Official Title: Does Endurance Improve with the use of Passy-Muir Valve for Patients with Tracheostomy?

Clinical Trial Number: NCT04941456

Study Closeout: June 24, 2024

STUDY PROTOCOL AND STATISTICAL ANALYSIS PLAN

Methods

Research design: Six period Quasi-Randomized Crossover Controlled Study. Enrollment will occur based off tracheostomy census report, site investigators will perform weekly pull of tracheostomy report to recruit appropriate patients.

Patient population: Patients approached to consent for enrollment in the study will be participants admitted to Gaylord Hospital with tracheostomy who are medically stable for ambulation with Physical Therapy and for the use of PMV valve. All patients over the age of 18 will be considered for the study.

Enrollment criteria:

1. **Inclusion criteria**:
   a) Individual with tracheostomy who can tolerate daily 30 minute PT session with use of PMV and be able to maintain oxygen saturations above 88% with exertion.
   b) Ability to understand and respond to simple verbal instructions and one step commands in English well enough to consent without any Gaylord interpretation.
   c) Ability to ambulate a minimum of 10 feet with/without assistive device and with/without physical assistance.
2. **Exclusion Criteria**
   a) Active seizures
   b) Active Pregnancy
   c) Uncontrolled hypertension
   d) Cognitive deficits that would disrupt ability to provide informed consent
   e) Enteric infection control precautions
   f) Ongoing orthostasis
   g) Actively on decannulation protocol
   h) Medical instability that would cause a doctor to put therapy program on hold

Intervention: Standard intervention vs use of PMV to assess ambulation distance during 6MWT. The 6MWT will be performed each session to assess ambulation distance, alternating standard vs PMV intervention on sequential days to compare results. BORG Rating of Perceived Exertion (RPE) scale will be utilized pre and posttest daily to assess patient's subjective rating of physical exertion levels. Oxygen saturations and heart rate will be monitored pre and posttest via oximeter as well as during test if medically necessary.

Subject Assignment: Upon admission to Gaylord, appropriate patients are admitted under the inpatient program and tracked in the daily data pull of patient's with tracheostomy. Per hospital protocol, all patients will be evaluated by a physical therapist within the first 72 hours. If the patient meets criteria they will be asked to participate and then consented into the study by site investigators. Tracking forms will be compiled on inpatient therapy computers on research flash drive.

Study Timeline: Enrollment period will be 36 months and patients will receive two to six treatment sessions over a three week period. Treatment sessions will be scheduled in 30 minute increments to allot for testing time as well as collection of necessary data. Recruitment will remain open until we reach the goal of having 30 participants complete the full study. Partial data of early discharges, drop out due to changes in medical stability, or participants who are placed on

decannulation protocol during intervention period will still be included in the analysis. Data extraction will be retrieved from spreadsheets detailing results of 6MWT. Data will also be collected pre and post session on vital signs (HR and SaO2) to monitor physiologic appropriateness of exercise response and patient's perceived rate of exertion via the BORG RPE scale.

Primary outcomes: The primary outcome we wish to assess is participant **endurance** with or without a PMV attached to their tracheostomy tube. This will be assessed using two measures, the standardized 6MWT, and the Borg-RPE scale. While the reliability and validity of the 6MWT in patients with a tracheostomy tube haven't been extensively reported, it has been shown to have good validity and reliability in cardiopulmonary patients, patients with a diagnosis of chronic obstructive pulmonary disease (COPD)[1,2], and survivors of acute respiratory distress syndrome.[3] Further, the American Thoracic Society have made recommendations for use of the 6MWT as a pre- post-treatment comparison for several conditions, including pulmonary rehabilitation.[4] As such, we feel that it is valid to use 6MWT duration and distance as objective measures of participant endurance when comparing PMV and open tracheostomy. The Borg-RPE scale is a standardized subjective measure of an individual's perceived exertion upon completing an activity. The validity and reliability of Borg-RPE has been extensively assessed, and has been recommended as a valid measure to track patient progress during rehabilitation.[5-9] For this study, pre- and post-6MWT Borg-RPE assessments will be collected. Paper copies and notes of both assessments will be collected during the study session and then later transcribed into an electronic data collection sheet made in Microsoft Excel.

Secondary outcomes: Participant endurance and response to completing the 6MWT with or without a PMV will also be assessed through other metrics, including pre- and post-6MWT heart rate; pre- and post-6MWT oxygen saturation; post-6MWT supplemental oxygen requirements; and 6MWT assistive device usage. In addition to being physiological indicators of participant exertion and endurance,[10,11] several of these metrics have been found to positively correlate with the Borg-RPE scale.[5-9] Notes of these metrics will be collected during the study session and then later transcribed into an electronic data collection sheet made in Microsoft Excel.

General characteristics: Demographic characteristics that will be collected will include participant age, sex, and race/ethnicity. Other general characteristics that will be collected will include, as applicable, participant length of stay, discharge location, admitting diagnosis or condition that lead to tracheostomy, time to decannulation attempt, and decannulation attempt outcome. To promote study transparency and reproducibility, this information will be used to provide a descriptive overview of the study population to provide context for any reported findings. These data will be collected through manual review of Gaylord Hospital's electronic medical record system; they will be transcribed directly into an electronic data collection sheet made in Microsoft Excel.

Statistical Analysis

Data Analysis: Data were analyzed using GraphPad Prism (version 10; GraphPad Software, Boston, MA) and RStudio (version 4.2.2, Posit Software, PBC, Boston, MA]).

Descriptive data is reported as mean (standard deviation). If hypothesis testing was done, data were reported with a p-value, and significance was set at $\alpha=.05$. Data were determined to be missing completely at random and were dealt with via complete case analysis. Data were also assessed for violations in assumptions of their given tests, and were dealt with via non-parametric analysis as necessary.

Paired t-tests or Wilcoxon tests were utilized as necessary to evaluate between-group differences in continuous outcome variables.

References:

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