform Vasper™ sessions with escalating cuff pressures so that their heart rate and blood pressure responses could be determined and, then, extrapolated to see if Vasper™ might be useful in an IRB study of cardiac rehabilitation patients. What was found is that the subjects' heart rate response did not elevate with increasing cuff pressures from a control of zero through escalating pressures between 40 mmHg and 85 mmHg. However, the subjects' mean arterial blood pressure did increase. Even at 40 mmHg there was a statistically significant rise in MAP over the control of 0 mmHg and MAP continued to rise as compression rose to 85 mmHg. However, none of the MAPs were at a level that presented risk to the subject. This is the first study to document the heart rate and blood pressure responses to Vasper™ at

various levels of compression. This study is the first to demonstrate that these responses are maintained within a safe physiologic range.

CONCLUSIONS

We conclude that Vasper^{TM} HIIT BFR exercise with concomitant cooling is safe in a cross section of the general population of regular exercises. An IRB approved trial appears to be warranted to evaluate if Vasper^{TM} is safe and offers enhanced benefits to a cardiac rehab population over conventional rehab. Cardiac rehabilitation clients often are elderly and weakened. Using BFR has been shown to enhance strength and muscle gains (11). It remains to be seen if these enhanced benefits will occur in a cardiac rehab population.

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