Official Title: Assessing the Safety of Nighttime Passy-Muir Valve Use and its Impact on Sleep Quality in the Long-Term Acute Care Hospital Setting: a Cross-Over Controlled Study

Clinical Trial Number: NCT06229639

Use date of study closeout: 9/1/2016

STUDY PROTOCOL AND STATISTICAL ANALYSIS PLAN

Study Protocol

Eligible participants were inpatients 18 years of age or older, who were admitted to Gaylord Specialty Healthcare following tracheostomy placement during an acute care hospital stay, were eligible for decannulation, and who had a tracheostomy tube size of six or smaller and did not require ventilation assistance. These patients were initially referred to the study by a Respiratory Care Practitioner (RCP). Patients also needed to meet all criteria outlined in Gaylord's decannulation protocol, along with the specific criteria required for the study. (**Table 1**). Eligible patients were then approached for study enrollment. Enrolled participants were given the FDA-approved PMV #2001 for the study. The PMV is a bias-closed, no-leak speaking valve that allows patients to speak at a level consistent with their normal vocalization range.

Participants were monitored and evaluated using the same outcomes and safety metrics typically used during the study site's decannulation protocol. This included an initial and daily evaluation by a Pulmonary or Critical Care Medicine consultant and daily morning arterial blood gas (ABG) measurements by an RCP. The RCP then conveyed ABG measurement to the covering therapists and Pulmonary or Critical Care Medicine consultants at shift change. The RCP then communicated daily with the covering Independent Medical Practitioner (IP). If participants failed to meet the decannulation or study criteria at any point during the protocol, then the IP was notified, and the protocol was to be canceled.

PMV Trial – Study Day One and Night One

On day one of the study period, participants were given a PMV to use during the day. If the PMV was tolerated without any acute vital changes (i.e., adverse reactions; **Table 2**), participants were instructed to keep the PMV on after 22:00, when it would typically be removed if still in place (**Figure 1**). Throughout the night, participants were kept on continuous telemetry for the duration of the study protocol. Nursing staff monitored and recorded heart rate, blood pressure, and temperature every four hours (e.g., 22:00, 02:00, and 06:00). The Respiratory Therapist (RT) on duty recorded oxygen saturation, end-tidal carbon dioxide ($ETCO_2$) levels via nasal cannula, and respiratory rate. Supplemental O2 was given to participants as determined by the clinical opinion of the respiratory staff. Supplemental O2 was noted if given to participants but not categorized as a serious adverse reaction requiring trial termination.

If at any time the participants experienced serious adverse reactions such as respiratory distress, stridor, or $ETCO_2$ greater than 60, PMV removal was scheduled (**Table 2**), and initiation of ventilatory support was planned. The trial would then be terminated and deemed unsuccessful. In the event of an unsuccessful PMV trial, the RCP would inform the IP and acquire ABG measurements. If this procedure did not improve the participant's respiratory condition, the next step would be to initiate ventilator support and request a chest X-ray.

Following night one, participants completed the Richards-Campbell Sleep Questionnaire (RCSQ) upon waking. The RCSQ is a six-question self-report questionnaire used to assess ICU patients' sleep quality.[15] These six questions assess the domains of sleep depth, sleep latency, awakenings, ability to return to sleep, overall sleep quality, and overnight noise level.[15] The responses were recorded on a 100 mm visual analog scale, with higher scores indicating better sleep levels than lower scores. The mean score represents the general perception of sleep quality, which was the secondary outcome of this study, evaluated by the sleep domain scores derived from the Richards-Campbell Sleep Questionnaire.

Tracheostomy Plug Trial – Day Two and Night Two

If study day one and night one were successful, the protocol was continued to day two. During day two, participants wore a tracheostomy cap, also known as a plug. If the plug was tolerated without any adverse response, participants were instructed to keep the tracheostomy plug in place throughout the night. Again, nursing staff monitored and recorded heart rate, blood pressure, and temperature every four hours, and the RT on duty recorded oxygen saturation, $ETCO_2$ levels, and respiratory rate. Same as night one, if any adverse events or acute changes occurred, it was planned that the plug be removed, ventilator support would be started, and the trial considered a failure. If no adverse events occurred upon waking up following night two, the participants were again administered the RCSQ. Once completed, following night two, participants' roles in the study were done and continued with the decannulation protocol as appropriate.

Statistical Analysis

Continuous clinical and demographic characteristics were described with means and 95% confidence intervals, and categorical data were described with frequencies. Differences in categorical variables were evaluated using Fischer's exact test or Chi-Square testing as appropriate. Differences in continuous variables were analyzed using paired t-tests for normally distributed data and Wilcoxon signed-rank test for non-normally distributed data. Two-way ANOVA analysis and Tukey's multiple comparisons post-hoc test were used to analyze differences in continuous variables at three time points (22:00, 02:00, and 06:00). Complete case analysis was performed on the dataset, with only complete pairs of data from night one and night two at the three time points being included in the analysis. All data were analyzed via GraphPad Prism 9 (GraphPad Software, San Diego, CA). Statistical significance was defined as a p-value less than 0.05.

Criteria for Initiation of Decannulation Protocol and Other Study-Specific Criteria

Decannulation Criteria
Afebrile
Hemodynamically stable
Clear or stable chest x-ray
Controlled Secretions
Peak Cough Flow ≥160 L / m
Satisfactory on-going nutrition (low risk of aspiration)
No clinical evidence of tracheal obstruction
Ability to tolerate a speaking valve

Inclusion Criteria
Patient has evidence of respiratory insufficiency requiring a tracheostomy tube without current need for assisted ventilation.
Patient will be continuously monitored with telemetry.
Patient satisfies criteria for the deInitiationcannulation protocol and agrees to use the Passy Muir Valve during sleep.

Patient is able to follow directions following speech, language, and cognitive evaluations, or other screening completed during the Speech-Language Pathologist and physician assessment.
Patient is at least 18 years old.
An informed consent is signed by patient or Power of Attorney (POA).
Patient is able to tolerate the Passy Muir Valve during the day for a minimum of 6 continuous hours.
Patient has a maximum size #6 Shiley cuffless tracheostomy tube or equivalent.

Exclusion Criteria

Patient identified at time of admission as requiring invasive long-term assisted ventilation.
Patient with documented or suspected upper airway obstruction and/or surgery or permanent tracheostomy tube.
Patient is quadriplegic (due to the inability for a quadriplegic patient to manually self-remove the valve in case of emergency).
Patient or POA failed to sign consent.
Patient has a severe cognitive impairment as determined by a formal cognitive-linguistic evaluation by a licensed Speech Language Pathologist.
Patient unable to meet criteria for decannulation protocol or has failed decannulation protocol within last two weeks.