Pre-operative multi-sensory ICU simulation experience to reduce post-operative delirium in the cardiothoracic surgical population

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MAYO CLINIC

General Study Information

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Study Title: Pre-operative multi-sensory ICU simulation experience to reduce post-operative delirium in the cardiothoracic surgical population

Protocol version number and date: V.1. 08192019

Research Question and Aims

Hypothesis: A pre-ICU simulation session will decrease the incidence and severity of post-operative delirium in the ICU after an elective cardiothoracic surgical procedure.

Aims, purpose, or objectives: The purpose of this project is to evaluate the effect of a pre-ICU admission simulation session on post-operative delirium in the elective cardiothoracic surgical population,

Background (*Include relevant experience, gaps in current knowledge, preliminary data, etc*.):

Cardiothoracic patients are at a high risk for post-operative delirium in the intensive care unit (ICU). Approximately 50% of patients admitted to the intensive care unit develop or are impacted by some form of acute delirium. This can lead to a three-fold increase in 6-month mortality, increased time on the mechanical ventilator, elongated hospital length of stay, and nearly 50% of those patients affected having a cognitive impairment at hospital discharge some with long term cognitive impairment (approximately 1 in 3 patients). Specifically, delirium incidence in the post-cardiac surgery population is between 26-52%. Delirium in this population specifically has been associated with increased mortality, stroke risk, hospital readmission and cognitive dysfunction as well as poorer functional status.

The literature supports the use of pre-operative educational experiences as a mechanism to reduce delirium incidence.

The initial phase of this project is to identify the baseline rate of delirium in the cardiothoracic surgical intensive care unit. Anecdotal data from practitioners in this unit indicate that post-operative delirium across “surgical procedure types” is a strong concern. A primary gap in this population’s care is that our institution does not have a program in place to prepare patients for the experience they will have admitted to the ICU post-operatively.

The initial phase of this project will include baseline data collection over a period of 3 months to determine current delirium rates (CAM-ICU) and other ICU outcome metrics including ventilator time, use of sedatives and antipsychotics, restraint use rates, and ICU and hospital length of stay.

Following initial baseline data collection, the intervention will be to provide a pre-cardiothoracic surgery patient a multi-sensory pre-recorded virtual reality ICU simulation experience to introduce them to the senses they can

expect to encounter post-operatively when admitted to the critical care unit. This is intended as a mechanism to reduce post-operative delirium in this population by allowing them to "become familiar" with the sights/sounds/tactile experiences in the ICU so that they are not completely foreign to the patient upon admission post-operatively.

Study Design and Methods

Methods: *Describe in lay terms, completely detailing the research activities that will be conducted by Mayo Clinic staff under this protocol.*

Data collection and Outcome Metrics :

- CAM-ICU scores in the post-operative setting
- Incidence of acute delirium in the post-operative setting
- Time of intravenous sedation in the post-operative setting
- Time of mechanical ventilator in the post-operative setting
- Incidence of anti-psychotic medication administration to treat delirium
- Incidence and duration of cardiopulmonary bypass "pump time"
- Metrics will be stratified based on type of operative procedure, operative time, age, gender, necessity for return to operating room prior to initial extubation

The data source will be the electronic medical record. Baseline retrospective data will be collected on patients prior recorded prior to the start date of this IRB submission; prospective patients undergoing simulation session will have data recorded post IRB start date. Data collection form attached with IRB submission.

Charts of all initial post cardiac surgery patients admitted directly to the ICU who meet the above criteria will be reviewed.

Pre ICU Simulation Survey – Patient

1. You are going to be admitted to the intensive care unit after your surgery. What are your thoughts / feelings / fears regarding your upcoming ICU stay?

Post-ICU Simulation, intervention patients will be surveyed with the following questions:

1. What was the biggest take-home point you learned during your virtual reality ICU simulation experience?

2. How do you hope that this ICU simulation experience will impact your actual ICU experience after your cardiac surgery?

Post actual ICU experience, intervention patients will be surveyed in person with the following questions:

1. Please describe your ICU experience.

2. What do you remember from your virtual reality pre-operative ICU simulation experience?
3. Did you experience any of the things you experienced in the virtual reality ICU simulation during your actual ICU experience? Please describe.
4. How do you feel that your pre-operative virtual reality ICU simulation experience impacted your or prepared you for your actual ICU experience?
5. Did you feel that the pre-operative virtual reality ICU simulation experience was beneficial?
6. What about your actual ICU experience was unfamiliar to you?
7. How would you modify the pre-operative virtual reality ICU simulation experience to improve your actual ICU experience?

Informed consent for research will be obtained by a member of the research team in the pre-surgical clinic setting; a future date for the simulation session will then be mutually agreed upon by study staff and patient/family.

Following informed consent for research, the pre-surgical patient will be asked to view a 10 minutes pre-recorded virtual reality simulation session from the perspective of a postoperative ICU patient. This virtual reality simulation session has been recorded in the Mayo Clinic Simulation Center under the guidance of study team members from Critical Care, and Cardiothoracic surgery.

The multi-sensory ICU simulation experience will include the following:

- View on a virtual reality head set
- Introduce to different care team members
- Introduction to common equipment found in the patient room in the intensive care unit
- Introduction to common experiences, sounds, sights and procedures in the intensive care unit
- Total video duration: 10 minutes

Subject Information

Target accrual is the proposed total number of subjects to be included in this study at Mayo Clinic. A "Subject" may include medical records, images, or specimens generated at Mayo Clinic and/or received from external sources.

Target accrual: 50 historic patients for baseline metric; 50 current intervention patients to undergo simulation session.

Subject population (children, adults, groups): Adult

Inclusion Criteria: Baseline normal neurological function pre-operatively, planned use of mechanical ventilator with endotracheal tube post-operatively after planned cardiothoracic surgical procedure. Age: greater than 18 and less than 60.

Exclusion Criteria: Chronic dementia, Alzheimer's disease, or other chronic neurological disease (i.e. Bi-Polar). Chronic use of neurological altering medications such as benzodiazepines, psychotropic, anti-depressants, anxiolytics. Patient undergoing emergent surgery. Use of post-operative cardiopulmonary support devices such as ECMO (extracorporeal membrane oxygenation), intra-aortic balloon pump, total artificial heart, or other similar device. Age greater than 60; Age less than 18. Previous admission to an intensive care unit (intervention patients).

Review of medical records, images, specimens

☒ The study involves data that exist at the time of IRB submission **and** data that will be generated after IRB submission. Include this activity in the Methods section.

Examples

- The study plans to conduct a retrospective chart review and ask subjects to complete a questionnaire.
- The study plans to include subjects previously diagnosed with a specific disease and add newly diagnosed subjects in the future.

Data Analysis

Power analyses may not be appropriate if this is a feasibility or pilot study, but end-point analysis plans are always appropriate even if only exploratory. Provide all information requested below, or provide justification if not including all of the information.

Power Statement: Based on the literature indicating incidence of post-operative delirium in the post cardiothoracic surgical population and initial power analysis calculations, initial calculations indicate sample size of approximately 30 patients. Therefore, to accommodate for patient loss to follow-up will aim for sample size of 50 patients.

Data Analysis Plan: A comparative analysis of the outcome metrics described in the "Study Design and Methods" section will be completed between the pre-implementation baseline data and the post-implementation intervention data. This analysis will evaluate the effect of the multi-sensory ICU simulation experience on post-operative delirium in the cardiac surgical population. An additional post-implementation interview/survey will be conducted on post-intervention patients as described above.

Endpoints
Primary: Study to end when sample sizes are obtained.
Secondary: None.