Protocol #: 23-2470
Project Title: Postoperative Utilization of Incentive Spirometry with and without Electronic Patient Reminders
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I. Hypotheses and Specific Aims: The purpose of this study is to determine if the frequency of patients' use of incentive spirometry after surgery increases with visual and auditory electronic reminders, as compared to the no signal cohort. The short-term hypothesis is that patient performance of incentive spirometer (IS) (defined as frequency of adequate volume breaths) will be greater with the electronic reminders than without them (usual care). The long-term goal is to test whether improved patient performance of IS therapy after surgery is associated with reduced postoperative pulmonary complications (PPCs) and improved outcomes. Quantitative monitoring of IS use by patients will be measured the InSee device, which records the total number of inspiratory breaths achieved as well as the proportion of recorded breaths that patients have successfully completed.

II. Background and Significance: Surgical patients who develop atelectasis, pneumonia, and other pulmonary complications postoperatively have extended hospitalizations, higher morbidity, and mortality[1,2]. Incentive spirometry (IS) is routinely prescribed to patients after surgery to prevent atelectasis, hypoxemia, and pneumonia[3-10]. An incentive spirometer is a hand-held device that includes a mouthpiece and two columns with movable pistons that change position in response to inspiratory effort and volume. When used appropriately, IS is an effective strategy to optimize lung expansion and attempt preventing atelectasis. Although its value for preventing pulmonary complications has been questioned[11-13], all authors agree that the lack of significant benefit may be related to its implementation[14]. Indeed, its effectiveness heavily depends on patient adherence to therapy both in quantity (how often they use it) and quality (how deep individual breaths are)[14,15].

Patient compliance with recommendations of IS volume and frequency are key for its effectiveness, but IS performance in most studies is consistently poor or not reported[9,15]. As evidence of this, when adherence to incentive spirometry instructions are adequate patients experience reduced pulmonary complications, shorter length of stay and decreased readmissions[4,6]. Reasons for poor performance with IS recommendations of frequency and volume are multifactorial, and include expected postoperative symptoms like pain, nausea, and fatigue[16]. Of note, these are the very same symptoms that promote shallow breathing patterns and promote atelectasis after surgery, and thus addressing them is imperative to improve the ability of patients' to use IS devices as recommended.

An additional perceived reason by providers for patients inadequate IS use is forgetfulness, which after surgery is justified by residual sedation, frequent use of intravenous opioid analgesics, etc[16]. Therefore, testing the feature of automatic IS reminders as programmed and recorded by the InSee device is critical to confirm whether automatic reminders improve patient adherence to IS instructions. Only when IS orders are followed as recommended we will know its clinical effectiveness and potential impact to improve patients outcomes. In this project, we will test whether automatic reminders of IS use increase patient performance in the post-anesthesia care unit (PACU). This immediate and relatively short postoperative period poses intense barriers for IS performance (pain, residual sedation, administration of potent intravenous opioids, etc.) but a previous study suggests that adequate IS performance in the PACU can have a significant impact on the pulmonary outcomes of high risk patients beyond transfer to the floor[17].

III. Preliminary Studies/Progress Report: This will be our first attempt to test using electronic reminders of IS use with the InSee device. No preliminary studies are available.

IV. Research Methods

A. Outcome Measure(s):

Primary Outcomes
The primary outcome will be the rate of adequate incentive spirometry breaths by patients during the PACU stay. We will compare the hourly rates of adequate IS breaths by patients receiving the electronically monitored incentive spirometer with audible and visual reminders either enabled ("ON") or disabled ("OFF). Use compliance will be recorded and analyzed, separately by (a) the total number of inspiratory breaths achieved per hour, and (b) the number of successful attempts per hour.

Secondary Outcomes
Secondary outcomes will include: (a) the time it takes for the patient to achieve the first successful IS breath, starting from the moment after providing the IS device with instructions of use; (b) the postoperative length of oxygen (O_2) use; (c) the SpO2/FiO2 at discharge from PACU adjusted to the SpO2/FiO2 at admission into PACU; (d) the frequency of patients presenting, during the studied (PACU) period, any pulmonary complications (including, among others, pneumonia, hypoxemia defined as SpO2 <90%, need for non-invasive ventilation, e.g., CPAP/BiPAP, reintubation for respiratory reasons, bronchospasm, etc.); (e) the frequency of patients requiring ICU admission immediately after the PACU stay for respiratory reasons; (f) length of PACU stay.

B. Description of Population to be Enrolled:

The sample population will include up to 300 total patients (half in the alarms "ON" group, half in the "OFF" group), who require inpatient acute care, prescribed incentive spirometry, and meet all of the following inclusion criteria and none of the exclusion criteria provided.

Inclusion Criteria
Patients must meet all of the following inclusion criteria in order to participate in the study:

- be 18 years or older;
- have undergone a surgical procedure at the University of Colorado Hospital under general anesthesia;
- have incentive spirometry ordered by their provider, or incentive spirometry must be part of the study site's standard-of-care which is implemented by hospital staff;
- not have severe hearing or impaired visual acuity deficiency, in that they cannot hear or see the audible and visual signal of the InSee monitor.

Exclusion Criteria
The patient may not participate in the study if they meet any of the following criteria:

- have a severe hearing or visual acuity impairment that prevents them from hearing or seeing the audible and visual signals of the InSee monitor;
- inability to perform incentive spirometry due to refusal, cognitive impairment, neuromuscular weakness, anatomical or any other reasons (e.g., tracheotomy, oral surgery, unable to hold incentive spirometry device);
- are a part of a vulnerable population (e.g., pregnant, minors, prisoners).

C. Study Design and Research Methods:

Study Design. This is a ***pragmatic single-center alternating cohort study*** of surgical patients receiving incentive spirometry devices during their PACU stay with automatic

alarms in the InSee monitor either “ON” or “OFF” in alternating weeks. All patients will receive the same incentive spirometry instruction at their arrival to PACU. The **hypothesis** is that patients receiving automatic audible and visual alarms will have increased rates of successful incentive spirometry breaths compared to patients receiving no alarms.

Research Methods. All eligible patients arriving to the PACU every day will be provided with an Vyaire Medical’s AirLife™ volumetric incentive spirometer and instructions to perform 3 IS breaths every 20 minutes until discharge from PACU. The IS device will be set up with the breath volume considered adequate based on recommendations for each patient’s gender, age and height. The bottom of the IS device will be attached to the InSee monitor. The InSee monitor will be removed when the patient is transferred to the floor, and they will keep the IS device only as per usual care protocol at the University of Colorado Hospital. PACU discharge and disposition will be decided strictly by the patient’s clinical team. Participation in this study will not prolong or affect in any manner the care provided in the PACU.

In alternating days, all patients will have the InSee monitor with either auditory and visual notification signals “ON” or “OFF”:

- The ***“ON” cohort*** will receive the standard-of-care instructions for IS and information about the InSee monitor auditory and visual reminders. The “ON” cohort patients will receive audible and visual signals from the InSee monitor every 20 minutes and upon successfully reaching certain achievements.
- The ***“OFF” cohort*** will receive only the standard-of-care instructions for IS. The “OFF” patients will receive no signals from the InSee monitor.

The ***InSee monitor*** uses an infrared sensor which tracks the movement of the spirometer’s piston, whose movement measures the volume of air that is inhaled. Using time-of-flight calculations cylinder movement is converted to tidal volume, which is the volume of air moved with each breath and is a key marker of respiratory function. As the patient uses the IS device, the attached InSee accessory monitors the tidal volume and how many times a patient reaches the programed goal target tidal volume. This data, along with other parameters (Table 1) that the InSee device collects is stored in the instrument.

Table 1. Data stored by the InSee Monitor

Date and Time
Number of attempts above 250 mL
Number of successes
Target goal inhaled volume (L)
Maximum tidal volume (L)
Alarm frequency

For each patient, the InSee monitor will record the total number of IS breaths performed by the patient and the number of them that were of adequate volume as pre-set. Adequate or successful IS breaths will be considered as ≥50% of the estimated IS volume for each patient. We will extract this information at the end of the PACU stay and calculate the hourly rate of adequate inspiratory breaths (= adequate number of IS breaths / PACU duration (hours)). We will compare the hourly rates of adequate IS breaths by patients in the “ON” and the “OFF” cohorts. We will also collect data related to clinical course and respiratory therapies needed as well as PACU length of stay and need for transfer to the ICU, as described in the secondary outcomes section. We will compare these variables for the “ON” and “OFF” cohorts.

D. Description, Risks and Justification of Procedures and Data Collection Tools:

Instructions to Subjects

- ***Instructions about IS <u>for both cohorts</u>*:** The patient is instructed to sit upright, close their lips tightly around the mouthpiece of the incentive spirometer, to exhale, then to slowly inhale as deeply as possible. The patient must only breathe through their mouth for the IS device to function correctly. The patient is given instructions about the spirometer columns that measure inspiratory volume and effort. The patient will be instructed to perform inspiratory breaths that reach the pre-specified goal based on their gender, age and height, and to perform 3 of these breaths every 20 minutes.
- ***Instructions about the InSee monitor alarms <u>for the "ON" cohort only</u>***: The patient will be instructed that a timer will remind them when to use IS via a blinking red LED and audible signal in the InSee monitor. The patient is instructed that this signal stops once they use the IS device. The patient will also be instructed that an additional audible signal and a blinking green LED indicates successful achievement of the "goal" tidal volume. This success alarm is different than the alarm of inactivity.

IS device and InSee monitor

All subject will be provided with an AirLife™ volumetric incentive spirometer attached to a pre-programed InSee monitor, with either the alarms enabled or disabled. They will have this IS until the rest of the hospital stay, but they will only have the InSee attachment until the end of the PACU stay. The InSee monitor is a patented incentive spirometer accessory that quantitatively tracks many parameters (Table 1) including patient inspiratory attempts and successes, time of use, volumetric goals, and usage frequency of the IS device attached to the InSee monitor. No protected health information (PHI) is entered into or stored by the InSee monitor. The US FDA has determined that the InSee monitor represents a non-significant risk (NSR) device. The InSee monitor represents minimal risk to study patients.

Data Collection

The data to be collected manual from the electronic medical record is as follows: the patient's study ID (deidentified); cohort assignment (intervention vs. control); date of enrollment; age; sex; height; weight; surgical procedure; total opioid doses administered during the PACU stay; any neuromuscular reversal agent administered for suspected residual weakness; early discontinuation from using the IS device or the study and reason (if applicable); oxygen supplementation details during PACU stay and at discharge; pulmonary complications observed such as hypoxemia, atelectasis, pneumonia, bronchospasm, need for non-invasive ventilatory support (e.g., CPAP, BiPAP, etc.) or reintubation for respiratory reasons; any clinical events occurring during the study period in PACU; PACU length of stay; disposition after PACU (home, floor, ICU or other high-level unit of care; adverse events, serious adverse events, unexpected events or unanticipated device events will be recorded and graded in their severity and relatedness to the InSee monitor by the PI.

Data from the InSee monitor will be collected from the study device and uploaded to a study-specific database housed at the University of Colorado REDCap. All other study data will be entered manually on the provided case report forms (CRFs) and then transferred to REDCap. The manufacturer of the monitor (Tidal Medical) will provide training and technical assistance to the investigator and site staff on the procedural application, intended use, and performance characteristics of the investigational device.

Risks

- ***Immediate risks*** are considered minor and include mild fatigue, or incisional pain caused by patient overexertion while performing incentive spirometry. There are no associated long-term risks. The described immediate risks are associated with the use

of an incentive spirometer and they would be difficult to ascribe to the InSee monitor specifically. They are common immediately after surgery and require close monitoring and nursing care, which is the reason PACU is a mandatory phase of care for all surgical patients before they are transferred to the floor, higher level of care (ICU or Step-Down Unit) or are they are ready to be discharged home or back to a nursing facility. Nonetheless, if any of these events are greater than mild to moderate, patients can voluntarily refrain from using IS until they are able to continue. The risk of any adverse events or unanticipated device effect, or adverse events are extremely low because no invasive testing or intervention is associated with this study, the InSee monitor, or incentive spirometry. The InSee monitor has no patient interface, and will be thoroughly wiped cleaned following manufacturer's instructions before and after any contact with patients.

- The risk of ***loss of confidentiality*** to patients is low, but we will take any precautions possible to minimize this risk. Each participant will be provided with a study code or ID, but no PHI other than the date of surgery will be collected from any participant. Subject confidentiality is strictly held in trust by the participating investigators and participating staff. The study protocol, documentation, data, and all other information generated will be held in strict confidence and handled following COMIRB regulatory recommendations. No information concerning the study will be released to any unauthorized third party without prior written approval of the PI.

E. Potential Scientific Problems: Since no preliminary data is available for the InSee monitor, this is a pilot study and performing a power analysis is not feasible. Thus, it is possible that our study will not be powered to detect differences in clinical outcomes or hospital resource utilization, which is why we are focusing this first study on the clinical effectiveness of the InSee monitor to increase patient adherence to IS recommendations of quantity and quality. If we confirm that the InSee monitor alarms is effective to successfully achieve adequate patient performance of IS, we will design future studies to evaluate the long-term clinical impact of IS with the InSee monitor.

F. Data Analysis Plan: The data will be extracted and graphically and numerically summarized. We will compare the primary and secondary outcomes between both cohorts using by bivariable and multivariable logistic regression analyses, as appropriate. We will evaluate if the hourly rates of adequate IS use is greater in patients with the auditory and visual alarms enabled compared to patients with alarms disabled.

G. Summarize Knowledge to be Gained: We will evaluate if patients' use of IS devices increases with the presence of visual and auditory electronic reminders, as compared to the no signal cohort. Quantitative monitoring of adequate IS performance will be measured using the InSee monitor, a device used to measure the total number of inspiratory breaths achieved as well as the proportion of successfully completed inspiratory breaths. This is important to later determine if following the IS recommendations can reduce pulmonary complications and improve clinical outcomes.

H. References:

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