Describing Balance Function in Patients Post-COVID-19

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Purpose of the Study

We hypothesize that patients with COVID-19 will have residual balance dysfunction that are more similar to those with neurological dysfunction than respiratory illness.

Background & Significance

People with cardiorespiratory dysfunction specifically chronic obstructive pulmonary disease (COPD) and lung transplantation have postural instability and increased risk of falls compared to age matched controls. People with COPD are 55% more likely to have falls than their non-COPD counterparts. It is speculated that this increase in fall risk is due to muscle weakness, attention and ability to dual task, decline in activity, polyneuropathy, and pain.

Ninety percent of patients with a history of COVID-19 report at least 1 neurological symptom. The neurological symptoms can occur before, during, or after the respiratory symptoms. Neurological symptoms include gustatory and olfactory dysfunction (35-88%), myalgia (19%), headache (15%), altered mental status, confusion or delirium (9%), and dizziness (9%). In an early report from Italy, they describe myopathy and neuropathy in addition to impaired balance and gait. Balance deficits could logically follow many of these neurological signs and symptoms. Although there is anecdotal evidence for imbalance immediately and long after COVID-19, we are unable to find a study that looked at balance quantitatively. Understanding balance dysfunction following COVID-19 can assist medical personnel in directing intervention for gait and balance dysfunction.

The act of maintaining upright posture or balance depends on both sensory and motor responses. Sensory information from vision, vestibular and somatosensory provide reference about where the body is in space and how it is moving so that appropriate motor responses can be generated. One can hypothesize that in patients with respiratory dysfunction, balance is affected through a lack of oxygen to the muscles making it a motor balance dysfunction. With neurologic dysfunction, difficulties can be seen with both the sensory and motor systems. Our balance outcome measures can differentiate between motor and sensory balance dysfunction. The TImed “Up & Go” is a measure of motor balance while the modified Clinical Test of Sensory Interaction measures the brain's use of visual, vestibular, and somatosensory for balance. We will describe the differences in the results of the TUG and the mCTSIB in patients with COVID-19 with previously documented balance dysfunction in patients with respiratory and neurological dysfunction (from existing literature).

Design & Procedures

Subjects who meet inclusion criteria (see below) will complete informed consent by the PI or one of the sub-investigators.

Subjects will complete the Activities-Specific Balance Confidence (ABC) Scale, provide number of falls in the past year and since hospital admission, and indicate their dizziness level on a 0-10 visual analog scale (VAS) for current, best and worst in the last 24 hours, and provide a description of dizziness (Asked “How would you describe your dizziness?”).

HR, RR, BP, and SpO2 will be measured at rest and after all outcome measures are completed. RPE (0-10 per modified Borg scale) will be measured after each outcome measure. In addition, HR will be measured after each outcome measure. SpO2 will be continually monitored via pulse oximetry.

Fraction of inspired oxygen (FiO2) will be titrated per MD orders. If SpO2 drops below MD-specified parameters, patients will first be given a 3-minute seated rest break. If SpO2 recovers above MD-specified parameters after rest break, activity will resume. If SpO2 remains below MD-specified parameters after rest break or continues to drop with activity, FiO2 will be titrated to maintain SpO2 within MD-specified parameters.

The Timed "Up & Go" (TUG) and Modified Clinical Test of Sensory Interaction in Balance (mCTSIB) outcome measures will be randomized per Excel's RAND function and performed in the order assigned.

During the TUG, subjects will be timed while standing from a standard chair, walking 3 meters at self-selected speed, turning around, walking back, and sitting back down. Subjects will be guarded by a physical therapist while they are walking to prevent falls.

During the mCTSIB, subjects will be timed (for a maximum of 30 seconds) standing on a firm surface, eyes open and eyes closed, then on a foam surface (Airex pad), eyes open and eyes closed. Subjects will have their arms folded across the chest and feet shoulder distance apart. If it is felt by the investigators that the subjects did not perform at their best level, they will be given a second trial. Subjects will be guarded by a physical therapist during balance activities to prevent falls.

Performance on the outcome measures will be recorded on a data sheet and entered into the spreadsheet manually.

Data will be recorded in a password-protected computerized database. Comorbidities and medications will be included from the medical record. Only Duke study personnel will access the medical record. The database will be de-identified before sharing with the co-investigators who are not Duke employees by a Duke employee.

This is a descriptive study and no intervention will be provided. All the examination/outcome measures are standard measures used in physical therapy.

Selection of Subjects

Inclusion Criteria:

- Age > 18 years and < 90 years
- Primary or secondary diagnosis of COVID- 19 during hospitalization and off COVID-19 isolation
- Receiving care in acute inpatient
- Ability to ambulate 20' with or without an assistive device without dropping >10% of resting SpO2 (determined from existing PT evaluation)
- Ability to stand with no more than contact guard assistance (determined from existing PT evaluation)
- Not requiring use of mechanical ventilation
- Minimum resting SpO2 of 88% with or without supplemental oxygen
- No neurological or orthopedic dysfunction that would affect balance
- Cognitively intact and able to follow directions and provide consent

Exclusion Criteria:

- History of 2 or more falls in the year prior to COVID-19 diagnosis or history of balance dysfunction

Subject Recruitment and Compensation

Potential participants will be identified by Duke study personnel using Maestro Care filters (i.e. COVID-19 and active physical therapy consults). Once identified, patients will be screened via chart review to ensure they meet inclusion and exclusion criteria for the study. The treating physical therapist or assigned nurse will approach all patients who meet the inclusion and exclusion criteria to see if they are interested in participating. Additional screening for current resting SpO2 parameters and number of falls will occur upon approach as this information cannot be obtained via chart review. Consent will be obtained from either the PI or one of the sub-investigators. No compensation will be provided.

No sample size calculations were performed as this is a descriptive study. We plan to approach up to 40 subjects with a goal sample size of around 30-35 to describe balance in COVID-19.

Risk/Benefit Assessment

The study has small risk and no direct patient benefit but has the potential to provide information for patients who may benefit from future interventions aimed at addressing balance deficits in patients with COVID-19. Physical activity is generally considered to be safe for patients with cardiorespiratory conditions, but patients may incur the following risks:

- Risk of falls or musculoskeletal soreness or injury. This is not greater than what is experienced during standard physical therapy treatment. Subjects will be guarded to prevent falls.

- Risk of increased respiratory symptoms but these will be monitored and examination will be discontinued if subjects' SpO2 drops > 10% of resting SpO2. Any increased symptoms should be transitory.

Data Analysis & Statistical Considerations

This is a descriptive study so scores on the balance tests will be described by means and standard deviations for each group. Spearman correlation coefficients or linear regression will be used to determine if vital signs influence the balance scores.

Data & Safety Monitoring

The investigators will monitor for adverse events and report as required to the IRB. As there is no increase in risk beyond what is experienced in standard physical therapy intervention, no data monitoring committee will be used.

Duke study personnel who are interacting with patients will follow all Duke COVID-19 policies. Any required PPE will be worn during study visits. Inclusion criteria requires that patients be off isolation prior to approach for the study.