Clinical Research Proposal

By Ari Pollack

Protocol Title: Correlates of physical performance in healthy subjects

Research/Protocol Objective

The aim of the study is to compare the effect of experimental mental stress conditions on sympathovagal balance (assessed as the ratio of low-frequency power to high-frequency power in a frequency domain analysis of resting heart rate variability) in healthy subjects with and without a stress-related decrease in physical performance (assessed as the percentage of baskets during a standardized basketball free throw shooting task under higher vs. lower stress conditions).

Hypothesis to be tested: Subjects with a decrease in performance (lower percentage of baskets during a standardized basketball free throw shooting task under higher vs. lower stress conditions) will have increased sympathovagal balance (decreased HRV or increased ratio of low-frequency power to high-frequency power) than non-chokers at rest, and in response to mental stress conditions compared with that of subjects with no decrease in performance under higher vs. lower stress conditions.

Study Purpose and Rationale

Basketball player Nick Anderson, a 70% free-throw shooter, shockingly missed four consecutive free-throws during the final 10 seconds of Game 1 of the 1995 NBA Finals, costing his team a seemingly secured victory. At the 1999 British Open, golfer Jean Van de Velde, whose lead was so commanding that his name had already begun to be engraved on the trophy, infamously triple-bogeyed the final hole and ultimately lost the tournament. These unthinkable collapses are just a few of many memorable instances in which athletes demonstrate a marked deviation from their expected level of physical performance (or in colloquial terms "choked") under the pressure of competition. These events lead us to question why certain individuals choke under the intense pressure of competition whereas others conquer the psychological stress and come up "clutch?" Moreover, does a quantitative measure exist to evaluate and identify those individuals more susceptible to choking?

To date, the phenomenon of "choking" has primarily been studied through a behavioral/cognitive lens. Baumeister, a pioneer of research on "choking", defined pressure as "any factor or combination of factors that increases the importance of performing well on a particular occasion" and "choking" as "performance decrements under pressure circumstances."[1] He and numerous researchers endorse a self-focus model for choking that proposes that performance under pressure heightens anxiety and increases self-consciousness, which in turn causes an individual to try to consciously control sensorimotor skills previously automated/well-learned with practice (i.e. free-throw shooting, putting).[1-9] This conscious reinvestment inhibits the fluency of the automated skill and leads to choking. Other researchers support a distraction model for choking that suggests that performance pressure raises anxiety and distracts individuals from the task at hand, and in doing so, diverts their attention to task-irrelevant cues such as the stakes of the situation.[10-15] This shift in focus predisposes to choking.

Additionally, several studies on the intrinsic characteristics that make certain individuals susceptible to choking have shown that both a high "trait" anxiety and self-consciousness correlate with poor performance under pressure.[4, 15-23]

Despite these advances in the theoretical conceptualization of choking, little has been studied with respect to the psychophysiological correlates of choking, or more specifically, the neurocardiac difference, if any, between chokers and non-chokers. Heart rate variability is the beat-to-beat fluctuation of the heart period (inter-beat or RR interval) and serves as a neurocardiac index of the sympathovagal control of heart rate.

Spectral (i.e. frequency domain) analysis of heart rate variability decomposes the RR interval data into 2 distinct frequency bands. The ratio of low frequency power (.04-.14 Hz, mediated by interplay of sympathetic and parasympathetic signaling at the sino-atrial node) and high-frequency power (0.15-0.40 Hz, mediated predominantly by parasympathetic signaling at the sino-atrial node linked to the respiratory cycle, provide an index of the sympathovagal balance of autonomic control of heart rate.[24-29] This non-invasive measure of neurocardiac control has been shown to be sensitive to acute changes in physical and mental stress, and has been linked to clinical outcomes in cardiac disease populations.[24-39] Given these findings and the fact that performance pressure is proposed to be a variant form of mental stress, we hypothesize that chokers will have increased sympathovagal balance than non-chokers at rest, and in response to high stress free throw shooting and mental arithmetic tasks. If so, the neurocardiac effects of a simple mental stress exercise may serve as a potential tool for scouting and identifying "clutch" athletes off of the playing field.

<u>Study Design and Statistical Procedures</u>

The current proposal will prospectively measure heart rate variability in healthy subjects who currently play competitive basketball during low and high pressure free-throw shooting conditions and during a period of mental stress induced by performing mental arithmetic. Subjects will be categorized as chokers and non-chokers based on their free-throw shooting performance. Baumeister's definition of choking (performance decrements under high stress conditions) allows room for interpretation; that is, the level of performance decrement, or threshold for choking, is subjective. Theoretically, we therefore could define choking as any performance decrement in free-throw shooting percentage when high stress performance is compared with low stress performance. In this study, it will be defined as making 2 less free throws in the high pressure situation.

Participation in the study will require two separate study visit. The first visit will include screening procedures and the field experiments of free throw shooting as described below (2-4 hours). The second visit will include the mental arithmetic stress test procedures as described below (1-2 hours).

Use of deception in study protocol. Since the primary objective of the study is to compare the effects of lower vs. higher stress conditions on physical performance and neurocardiac control, the study subjects cannot be aware of the purpose of the experimental conditions creating higher stress during the conduct of the study. Subjects will be told that the two series of free throw shooting tasks are to determine the reproducibility of task performance and heart rate in non-professional athletes. The rationale presented for the mental stress task will be to determine if there is any association between concentration required for math skills performance compared with that required free throw shooting performance. The changes in environment during free throw shooting to create the higher stress condition (described below) will be explained as a chance event. After all of the subjects have completed participation in the study, we will contact each subject and debrief them to reveal the full details of the study purpose and design.

Heart rate variability. Heart rate variability will be measured during free throw shooting non-invasively with a Polar® RS800CX heart monitor. During mental stress testing, heart rate variability will be measured with both the Polar monitor and traditional electrocardiogram leads during the mental arithmetic stress test. Previous studies have demonstrated excellent concordance of RR interval data derived from the Polar monitor and traditional electrocardiogram leads. The first and last 60 seconds of recorded data will be discarded prior to analysis. The raw RR interval data will next be tabulated and filtered to exclude atrial and ventricular premature contractions. These data will then undergo time domain analysis and Fast Fourier Transform spectral, or frequency domain, analysis using customized software. All of the heart rate variability data will be analyzed by study personnel blinded to the performance categorization of the study subject (choker vs. non-choker).

Basketball free-throw shooting. Free throw shooting is a complex sensorimotor skill that is automated or "overlearned" with practice, and therefore, is a potentially pressure-sensitive skill for experienced basketball players.[40] Each subject will use the same NCAA regulation size and weight leather basketball for the free throw shooting task. The subject will be asked to shoot 20 free throws within 10 minutes with a 1 minute break after the first 10 free throws. The percentage of successful free throws will be recorded as the measure of performance. We will use previously described experimental conditions to create lower vs. higher stress conditions for the two free-throw shooting tasks as described below.[4, 5] Typed instructions will be read to each individual before each free throw shooting task.

Mental arithmetic exercise. Mental arithmetic (serial 7 subtractions) is an established form of mental stress testing.[34-39] Subjects will do serial subtractions of random 4-digit numbers that will be announced at 1-minute intervals. Blood pressure will be measured with the cuff method in the seated position before and immediately after the mental stress test.

The primary endpoints for the study are the mean rest as well as the mean change in sympathovagal balance (ratio of low to high frequency power derived from analysis of heart rate variability) from rest conditions to experimental mental stress conditions in the two groups. Free-throw shooting performance will be measured as the proportion of successful baskets. Subjects with a negative differential score (greater than 2) will be classified as chokers while those with a non-negative differential score will be classified as non-chokers. Subsequent analyses will compare the primary endpoint and secondary endpoints (time-domain measures of heart rate variability, mean heart rate, blood pressure) between groups. Additionally, correlational analysis will be used to examine the relationships between the variables being compared.

Sample size estimation. In a previous study on the effects of stress on free throw shooting performance, 50% of the subjects were classified as "chokers" with decreased free throw shooting performance under the higher mental stress conditions.[4] Based on prior data from a cohort of young athletic subjects, we anticipate that the ratio of low frequency to high frequency power at rest will be 1.64±0.62 (mean±SD).[44] In response to mental stress, we anticipate that chokers will demonstrate an increase in the ratio of low frequency to high frequency power whereas non-chokers will demonstrate less increase or possibly a decrease in the ratio of low frequency to high frequency power. A difference between groups of 0.8 would be considered a physiological important difference between groups.[45] An unpaired t-test will be used to compare the specific variables between the two groups. In order to achieve a power of 80% with a p-value of 0.05, a minimum of n= 10 is needed in each group to detect such differences. However, to account for drop-out rates and the possibility of uneven distribution will possibly occur in the cohorts, we will recruit 40 individuals.

Study Procedure

Visit 1: Subjects will be invited in groups of 5, since part of the high pressure free throw shooting task described below requires that free throw shooter be observed by other study subjects. Inclusion/exclusion criteria (described below under "Human Subjects") will be reviewed for each subject in a private setting to determine eligibility. Screening procedures will include a brief medical history, history of basketball activities, and recording vital signs (resting pulse and blood pressure) and will be conducted in a private setting.

After completion of consent and screening procedures in a private setting (room with a closed door), the following study procedures will be performed in an open gymnasium setting. For the low pressure free throw shooting task, the instructions will indicate that their shooting performance will be recorded by study personnel, but that the results will be not be counted in the final study analysis. Data will be collected on a clipboard by study personnel out of the line of sight of the subject. Only one subject at a time will be permitted in the gymnasium area. We note that some pressure may exist during this condition since the free throw shooting task is carried out in front of the research team, but it will be low relative to the high pressure condition. Before the start of the free throw shooting task, subjects will be fitted with a Polar heart monitor. After a 5-shot warm-up, subjects will shoot 25 free-throws with a 1 minute break at the halfway point. Afterwards, they will be given their score and a time to return for the high pressure testing condition (approximately 1-2 hours later that day). In order to limit tje study to subjects with a reasonably high skill level, subjects who are successful in <50% of their free throws during the low pressure condition will be excluded from further study. These excluded subjects will be paid $15 for their participation and will be debriefed after all study enrollment is completed. We will tell subjects that a minimum proficiency of 50% successful free throw shooting is required to continue in the study, since the ability to accurately assess reproducibility in free throw shooting is not reliable when the initial performance is <50%.

After returning to the gymnasium, returning subjects will be read instructions for the high stress condition as a group. They will again be fitted with a heart monitor and receive a 5-shot warm-up prior to shooting 25 free-throws with a 1 minute break at the halfway point. Increased stress conditions will consist of a non-interactive audience (each subject will shoot in front the other subjects participating that day), continuous simulated video recording for analysis by an investigator posing as a shooting coach (no tape in camera), a large visible scoreboard in the line of sight of the subject (rather than recording on a clipboard by study personnel), and a small financial incentive (an extra $15 to the individual in the group with the highest score). Additionally, with regard to those with worse performances, $1 will be taken for each free throw missed when compared to the low-pressure situation i.e. $5 for making 5 less free throws in the 2nd session (max $5). This type of "ego-threatening" scheme has successfully been used to create performance pressure and induce choking in previous studies.[2-5, 15, 16, 42, 43] After completion of the free throw shooting task under these conditions, subjects will be given an appointment for the second study visit (mental arithmetic exercise). Subjects will be paid half of their monetary reimbursement ($10-$15) at this time. The subject with the highest free throw shooting performance will receive an additional $15. They will be given the remainder at the conclusion of their participation in the study.

Visit 2 Mental Arithmetic Task (1-2 hours): Subjects will complete the mental arithmetic exercise within 2-14 days of the free-throw shooting task. Their seated blood pressure and heart rate will be recorded and they will be fitted with a Polar and electrocardiographic lead heart rate recording devices. Subjects will then be placed in a quiet, dimly lit room and encouraged to relax. HRV will be recorded during for 8-minute at seated rest position, during, and for 8 minutes after completion of the mental arithmetic stress test. Subjects will receive the remainder of the monetary reimbursement ($15) after completion of these study procedures.

After completion of all study procedures in all subjects, telephone calls will be made to each participant to debrief them regarding the deception used in the study protocol. The full details of the study procedures and study rationale will be explained and any questions will be answered.

<u>Study Drugs or Devices</u>

Polar Heart Monitor described above

<u>Study Subjects/Inclusion/Exclusion Criteria</u>

Inclusion criteria:

1. Males ≥ 18 years-old
2. Currently playing competitive basketball
3. Normal rest heart rate (between 60-100 bpm inclusive) and blood pressure (systolic 90-140 mmHg inclusive and diastolic 60-90 mmHg inclusive)

Exclusion criteria:

1. Known history of hypertension or any other chronic illness requiring medications or other forms of chronic treatment.
2. Active infection or allergies

3. Chronic medication use
4. Current smokers (< 6 months)
5. Any other condition that in the opinion of the investigators would alter the safety of participation, or interfere with the ability to adhere to study procedures.

Recruitment

Recruitment will be performed in accordance with the policies of CUMC. Recruitment will not be based ethnicity or socioeconomic background. Since this is a pilot study with and there are known gender differences in neurocardiac control, we are choosing to enroll only male subjects in order to decrease variance in the baseline heart rate variability. We intend to use these pilot study findings to obtain financial support for future studies on the physiological correlates of choking in both men and women. Subjects will be ≥ 18 years-old and must currently play competitive basketball ranging from intramural or local basketball leagues to the National Collegiate Athletic Association level. This inclusion criterion will ensure that free-throw shooting is an "overlearned" skill for the subject population. A reasonably high and consistent skill-level will be achieved by excluding subjects who make less than 50% of their free-throws during the low pressure testing condition. Subjects will not be aware of this exclusion criterion so as to maintain a low pressure environment.

Confidentiality of Study Data

Every effort will be made to protect the confidentiality of patient records, although patients will be informed that absolute confidentiality cannot be guaranteed. By signing the informed consent documents, the patients grant their permission for their information to be made available to the following:
-The investigator, research staff and other health professionals (if applicable) who may be evaluating the study
-Authorized representatives of the U.S. Food and Drug Administration, Office of Human Research Protection or other government regulatory agencies
-The Columbia University Medical Center Institutional Review Board

All reports and communications relating to study subjects will identify the subject only by his/her initials and case number. The investigator will complete subject identification on a confidential site log, which will be used for the purposes of traceability and follow-up. This will be treated with strict adherence to professional standards of confidentiality, and will be filed under adequate security and restricted accessibility.

Potential Conflict of Interest

n/a

Location of the Study

The free-throw portion of the study will be conducted at the downtown Columbia University Gymnasium as well as the screening process. The arithmetic portion will be conducted at the CRC, 10th Floor PH building.

Potential Risks

There are no known risks associated with the measurement of heart rate variability (i.e. EKG monitoring). EKG leads can irritate the skin in some individuals. Tightly inflating the blood pressure cuff in order to record blood pressure may be associated with local arm discomfort that is quickly relieved by deflating the cuff. Rarely, this can lead to bruising of the arm, with the risk of bruising being higher if the subject is taking aspirin or other blood-thinning medication. Free-throw shooting and the mental arithmetic exercise do not pose any anticipated physical risks, though transient psychological strain may be experienced during these tasks. Additionally, we recognize that not fully disclosing the details/purpose of the study until the very end may cause subjects to feel deceived and/or upset.

Potential Benefits

No direct benefit will be derived amongst participants in the study aside from monetary compensation. However, this data perhaps will yield an important physiologic correlate in terms of deciphering the ability of given individual to perform well in a high-pressure situation

Alternatives

The alternatives include not participating in the study.

Compensation for participation

Subjects will receive compensation according to the following criteria:

1. Subjects will receive $15 if they meet enrollment criteria and complete the first free throw shooting session.
2. Subjects will receive $15 if they complete the highest percentage of free throws in the second free throw shooting session. They can also loose up to $5 for a decrease in performance.
3. Subjects will receive $15 after completion of the mental arithmetic task session.

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