Baylor Hamilton Heart and Vascular Hospital

(Cardiovascular Rehabilitation Department**)**

Use of the PRIMUS to Assess Strength Outcomes in a Cardiac Rehabilitation Setting

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1.0 OBJECTIVE

In a prospective study involving 130 cardiac rehabilitation patients muscular strength will be measured with a force dynamometer (PRIMUS) on six commonly performed activities. During the first session of cardiac rehabilitation, each subject's date of birth, height, and weight will be recorded. To ensure safety, cardiovascular nurse specialists and exercise physiologists will monitor the patients for hypertension (blood pressure >240/110 mm Hg), arrhythmias, angina, dizziness, pain, shortness of breath, and perceived exertion. The subjects will be asked to complete a pre-activity confidence survey. On the second day of cardiac rehabilitation, a clinical exercise specialist will the PRIMUS equipment to obtain force measurements on the six activities including: rising from a bed, rising from a chair, opening a door, lifting an object from the floor and/or placing an object overhead. Following the performance of the activities, the patients will be asked to complete a post-activity confidence survey.

1.1 HYPOTHESIS

The purpose of this study is to determine if performed force measurements yield a different recommended weight lifted during the sternotomy healing process than the traditional gold standard of 5 pounds. A secondary endpoint data obtained will be scores from the pre and post-activity questionnaires.

1.2 STATISTICAL METHODOLOGY

Continuous variables will be reported as means and standard deviations or medians and interquartile ranges, if skewed. Categorical variables will be reported as frequencies and per cents. To do so, patients will use the PRIMUS equipment to obtain the maximum force pounds performed during six activities. Then, their new recommended weight to lift will be 30% and 50% of that maximum. We will use a one sample t-test to determine if a difference exists between the gold standard recommendation and the force performed in the activities.

With a sample size of 130 subjects, we will have in excess of 90% power to detect a difference of 5 pounds from the gold standard recommendation, assuming a standard deviation of 5 and a type I error rate of 0.05 in a two-tailed test. With this sample size, the data will likely be normally distributed, which is a necessary assumption to perform the one sample t-test. However, if the data do not meet this assumption, we will proceed using a nonparametric alternative, the Wilcoxon Rank Sum Test.

Additionally, to examine the change in confidence after from performing the 6 activities, 2 surveys will be administered: 1 prior to treatment and 1 after treatment. In the survey, subjects will be asked to rate their confidence using a 7-point Likert scale to perform selected daily tasks. Subjects' perceptions of confidence will be reported and analyzed in several ways. We will consider the changes from each of the 7 categories, the change in

percent of 'top box' responses, and the changes in stratified responses (positive, neutral, negative).

2.0 BACKGROUND

Coronary artery bypass grafting (CABG) and other procedures (VALVE) involving median sternotomy carry the risk of sternal wound complications that can lead to increased morbidity, reduced quality of life, prolonged or repeated hospitalization, increased health care costs, and, for serious cases, mortality rates of 15% to 40%. Because the consequences of sternal complications can be grave, sternotomy patients require educational guidance before being discharged from the hospital.

Authors of the first discharge education materials focused on restricting the loads patients could lift for specific time periods that were considered appropriate for sternal healing. The resulting sternal precautions likely stemmed from expert opinion or were based on anecdotal rather than direct evidence and, consequently, vary widely among hospitals and rehabilitation centers around the world. In general, sternal precautions are very restrictive and are applied broadly instead of being tailored to the patient. A common example from the USA is to avoid lifting more than 5 pounds.

Sternal precautions are intended to help protect patients after median sternotomy, but instead, they may inadvertently impede recovery. A restriction such as "don't lift more than 5 pounds" can reinforce fear of activity, leading to the substantial muscle atrophy that occurs during short-term disuse. Worldwide, median sternotomies are performed during an estimated 800,000 CABG procedures and an indeterminate number of valve surgeries each year, so the potential scope of problems arising from the ongoing use of restrictive sternal precautions is sobering.

Many patients are referred to cardiac rehabilitation programs following sternotomy. Cardiac rehabilitation is a program of supervised exercise and risk factor education prescribed by the patient's physician. Traditionally, the exercise prescription comprises aerobic activities such as walking and cycling, which utilize large muscle groups in rhythmic contractions and improve exercise tolerance and functional capacity. However, according to common goals that patients claim, they are more interested in being able to return to activities of daily living such as the following: rising from a bed, rising from a chair, opening a door, lifting objects from the floor and/or placing objects overhead. These movements are reflected in a new philosophy (Keep Your Move in the Tube™) for replacement of traditional sternal precautions. The Baylor Institute for Rehabilitation and the post-sternotomy surgical unit on 13 Roberts have adopted and currently using the Keep Your Move in the Tube philosophy.

Use of the PRIMUS will enable us to document the force pounds that patients can actually lift. If this information was available to cardiac rehabilitation clinicians, specific exercise prescriptions could be made to help patients reach their goals and gain confidence after a cardiac event.

3.0 PATIENT SELECTION

3.1 Patient Inclusion Criteria

All participants who are referred to Cardiac Rehabilitation with a qualifying diagnosis: CABG or VALVE. A total of 130 male and female volunteers who are 18 to 80 years of age will be asked to participate in the study. Subjects may be of any ethnic background and socio-economic status.

3.2 Patient Exclusion Criteria

Refusal to participate
Sternal dehiscence
Permanent pacemaker
Permanent defibrillator
Unstable angina
History of heart transplant
History of hernia
History of aneurysm
Physical disability that limits resistance training
Uncontrolled hypertension (systolic 160 mmHg or diastolic > 100 mmHg)
Symptomatic dysrhythmias
History of aortic dissection

3.3 Inclusion of Women and Minorities

Women
Minorities

4.0 STUDY PLAN

On day 1 (evaluation day), patients will report to the cardiovascular rehabilitation department. Patients will complete a medical history form and medications will be documented. The patient's case manager will review these documents with the patient, describe the cardiac rehabilitation program to the patients, and assess the patient's resting heart rate, blood pressure, height, and weight. During this evaluation session, the study will be presented to patients who meet the inclusion criteria. The nurse will conclude this session by assessing the patient for signs of edema, incision infection, and any other heart or lung problems.

On day 2 (testing day), to ensure safety, nurses and exercise physiologists will monitor the patients for hypertension, arrhythmias, angina, dizziness, pain, shortness of breath, and perceived exertion. Patients will be asked to review and sign the informed consent and a confidence survey. Thereafter, through use of a stethoscope placed above the sternum and clavicle, a cardiovascular nurse specialist will listen and document any findings of sternal clicking, moving, or grating as subject performs a repetitive chest fly routine. The PRIMUS force dynamometer will then be used to obtain one repetition maximum (1RM) strength measurements during the activities including: placing an object overhead, picking up object up from the ground, and opening a door. Once a one 1RM has been determined, the patient will then perform 5-20 repetitions at 30% and 50% 1RM of the same three exercises. Then, dynamic movements that mimic rising from a bed and rising from a chair will be performed three times by pushing against the PRIMUS force dynamometer. A post session confidence survey will be filled out by the subject. Following completion of the activities, the cardiovascular nurse specialist will listen to the sternum for changes in clicking, moving or grating. Final measurements will be assessed, including a recovery lead II ECG, heart rate, and blood pressure.

5.0 EXPECTED ADVERSE EVENTS

Potential Physical Risks:

Potential risks include: high blood pressure, sternal dehiscence, fast breathing, fatigue, muscle soreness, chest pain, heart palpitations, myocardial irritability, syncope, chest discomfort and MI.

Potential Psychological Risks:

Subjects may feel pressure to perform well for the investigators and peers. Patients might feel anxious about performing the specific exercise protocol.

Potential Social Risks:

Subjects may feel self-conscious if unable to perform the specific exercise protocol appropriately.

Potential Economic Risks:

None are expected.

Potential Legal Risks:

There could be the threat of lawsuit if subject experiences harm during participation in the specific exercise protocol.

6.0 POTENTIAL BENEFITS

Potential direct benefits to research subjects:

The subjects may experience mental and social fulfillment as a result of participation in this study.

Potential future benefits to individuals with the condition being studied:

Professionals rehabilitating cardiac patients will have valuable data that might be used to help heart patients safely and confidently return to work and activities of daily living.

Potential benefits to society in general:

Patients who have a heart event may be able enjoy their livelihood by returning to work and performing their leisure activities.

Potential benefits to others involved in the research:

There might be a developed appreciation of the confidence and strength necessary for safe return to work and participation in leisure activities.

Provisions in place to protect confidentiality of research related information:

Only designated research staff will perform the data collection and analysis process.

Provisions in place to protect the privacy of the research subjects:

Additional provisions specific to your department Patient information will be secured in research office.

Provisions in place to protect the PHI collected during the study:
No patient identifiers will be used during statistical evaluation and/or preparation of manuscript for publication.

Risk/benefit ratio:

Well known benefits of cardiac rehabilitation include improved strength and confidence anxiety. When considering the benefits of participation in the specific activity protocol resistance training activity, the risks identified above seem justified. Investigators will also be exceedingly careful and will also explain in detail the appropriate method for lifting during the specific activity movements. For those who increase their strength earlier in the rehabilitation process, they may gain the confidence to perform activities outside of the rehabilitation area in a safe manner. This finding would be of great importance to help our patients and we think the risks are worth these potential benefits.

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