**Project Description/Protocol**

**Title:**

Determining the Safety and Benefits of Exercising Tracheostomised Mechanically Ventilated Patients with Passy-Muir Speaking Valves

**Project Team Roles and Responsibilities:**

1. Mr Luke Churchill - Critical Care, Physiotherapy Department, Ground Floor, the Prince Charles Hospital, Chermside, QLD, 4032.

Role: Chief investigator/lead researcher for the project. Responsible for the screening of eligible patients, recruitment of patients and data collection which will include the training of other staff to collect data for the project. Also lead author for

publications created from this project.

1. Dr Allison Mandrusiak - Senior Lecturer in Physiotherapy, The University of Queensland, Therapies Building 84(A), Service Road, St Lucia, QLD, 4067.

Role: Chief mentor for research project providing guidance for the following: project design, participant recruitment, obtaining consent, data collection and editing of publications created from this project.

1. Mr Oystein Tronstad – Clinical Lead – Cardiac / Surgical / Critical Care Services, Physiotherapy Department, Ground Floor, the Prince Charles Hospital, Chermside, QLD, 4032.

Role: Co-mentor for research project providing guidance for the following: project design, participant recruitment, obtaining consent, data collection and training for research equipment modalities.

1. Dr Jennifer Paratz – Senior Research Fellow, School of Allied Health Sciences, Gold Coast campus, Griffith University, QLD, 4222.

Role: Co-mentor for research project providing guidance for the following: project design, participant recruitment, obtaining consent, data collection, statistical analysis and editing of publications created from this project.

1. Dr Peter Thomas –Team Leader – Critical Care, Physiotherapy Department, Level 2, Ned Hanlon Building, Royal Brisbane and Women's Hospital, Herston, QLD, 4006.

Role: Co-mentor for research project providing guidance for the following: project design, participant recruitment, obtaining consent, data collection and editing of publications created from this project.

1. Mr Lawrence Caruana – Senior Physiotherapist, Physiotherapy Department, Ground Floor, the Prince Charles Hospital, Chermside, QLD, 4032.

Role: Associate investigator assisting with the following: project design, participant recruitment, obtaining consent, data collection and training for research equipment modalities.

**Resources:**

Equipment required for the project will be kindly loaned by the Prince Charles Research Group.

**Background:**

*Aims:*

1. To determine the safety of exercise with tracheostomised mechanically ventilated patients with a Passy-Muir speaking valve. Safety will be examined with two devices: (i) electrical impedance tomography (EIT) to determine lung recruitment and (ii) respiratory inductance plethysmography (RIP) to investigate respiratory mechanics.
2. To determine whether lung recruitment is improved for tracheostomised mechanically ventilated patients with a Passy-Muir speaking valve vs exercising with no valve.
3. To investigate the length of time until decannulation for tracheostomised mechanically ventilated patients that exercise with or without a Passy-Muir speaking valve.
4. To investigate whether anxiety levels and quality of life are improved for tracheostomised mechanically ventilated patients with a Passy-Muir speaking valve vs exercising with no valve.

*Key Questions:*

1. Does a Passy-Muir speaking valve improve lung recruitment during and/or after exercise for tracheostomised mechanically ventilated patients compared to no speaking valve?
2. Does a Passy-Muir speaking valve improve respiratory mechanics for tracheostomised mechanically ventilated patients during exercise compared to no speaking valve?
3. Does the length of time until decannulation decrease for tracheostomised mechanically ventilated patients that exercise with a Passy-Muir speaking valve compared to no speaking valve?
4. Does anxiety decrease and quality of life increase for tracheostomised mechanically ventilated patients that exercise with a Passy-Muir speaking valve compared to no speaking valve?

*Literature Review:*

An admission to the ICU may result in prolonged immobility, deconditioning, muscle weakness and a reduced quality of life and physical function after hospital discharge. Depending on the type and severity of their condition, patients may require respiratory support in the form of mechanical ventilation (MV). Patients admitted to ICU requiring MV have higher associated mortality rates compared to those without respiratory support(1). It is estimated that MV rates in Australia and New Zealand, are as high as 53%(2). Furthermore, patients that require prolonged MV have an increased ICU length of stay (LOS), hospital LOS and higher mortality rates(3).

During a period of prolonged MV or foreseeable prolonged ventilation, intensivists will consider whether patients would benefit from a tracheostomy. A recent systematic review demonstrated that early tracheostomies resulted in decreased ventilator days, decreased ICU LOS, shorter sedation periods and reduced long-term mortality when compared to late tracheostomies(4). Other benefits of a tracheostomy during MV include: improved communication, increased oral intake and improved respiratory mechanics(5, 6).

For tracheostomised patients, benefits of utilising speaking valves (SVs) include: less accumulated secretions, decreased carbon dioxide retention, decreased respiratory rate, improved lung recruitment and greater verbal communication(5-7). Unfortunately the use of SVs has been limited due to concerns of lung derecruitment during a period of cuff deflation or conversely in some patients, hyperinflation. Fortunately recent studies have addressed these safety concerns by demonstrating that SVs did not cause derecruitment or hyperinflation of the lung, rather resulted in improved lung recruitment(5, 6, 8). It is important to note that these studies were completed with patients at rest, therefore the effect on the lungs during physiotherapy or exercise still needs to be investigated.

The benefits of early exercise for patients in ICU have been well documented including: decreased ICU LOS, hospital LOS and more ventilator-free days(9-13). This literature supports the use of early exercise, however the safety and benefits in tracheostomised patients with SVs still needs to be investigated. Thus, this study will examine the effect on the lungs during exercise within tracheostomised patients with SVs.

*Expected outcomes:*

We hypothesise that whilst exercising tracheostomised patients, SVs cause no significant derecruitment or hyperinflation of the lung. Conversely, we hypothesise that it will result in improved lung recruitment as has been demonstrated for patients at rest(5, 6, 8). We hypothesise that better lung recruitment leads to an improved ability to exercise whilst in ICU, resulting in significant decreases in ICU LOS and improved patient function on discharge from ICU. We also hypothesise that an ability to communicate during exercise for tracheostomy patients will result in decreased anxiety and an overall improvement in QOL.

**Project Design:**

*Design*

Randomised Crossover Controlled Trial

*Participants*

We will aim to recruit 20 consecutive tracheostomised patients admitted to the TPCH ICU. Participants will be invited to participate if they fit the inclusion criteria after being screened for suitability by one of the researchers.

*Consent*

Potential participants will be identified by an investigator and screened for suitability in consultation with the treating medical officer. Screening of patients will occur prior to consent. The chief investigator will approach the suitable participants to discuss the study, and a patient information and consent form will be provided. After having explained the study, the participant will then be asked whether they consent to be included in the study. They will be given the opportunity to think about this before committing, and to discuss with their family / next of kin if they wish to do this before consenting.

*Inclusion criteria*

* Adult patients admitted to ICU with a tracheostomy.
* Adult patients admitted to a hospital ward or discharged to a ward from ICU with a tracheostomy.

*Exclusion criteria*

* Age under 18
* Patients unable or unwilling to provide informed consent
* Injuries to lower limbs preventing them from being able to participate in exercise therapy
* Has rest in bed orders and/or has bilateral non-weight bearing orders for the lower limbs and/or has lower limb movement restrictions preventing them from being able to do cycle ergometry
* Cardiovascular instability as determined clinically by the treating therapist or medical staff
* Proven or suspected acute primary brain pathology (e.g. traumatic brain injury, stroke, hypoxic brain injury)
* Death is deemed imminent and inevitable

*Study plan*

Patients will be approached and informed consent gained prior to commencing the study.

Participants will be randomly allocated initially into one of two groups; exercise with a SV in-situ or exercise without a SV. The participants will serve as their own control within the study when crossover occur between groups with at least a two hour washout period to allow participants to fully recover between exercise sessions. The participants will be reviewed as per current clinical practice, and a decision will be made whether they are safe for a speaking valve. Safety for a speaking valve will be determined by the speech therapist and medical team in collaboration with a physiotherapist. This will be determined by following the Austin Health Tracheostomy Review and Management Service (TRAMS) clinical procedure guideline, whereby patients display none of the following signs:

* Respiratory distress and increased work of breathing,
* Increased or copious secretions
* Upper airway obstruction
* Difficulty passing a suction catheter

Safety for the use of the MOTOmed® Letto will be determined by the physiotherapist and medical team following the safety precautions of the manufacturer.

The exercise component will include five minutes of MOTOmed Letto cycling, starting with a resistance of zero and increasing the resistance by one level each minute. The MOTOmed® Letto is a lower limb cycle ergometer that allows the lower limbs to be trained passively, motor-assisted and actively. The patient can exercise either lying in bed or sitting in a chair. The exercise will cease at five minutes or if any serious adverse events occur.

Serious adverse events are defined as:

* Cardiopulmonary arrest,
* Sustained rapid atrial fibrillation > three minutes,
* Ventricular tachycardia or other dangerous rhythms,
* Unplanned tracheostomy removal,
* Line removal requiring urgent replacement
* Desaturation <80% for greater than three minutes.

EIT will be used throughout the exercise to measure end expiratory lung impedance (EELI) and RIP will be used to capture respiratory muscle activity.

*Data Collection*

Data that is collected during the project will be re-identifiable via a coding system. This will protect any 'health' or 'personal' data from being identified outside of the research project. Data will be collected via the following modalities: Electrical Impedance Tomography (EIT), inductance plethysmography (RIP) and Quality of Life (QoL) questionnaires.

Data will be recorded at three time points:

1. Baseline – 15 minutes prior to beginning exercise,
2. Throughout exercise period,
3. 30 minutes post exercise.

*Data Management*

Paper data collection form will be kept in a locked filing cabinet located in the physiotherapy clinical leaders staff room. Limited personnel have access to this. Electronic data will be stored in a password protected excel spreadsheet.

All records will be destroyed (permanently deleted or shredded as appropriate) after 15 years, as per ‘Good Clinical Practice’ (GCP) guidelines. The paper data collection will be placed in a confidential bin and then shredded. Electronic data will be erased and deleted.

*Data analysis*

Data will be analysed offline post data collection using commercially available Draeger software (Draeger EIT Data Analysis Tool 6.1). EELI will be averaged across the readings and displayed as mean EELI for each of the four data collection periods. To compare two groups over time periods, a generalised linear mixed model will be used for RR, EtCO2, HR and SpO2. The level of significance will be set at p <0.05 throughout, with 95 % confidence intervals quoted where appropriate. All statistical analyses will be conducted using a data program such as STATATM.

*Risk*

Previously there has been anecdotal evidence of adverse events with lower limb ergometry in the specific population of spinal cord injuries (SCI)(20). It is unlikely that this patient cohort will be encountered during this period as the Prince Charles Hospital typically doesn’t treat SCI patients. However, a systematic review that investigated a variety of cardiovascular exercises for SCI patients concluded that there is no evidence to suggest that cardiovascular exercise (including lower limb cycle ergometry) in this population group is harmful when prescribed with safety precautions and following the exercise equipment guidelines(21). Participants in this study will only receive lower limb training if deemed safe by the medical team and would receive exercise training as part of standard clinical practice. As previously mentioned, recent studies have addressed lung mechanics concerns by demonstrating that SVs did not cause derecruitment or hyperinflation of the lung and demonstrated improved lung recruitment(11, 12, 14) with patients at rest.

Given that the risks are very low and the benefits to early exercise are well documented, by evaluating the safety criteria for lower limb MOTOmed Letto exercise, we believe the benefits far outweigh the risks.

*Outcome Measures*

Outcome measures will include:

* Ventilator-delivered positive end expiratory pressure (PEEP),
* Fraction of inspired oxygen (Fi02),
* Heart rate (HR) and peripheral capillary oxygen saturation (SpO2) using a pulse oximeter
* End tidal carbon dioxide (EtCO2).
* End expiratory lunch volumes (EELV)
* End expiratory lung impedence (EELI)
* Rib cage and abdominal mobility via abdominal-to-chest ratio (A:C)
* Rating of perceived exertion (RPE) via a modified Borg scale
* Distance completed on the lower limb ergometer
* Watts generated during exercise

**Project Benefits:**

There is currently no information available regarding whether it is safe to exercise tracheostomised patients with Passy-Muir SVs. There are indications with tracheostomised patients, that SVs can improve lung recruitment when patients are at rest(11, 12, 14). By establishing whether it is safe to exercise tracheostomised patients with Pass-Muir SVs; this may improve outcomes for patients admitted to ICU such as:

* Decreased ICU and hospital length of stay
* Decreased time requiring mechanical ventilation
* Decreased health care costs
* Improved function on discharge from ICU
* Improved ability to communicate whilst exercising
* Decreased anxiety levels during exercises
* Improved long term physical function and quality of life

**Results, Outcomes and Future Plans:**

The aim is to have completed the study with analysis of data and report findings written up by September 2019. The article will then be submitted for publication to a relevant and accepting journal. Patients will not be identified in the dissemination of results. It is intended that that the results from this research project will be disseminated via conference presentations, posters at the hospital and publications. If the results indicate improvements in lung recruitment and better exercise outcomes (eg. distance covered and watts generated), this will be presented at the local ICU meeting and will be implemented clinically to ensure that future patients benefit from this. Future research will then be completed in higher intensity cardiovascular exercise and strength training exercises. Specifically for strength training exercises, the theory of potential increased force with a speaking valve (by enabling a Valsalva manoeuvre with a closed glottis) will be investigated.

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