STUDY DOCUMENT COVER PAGE

Official Title

Effects of Myofascial Release on Cardiac Patients after Median Sternotomy

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Informed Consent Form (ICF) with Statistical Analysis Plan

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Study Title

Effects of Myofascial Release on Cardiac Patients after Median Sternotomy

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Introduction

You are invited to participate in a clinical research study. This consent form explains the purpose, procedures, risks, and benefits of the study. Participation is voluntary, and you may withdraw at any time without affecting your medical care.

Purpose of the Study

This single-center clinical trial conducted in Taiwan aims to evaluate the effects of myofascial release (MFR) on respiratory muscle strength, pulmonary function, chest wall mobility, electromyographic activity of the diaphragm and sternocleidomastoid muscles, and postoperative chest pain in patients after median sternotomy.

Background

Median sternotomy may impair respiratory function after surgery. Previous studies have shown that exercise training may improve functional capacity. However, evidence regarding the effects of myofascial release remains limited. This study aims to investigate whether myofascial release provides additional benefits for postoperative cardiac patients.

Eligibility Criteria

Inclusion criteria:
• Age ≥18 years
• Able to communicate verbally
• Diagnosed with coronary artery, valvular, or aortic disease
• Underwent median sternotomy
• Able to sign informed consent

Exclusion criteria:
• Pacemaker implantation
• Ventricular assist device implantation
• Cognitive impairment
• Chronic obstructive pulmonary disease (COPD)
• Previous thoracic surgery
• ICU stay >14 days
• Central nervous system disorders (e.g., stroke, spinal cord injury, traumatic brain injury)

Study Procedures

Participants will undergo assessments at three time points: preoperative assessment (Tp), baseline assessment after transfer from ICU to ward (T0), and post-intervention assessment after seven sessions of myofascial release (T1).

Outcome measurements include:
• Maximum Inspiratory Pressure (MIP)
• Maximum Expiratory Pressure (MEP)
• Pulmonary function tests (FVC, FEV1, FEV1/FVC ratio, MVV)
• Chest wall mobility
• Surface electromyography (sEMG) of the diaphragm and sternocleidomastoid muscles
• Pain assessment using Numeric Rating Scale (NRS)

Intervention

Participants will be randomly assigned to an intervention group or control group.

The intervention group will receive standard physical therapy plus myofascial release therapy once daily for 7 sessions (approximately 15 minutes each session). Standard physical therapy includes ambulation, incentive spirometry training (Triflow), and functional training.

The control group will receive standard physical therapy only.

Statistical Analysis

Study data will be analyzed using IBM SPSS Statistics version 20.0. Statistical significance will be set at $\alpha = 0.05$. Continuous variables will be presented as mean ± standard deviation (mean ± SD), while categorical variables will be presented as frequency and percentage (n, %).

Prior to statistical analysis, data normality will be assessed using the Shapiro–Wilk test. If the data are not normally distributed, non-parametric statistical methods, including the Wilcoxon signed-rank test

and Mann–Whitney U test, will be applied as appropriate.

Descriptive statistics will summarize participants' baseline characteristics, including sex, age, body mass index (BMI), primary diagnosis, surgical procedure, postoperative days, and duration of mechanical ventilation.

Differences between the intervention group and control group across different assessment time points (Tp, T0, and T1) will be analyzed using two-way repeated measures ANOVA.

Risks and Discomforts

Possible risks include mild discomfort, fatigue, temporary skin redness or itching caused by EMG electrodes, and temporary soreness during breathing tests. Participants will be monitored throughout the study, and appropriate medical care will be provided if needed.

Benefits

Potential benefits include improved respiratory muscle strength, pulmonary function, chest wall mobility, and pain reduction. The findings may also benefit future patients undergoing cardiac surgery.

Confidentiality

All collected data will remain confidential. Participants will be identified using study codes instead of names. Data will be securely stored and used only for research purposes. Authorized personnel, ethics committees, and regulatory authorities may review study records as required by law.

Voluntary Participation and Withdrawal

Participation is voluntary. You may withdraw from the study at any time without penalty or impact on your medical care. The investigator may also discontinue your participation if necessary for safety reasons.

Compensation and Medical Care

If study-related injury occurs, Kaohsiung Veterans General Hospital will provide appropriate medical care. No additional financial compensation or insurance is provided for participation in this study.

Data Retention

Research data may be retained for up to 10 years for future research purposes after approval by the Institutional Review Board (IRB).

Participant Rights

You may ask questions at any time during the study. If significant new information becomes available that may affect your willingness to continue participation, you will be informed promptly.

Funding Source

This study is funded by an institutional research grant.

Consent Statement

I have read and understood the information provided above. I voluntarily agree to participate in this study.

Participant Name: _____

Signature: _____

Date: _____