

**Research Project Protocol**

***NON-VENTILATED PRONE POSITIONING IN THE COVID-19 POPULATION***

**Institution(s) where project is to be conducted:** Baylor St. Luke's Medical Center

**Departments Involved:** 7 Tower

**Time Period:** October 2021- April 2022

**Will any data be collected during patients' hospitalization?** Yes

## Protocol Title, Version Number, and Version Date

Title: NON-VENTILATED PRONE POSITIONING IN COVID-19 POPULATION

Protocol Version Number: 1

Protocol Version Date: 6/11/21

CSHRI IRBNet ID: 1766880-1

**THIS STUDY DOES NOT REQUIRE BAYLOR IRB APPROVAL.**

### 1) Funding Source

The researchers' primary funding will come from Baylor St. Luke's Friends of Nursing Foundation. This foundation's aim is to support nurses in their professional practice development. They have no financial conflict of interest with the researchers or the researchers' institution.

### 2) Objectives and Hypothesis(es)

The project goal is to investigate the efficacy of proning COVID-19 hypoxemic patients who are hospitalized at Baylor St. Luke's in an acute care, telemetry-monitored unit. The researchers will be using a systematic approach to educate patients and staff about patient self-proning, implementing self-proning every 2 hours, and monitoring escalation of oxygen levels, as well as length of the study period.

**Objectives:** This study is intended to explore the effects of proning on non-ventilated COVID-19 hypoxemic patients hospitalized in a telemetry-monitored, acute care unit. In addition, the hope is to delay intubation and/or escalation of respiratory interventions, while contributing to the growing body of knowledge related to COVID-19 treatment and care.

**Hypotheses:** The researchers expect to see an improvement in oxygen saturation levels as evidenced by no escalation of respiratory care (i.e. higher levels of oxygen needed, transfer to higher level of care), resulting in shorter lengths of stay for the intervention population.

### 3) Background/Scientific Rationale and Significance

*Describe the relevant prior experience and gaps in current knowledge.*

Colloquially, proning has been propagated to increase oxygen saturation in patients in respiratory distress. Since the COVID-19 virus's primary symptomatology is respiratory in nature, proning has re-emerged as a viable option, and research is ongoing in the intensive care unit (ICU) patient population about its effectiveness. However, there has been minimal research around proning methodology in the alert, oriented, and independent patient who has

been confirmed COVID-19 positive and has been admitted to a non-ICU setting. Therefore this study aims to address this lack of evidence.

#### Describe any relevant preliminary data.

Kallet (2015) summarized the physiological mechanism that prone position improves oxygenation in moderate to severe ARDS patients. First, a prone position can make the dorsal region more elevated, which leads to evenly distributed tidal volume in the lung. Second, a prone position decreases the pressure that the lung receives from the heart and abdomen, which can increase resting lung volume in dorsocaudal regions. Third, when patients are in a prone position, the pressure from mass tissue in the dorsal wall can make pleural pressure more evenly distributed in the lung.

A meta-analysis with randomized controlled trials indicated that prone positioning became a life-saving intervention for mechanically ventilated ICU patients with moderate to severe ARDS when it is applied for at least 12 hours daily (Munshi et al., 2017). Ding et al. (2020) evaluated the outcome of intubation in ARDS patients whose average prone positioning (PP) was 2 hours. These patients received oxygen with high-flow nasal cannula (HFNC) and non-invasive ventilation (NIV), or only non-invasive ventilation. Ding et al. (2020) concluded that the prone position helped ICU ARDS patients avoid intubation when combined with other non – invasive oxygenation intervention in the early stage of ARDS. The results of a randomized controlled trial indicated that the outcome of early application of prone position in ICU ARDS patients demonstrated a significantly decreased 28-day and 90-days mortality (Guerin et al., 2013). The study included 466 patients from healthcare multicenters. The patients were divided into two groups, a prone group with 237 patients, and a supine group with 229 patients. The patients in the prone group were subjected to prone-positioning for at least 16 hours. In contrast, the patients in the supine group were left in the supine position. The study found a 28-day mortality; 16% in prone group vs. 32.8% in supine group (P, 0.001); hazard ratio for death was 0.39 in prone group vs. 0.44 in supine group (P, 0.001), and unadjusted 90-day mortality was 23.6% in prone group vs. 41.0% in supine group (P, 0.001) (Guerin et al., 2013). Based on the above evidence - prone positioning has been recommended by the World Health Organization (WHO) as one of the better interventions for mechanically ventilated patients with moderate-severe ARDS within ICU (World Health Organization, 2020). Cardona et al. (2021) in a meta-analysis of observational studies found ICU patients with COVID-19 with non-invasive oxygen interventions and awake prone positioning, the intubation rate was 28% and mortality rate was 14%.

Weatherald et al. (2021) reported that prone positioning promised an improvement in oxygenation while patients were in the prone position. The review included 35 studies with 414 patients from various clinical settings. Twenty-nine of these studies report on the use of awake prone positioning in COVID-19 patients. Among 35 studies, only one study included data from the control group. All studies demonstrated improvement in oxygenation while patients were in the prone position except one.

Another study of 50 patients in an ED setting reported that using an awake prone position in managing COVID 19 pneumonia showed some benefits in improving acute hypoxemia (Caputo et al., 2020). McNicholas et al. (2020)

emphasized that to date there is still a lack of randomized control trials that support the benefit of awake prone position on COVID-19 pneumonia patients with hypoxia. Furthermore, there was no study that revealed whether or not non-ventilated prone positions change mortality rate in patients with COVID-19 ARDS.

Proning has been attempted before in the healthcare setting. An emergency department (ED) in New York asked 50 patients to self-prone for 5 minutes, and recorded their oxygen saturation both before and after the intervention. This study saw an improvement of at least 10% in oxygen saturation across the sample, although 13 of those patients later had to be intubated within 24 hours of arriving at this ED (Caputo et al., 2020). Another study, conducted in non-ICU units in Italy, surveyed 50 patients confirmed with COVID-19, reported increased PaO<sub>2</sub> levels from proning for 10 minutes, and those levels were able to be sustained after proning in approximately half the patients (Coppa, et.al., 2020).

Nursing clinicians Holland (2020) and McKenna et al. (2018) discussed the important role of nurse clinicians utilizing prone position therapy to promote positive patient outcomes. These authors describe clinician roles as initiating multidisciplinary discussions, helping to apply prone positions, educating on the technique of prone position, supporting patients who undergo prone positioning, and evaluating outcomes. Our nurse researchers aim to add to the body of evidence surrounding positive outcomes of proning in the acute care setting of non-intubated COVID-19 patients.

#### **4) Inclusion and Exclusion Criteria**

##### **Inclusion Criteria:**

The inclusion criteria for this research study are patients that have been confirmed COVID-19 positive on an acute-care, telemetry-monitored, non-ICU unit and are considered hypoxemic. Hypoxemic is defined as experiencing rising oxygen requirements as evidenced by increasing levels of supplemental oxygen (i.e. starting at 1-2 L nasal cannula and increasing oxygen need from that level, up to 6 L on nasal cannula.) The patient must also be conscious and oriented, as well as able to change positions independently (meaning that it would not take an increased amount of energy or effort to position independently. Subjects will be patients 18 years and older. If the patient is unable to speak, read, or write English, an alternative consent in their language will be utilized.

##### **Exclusion Criteria:**

The exclusion criteria included those that are not COVID 19 positive. Those patients that are COVID -19 positive and in an ICU setting, or in need of ICU level respiratory treatments and interventions would be excluded, as well as those with respiratory distress (defined as immediate need for intubation, respiratory rate over 35, PaCO<sub>2</sub> level above 65, and accessory muscle use) or in hemodynamic instability (systolic blood pressure below 90) or arrhythmia. The researchers would also exclude patients that have agitation or who have altered mental status, unstable spine/thoracic injury or recent abdominal surgery, significant pressure ulcers (above stage 1), pregnant patients past the 2<sup>nd</sup> trimester, and patients that have concerning neurological issues (such as seizures). Patients that are unable to change positions independently will also be excluded.

*Describe how individuals will be screened for eligibility.*

This is a single-center prospective study which will be conducted over a period of 8 months on a telemetry-monitored, acute care unit in a large tertiary teaching hospital in Houston, Texas. Randomized sampling will be used to recruit and consent 96 patients that meet the study inclusion criteria (48 in the intervention group and 48 in the control group). This study will seek approval from the Common Spirit Health Institutional Review Board, and all participants receiving the intervention will be consented (see consent form attached).

## **5) Number of Subjects**

The sample size will be 96 patients (48 patients in the intervention group and 48 patients in the control group).

## **6) Study Timelines**

1. June 2021- obtain IRB approval
2. End of June 2021 - meet with manager/unit educator of covid positive unit to discuss unit education and data collection
3. July 2021 - approximately January 2022 - Data Collection, enroll subjects as collection occurs
4. February - March 2022 - Data analysis
5. April 2022 - Finish analysis and write study

## **7) Study Endpoints**

Primary endpoint of this study is a shorter length of stay for the intervention group. Secondary endpoints include decreased need for oxygen supplementation as evidenced by higher oxygen saturation levels, decreased need to be admitted to the intensive care unit, and decreased reports of pressure injuries (as identified by BSLMC protocol).

## **8) Procedures Involved**

**Study Design:** This will be a prospective randomized cohort study in which data will be collected for over 14 days or until discharged or transferred to a lower level of care from the telemetry-monitored, acute care unit. Data collected on study participants will include the need for escalating respiratory care as well as length of stay in the acute care unit. Comparative analysis will be conducted with retrospective data collected from hospitalized patients (the control group) with a diagnosis of COVID-19 on a non-ICU acute care, telemetry-monitored unit that meets the hypoxemia criteria, but that will not receive the proning intervention. The data from the control group will be collected by a retrospective chart analysis after 14 days past their discharge date.

On a confirmed COVID-19 non-ICU acute care, telemetry-monitored unit, there will be two sets of patients: patients that will receive the intervention of proning plus standard of care, and patients that receive standard of care, but not the proning intervention. Confirmed COVID-19 positive patients are randomly assigned by bed control to a room upon admission to the unit. Patients will be randomized upon admission to the acute care, telemetry-monitored unit, and selected based

on inclusion criteria. The patients that will be prone will be identified by a door slot "slider" that is purple. Timing devices will be purchased and placed at the nurses' station, and checklists to indicate proning times will be placed inside the room with a patient identification sticker. The researchers will be following the proning protocol for acute care patients provided by CommonSpirit Health (CSH).

Patients will consent to participation (using an approved consent document from the CSH IRB), and an order for the proning protocol will be entered in the EMR by the physician. The patient will be educated about self-proning, and instructed to self-prone every 2 hours. The nursing staff will document patient position on the checklists every 2 hours.

1. Upon initiation of the initial proning, the patient will be monitored by the RN for adverse effects for 15 minutes (such as inability to tolerate position or signs of respiratory distress).
2. If the patient tolerates the proning well, the procedure can continue and the RN will set the timer for 2 hours, enter the patient's oxygen saturation into the EMR, and document the position (prone or supine) on the checklist. O2 saturation will be documented at least every 4 hours per unit protocol.
3. The 2 hour timer will be reset each set of 2 hours by the nursing staff, and the intervention will continue until the end of the study period or until the patient is discharged or transferred from that unit.
4. The checklists will be placed in a binder at the nurses' station at the end of each shift and collected daily by a member of the research team.
5. This intervention for each "proned" patient will continue until either of the following occur: either the patient is discharged or transferred to a lower level of care from the acute care floor, or 14 days have passed.
6. A retrospective chart review will be completed by the research team to ascertain length of stay on the acute care, telemetry monitored unit, as well as the need for escalation of respiratory care. Escalation is defined by a need for oxygen requirements above 6 liters of oxygen on the nasal cannula.

*If the patient is assigned to the control group, that patient will receive the standard of care treatment designated by BSLMC policy per their condition on the COVID-19, acute care, telemetry-monitored unit.*

**Data Analysis:** Retrospective data analysis will be conducted by the research team with data collected from the electronic medical record as well as the checklists (oxygen saturation, demographics, proning protocol) for both the interventional and control group. See attached documents for consent/proning protocol documents.

This study will be a prospective cohort study in which data will be collected on subjects for the designated time period. Data will be collected from the electronic medical record as well as the checklists. Data collection will include basic patient demographics, specifically age and gender, height, weight and ethnicity. Clinical data to be collected include O2 saturation, respiratory support methods, proning duration/compliance, presence of hospital acquired pressure injuries,

and need to escalate care to ICU, including initiation of mechanical ventilation. The same data will be collected for the control group - except for proning duration/compliance as they will not receive this intervention.

## **9) Data and Specimen Banking**

The data obtained from this study will be basic patient demographics, specifically age and gender, height, weight and ethnicity. The patient medical record number, name, and date of admission/discharge are included as PHI necessary to complete this study. Clinical data to be collected include O2 saturation, respiratory support methods, proning duration/compliance, presence of hospital acquired pressure injuries, and need to escalate care to ICU, including initiation of mechanical ventilation. The REDCap project IDs are 2817 and 3682 for reference.

Upon consent to the study, the patient's medical record number will be recorded as the principal identifier, and the above demographic data will be collected from the electronic medical record. This information will be coded to a personal ID generated by the researchers' REDCap software by the principal investigator or members of the research team. The clinical data obtained during and after the intervention will be recorded from the electronic medical record and also linked to the personal ID in the REDCap software.

The list linking the medical record number to the personal ID will only be handled by members of the research team and will be destroyed electronically upon completion of data collection - approximately 8 months after the initial start of the study. This is to allow for easy access of associated data as the researchers update the ID profiles. All of the members of the research team have completed CITI training, as well as financial conflict of interest records.

The researchers do not anticipate any incidental findings that would impact the outcome of this study or the care of the patient. If the patient started the study and then wished to have their data removed, the patient would communicate that to the nurse assigned, who would then call the principal investigator (number provided to the unit). The investigator would then delete the profile from REDCap and remove the medical record number from the study records.

Data collection will proceed as follows:

1. Every calendar day after the patient has been consented and the intervention is occurring, the nurse assigned to the patient will chart O2 saturation, any presence of hospital acquired pressure injuries, and need to escalate care. This data will be recorded in the electronic medical record, and members of the research team will daily update the REDCap profile with that data.
2. The nurse assigned to the patient will also chart the position of the patient every 2 hours via a paper document (also attached). These paper documents will be placed in a binder at the nurse's station at the end of each shift and collected by the research team daily. The research team will document for each profile the patient's compliance with proning.

The risk of loss of confidentiality will be minimized by taking the following steps: (1) Data collected from study participants will be maintained in locked file cabinets or in password protected CHI servers managed and maintained by CHI Information Technology. (2) Subject names and other identifiers will be removed from study data and will be replaced by unique study numbers. (3) The documents connecting the subjects to their study

numbers will be kept separately from subject data and in locked file cabinets, in password protected CHI servers managed and maintained by CHI IT. (4) Study personnel will be the only individuals with filing cabinet keys and computer passwords. Study personnel will only access this data while at work.

## **10) Data Analysis Plan**

Retrospective data analysis will be conducted by the research team with data collected from the electronic medical record as well as the checklists (oxygen saturation, demographics, proning protocol) for both the interventional and control group. See attached documents for consent/proning protocol documents.

This study will be a randomized controlled trial. The primary outcome will be time (days) until discharge from the acute care unit to home or lower level of care (e.g., long-term care), and the primary hypothesis test will compare time-to-discharge between "prone" and "not prone" treatment arms.

A sample size of 48 patients per group (N=96) will provide 80% power to detect a 50% decline in time-to-discharge using a log-rank test.

## **11) Withdrawal of Subjects**

The researchers do not anticipate circumstances in which the subjects will be withdrawn from the research study without their consent. Patients who otherwise withdraw from the study will be censored on the withdrawal day with the following process: If the patient started the study and then wished to have their data removed, the patient would communicate that to the nurse assigned, who would then call the principal investigator (number provided to the unit). The investigator would then delete the profile from REDCap and remove the medical record number from the study records.

## **12) Risks to Subjects**

The researchers foresee minimal risks in this study to the participant. Possible risks include:

- Inability to maintain the prone position, possibly resulting in O2 desaturation and other negative respiratory effects, such as intubation
- Skin breakdown
- Patient discomfort in turning every 2 hours/patient inconvenience for documentation, especially overnight

## **13) Potential Benefits to Subjects**

The researchers foresee benefits to the patient for being involved in the study. These benefits should last for at least the length of the data collection on the patient. The benefits include:

- Shorter time to discharge or transfer to lower level of care (measured in days)
- Decreased need for O2 supplementation; higher O2 saturations recorded



## **14) Setting**

The research study will be conducted in St. Luke's Health - Baylor St. Luke's Medical Center - Houston, TX (address: 6720 Bertner Ave, Houston, TX 77030), in a telemetry-monitored, acute care unit for covid-positive patients. The researchers will consent randomly assigned patients from that unit, and the intervention will be contained to that unit.

The study is being propagated by BSLMC's Nursing Research and Education Council after having been approved by the CNO, and is being submitted for review by the CSH Institutional Review Board. After approval, the study will be commenced.

## **15) Resources Available**

The members of the research team are Marie Hodges, Nishant Varghese, Michael Guffey, Christi Knapp, Jenny Li, and Dr. Geraldine Jones.

All team members involved in the study are registered nurses (RNs) with bedside experience in an acute-care facility that provides high acuity patient care. The aforementioned team members have completed CITI training specific to conducting research via IRB approval and oversight under institutional guidelines, policies, and ethics. The members of this research team will be conducting this research for the continuation of evidence based practice amidst the COVID-19 pandemic that will provide much needed guidance for the treatment of the COVID-19 affected population. Each member of the study promotes adequate knowledge of the local study hospital, culture and larger local community.

The feasibility of recruiting the required number of suitable subjects within the agreed recruitment period is to be determined once data collection commences and is currently unknown. This will be addressed knowing that the active COVID-19 population is declining due to increased vaccinations and compliance by the general public with adhering to social distancing and wearing personal protective equipment. Given this, the percentage of potential subjects needing to be recruited will be based on the number of qualified study participants. The researchers estimate that in order to obtain statistically significant results, the sample size will need to be 96 patients minimum, with a goal of 130, splitting evenly into control and intervention groups. The research team will have access to the unit's patients at time of data collection per the unit manager and approval of the facility for the estimated time of data collection.

The research study will take place on a COVID-19, acute care, telemetry-monitored unit.

Each member of the research team is expected to devote time to this research study daily during the data collection period for approximately a half an hour each day. This will entail education of the nursing staff affected and collection of both the electronic and paper records. That process is as follows:

- At the beginning of each day, staff huddles occur on the unit at approximately 6:45 AM. A member of the research team will be present at huddle daily to educate the staff nurses on the proning intervention.
- Once each intervention patient is confirmed via random assignment, the research team member assigned that day will meet with the nurse assigned to the

intervention patient. The research team member will obtain consent from the patient. That team member will assess if the nurse needs help monitoring the patient for the initial 15 minutes of proning, and assist as needed.

- That team member will also educate the nurse assigned as to how often proning occurs (every 2 hours), to document patient position on the checklist every two hours, the proning protocol, and where to put the checklist at the end of their shift. The team member will leave upon confirmation of correct implementation of the study.
- The checklists from the intervention patients will end up in a binder at the end of the shift, and the binder will be emptied at that time by a member of the research team. These checklists' data will be entered into the computer by the research team, kept until the end of data collection period in a locked filing cabinet, and then destroyed at the end of the data collection period.

The resources for the patient should there be more than minimal harm caused include the medical resources of our facility.

## **16) Confidentiality**

There are 2 sets of data to be protected during this study: electronic and paper sets of data. The paper data will be only transported by members of the research team from the point of collection and stored in locked filing cabinets. This data will be destroyed at the end of the data collection period - approximately 8 months. The electronic data will be physically entered by members of the research team directly from the electronic medical record to the REDCap software database after being coded with a REDCap generated personal ID. The list of personal IDs linked to the medical record numbers will be destroyed at the end of the data analysis period - approximately 8 months. The REDCAP software is a web-based application used to capture data and create databases in an encrypted environment that is user-protected and HIPAA compliant. This electronic data will only be accessed by members of the research team during working hours at the facility, on CHI protected servers managed and maintained by CHI Information Technology.

The researchers do not anticipate any necessary breaks in confidentiality for the duration of this study.

The risk of loss of confidentiality will be minimized by taking the following steps: (1) Data collected from study participants will be maintained in locked file cabinets, in password protected CHI servers managed and maintained by CHI Information Technology. (2) Subject names and other identifiers will be removed from study data and will be replaced by unique study numbers. (3) The documents connecting the subjects to their study numbers will be kept separately from subject data and in locked file cabinets, in password protected CHI servers managed and maintained by CHI IT. (4) Study personnel will be the only individuals with filing cabinet keys and computer passwords. Study personnel will only access this data while at work.

## **17) Provisions to Protect the Privacy Interests of Subject**

During the informed consent process, the patient will be given the opportunity to ask questions and disclose any discomfort with the study or study procedure, with both the research team member and the nurse assigned to the patient. The process of patient confidentiality within the study will be fully explained to the

patient, as specified above - the fact that the researchers will only have access to demographic information, and not personal identifiers outside of medical record numbers, and that the data will be encoded upon entry into the secure database. If the patient wishes to withdraw from the study at any time, that process will be explained.

## **18) Consent Process**

Informed consent will be obtained at the bedside of the patient on the COVID-19 acute care, telemetry-monitored covid positive unit who is assigned to the intervention by a member of the research team. This process will be as follows:

- An order to self-prone and verify consent for proning will be entered into the computer by the doctor.
- The research team member will bring a paper copy of the consent to the patient (copy stored on the unit, attached to this submission), and fully explain the consent.
- The patient will be given the opportunity to ask questions and ask for further clarification.
- At the end of the consent process, the patient will be asked to explain the intervention back to the member getting consent.

This process should take in total about 15 minutes, and will be the same for every patient assigned for the intervention group. The patient will be allowed to decline the intervention.

If the patient cannot speak, read, or write English, an alternative consent will be provided in their language of choice, and consent will be obtained through the facility's interpretation device.

### ***Waiver or Alteration of the Consent Process***

For our patients assigned to the control group, a waiver of consent will be requested.

## **19) Process to Document Consent in Writing**

The study should present no more than minimal risk of harm to subjects. Nevertheless, the researchers will be collecting a written informed consent from the study participant, and storing those in a secure filing cabinet until the study analysis is complete (approximately 1 year). The consent document is attached to this submission.

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