INTEGRATED PULMONARY INDEX COMPARED TO PULSE OXIMETRY IN IDENTIFYING OPIOID-INDUCED RESPIRATORY DEPRESSION

by

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A capstone project proposal submitted to the School of Nursing The State University of New York at Buffalo In partial fulfillment of the requirements for the degree of Doctor of Nursing Practice

May 2018
DNP Capstone Project Approval Form

This is to certify that

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Integrated Pulmonary Index Compared to Pulse Oximetry in Identifying Opioid-Induced Respiratory Depression

on

April 20

(Date)

2018

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Acknowledgments

I would like to thank the numerous people who have contributed to the completion of my capstone. Each played an indispensable role and was essential to the successful defense of this project.

First, I would like to thank my capstone partner, Justin Mullaney. He was a critical member of this project and did an outstanding job in remaining composed and diligent through each step of the capstone process. His interpersonal skill directed the communication among hospital administrators, surgeons, and nursing personnel. He has been the motivating force towards the successful completion of our capstone project.

I would also like to thank my capstone advisors, Dr. Campbell-Heider and Dr. Spulecki for their guidance and advice throughout this project. They were helpful in ensuring I remained on track and that everything was completed professionally. They were always available when questions were raised and assisted in the editing of all capstone materials. I want to especially thank Dr. Spulecki for attending all of our meetings at the Sisters of Charity Hospital (SOCH).

The support of the personnel at SOCH was an essential aspect in the completion of this project. I would like to thank Dr. LaPointe and Dr. Falcone for allowing us to work with them. I would also like to thank Mary Young for coordinating our data collection with the anesthesia and nursing staff. All the individuals at SOCH were valuable resources that provided operating room schedules, medical records, and approval to conduct the research.

Last but not least, I want to thank my family for their support through this entire process. They have been a tremendous source of strength and inspiration. They have remained by my side through this entire time, and none of this would have been possible without their love and encouragement.
Abstract

**Problem under investigation:** Despite the frequency of opioid use throughout the perioperative period, there are no universally accepted guidelines to directly monitor respiratory depression.

**Objective:** Compare the effectiveness of the Integrated Pulmonary Index (IPI) to pulse oximetry (SpO2) in detecting Opioid-Induced Respiratory Depression (OIRD).

**Background Literature/Theoretical Framework:** There is vast research supporting the use of IPI for respiratory monitoring. Roy’s adaptation model provides the theoretical basis needed to utilize IPI and guide postoperative analgesic regimens.

**Project Methods:** Obtain preoperative IPI and SpO2 baselines from the subjects and monitor the number of OIRD instances postoperatively.

**Data Analysis:** A Spearman’s correlation was run to determine the relationship between the IPI and SpO2 values. The Friedman’s test was utilized to determine the difference in specificity of the monitoring tools. The Wilcoxon signed-rank test was used to compare monitoring precision between grouped variables.

**Results:** There is a positive correlation between IPI and SpO2, which is significant (r=0.519, p=0.003). The Wilcoxon Sign-Rank test did not find a difference in the precision between SpO2 and IPI.

**Conclusion:** IPI and SpO2 demonstrate a positive correlation for detecting OIRD postoperatively in orthopedic patients undergoing total knee or hip replacement.
Introduction/Background

The idea for this capstone was developed during my rotation at the Community General Hospital in Syracuse, NY. Within the facility, the majority of orthopedic procedures were managed with spinal anesthesia, peripheral nerve blocks, monitored anesthesia care and multimodal analgesics. Postoperatively these patients had a faster recovery, were less sedated and most importantly required fewer opioids. When comparing the anesthetic management of orthopedic patients from Syracuse to Buffalo, NY, the patients in Buffalo required more postoperative opioids. The excess of opioid administration can prolong recovery and even lead to opioid-induced respiratory depression (OIRD).

In the postoperative period, acute pain is routinely addressed using opioid analgesics. However, they have a number of side effects, of which, respiratory depression is potentially the most life-threatening (Dahan, Overdyk, Smith, Aarts, & Niesters, 2013). Postoperative OIRD is one of the leading causes of death and brain damage in the perioperative period (Lee et al., 2015). In the Joint Commission’s review of opioid-related events from their Sentinel Event Database from 2004 to 2011, improper monitoring after opioid use occurred in almost one-third of the events (Lee et al., 2015). As the complexity of analgesic therapies increases, priorities must be established to balance aggressive pain management, prevent adverse events, and to ensure high quality and safety of care (Jarzyna et al., 2011).

Despite the frequency of opioid use, there are still gaps in practice because there are no universally accepted guidelines to direct effective assessment and monitoring practices for patients (Jarzyna et al., 2011). There is a growing consensus that opioid-related adverse events are multifactorial and potentially preventable with improvement in the assessment of sedation and monitoring of oxygenation and ventilation (Lee et al., 2015). By determining which of these
monitoring parameters is most effective, patient outcomes may be improved and the practice of administering opioids as the first line therapy decreased.

Postoperative orthopedic patients receiving total hip and/or knee replacements can benefit from an improved method of OIRD monitoring. Currently, such patients are transferred from the operating room to the postoperative anesthesia care unit (PACU) and monitored for standard vital signs (heart rate, blood pressure, pulse oximetry and respiratory rate). Universal, continuous pulse oximetry surveillance has been shown to improve outcomes in a postoperative orthopedic setting (Curry & Jungquist, 2014). However, the use of a more sensitive and easily implemented assessment system, such as the IPI, is hypothetically superior in detecting OIRD. The Integrated Pulmonary Index (IPI), is a numerical value that is based on an algorithm that integrates four parameters: end-tidal carbon dioxide (EtCO$_2$), respiratory rate (RR), pulse oximetry (SpO$_2$), and pulse rate (PR), in the form of a single value ranging from 1 to 10 and displayed on a monitor (Vaessen & Knape, 2016). The IPI could potentially detect changes in a patient’s respiratory status early enough to allow for an intervention by the practitioner (Vaessen & Knape, 2016). Comparing the effectiveness of SpO$_2$ versus IPI monitoring in the total knee and hip replacement patient population is essential in improving the early detection and prevention of OIRD, as well as overall patient care.

**Literature Review**

The review of literature identified several studies that support a growing consensus that opioid-related adverse events are multifactorial and potentially preventable with improvements in the assessment of sedation levels and monitoring of oxygenation and ventilation (Lee et al., 2015). Curry & Jungquist (2014), reviewed the Dartmouth-Hitchcock Medical Center’s Patient Surveillance System (PSS), which required that all patients on the postoperative orthopedic unit...
be electronically monitored with continuous pulse oximetry, and that all threshold breaches to be transmitted to the caregivers in charge. This trial began as a before-and-after concurrence study with data analyzed pre- and post-intervention for the PSS unit and compared with two other units that care for surgical patients (Curry & Jungquist, 2014). The trial ultimately demonstrated that universal continuous pulse oximetry surveillance could improve outcomes on a postoperative orthopedic ward and that these results may hold true for other postoperative settings (Curry & Jungquist, 2014). Jungquist, Willens, Dunwoody, Klingman, and Polomano (2014) reviewed data from a long-term survey of the members from the American Society for Pain Management Nursing (ASPMN). The online survey used was sent electronically, and ASPMN members were invited via e-mail to participate. The study reviewed monitoring practices designed to avoid adverse events secondary to OIRD. It included representatives from 102 hospitals, located in 36 of the 50 states and one Middle-Eastern country. The survey showed that 28% of institutions used continuous pulse oximetry for all patients on intravenous patient-controlled analgesia therapy and some institutions used more than one type of monitoring device. However, more than half of the institutions surveyed did not implement any monitoring practices (Jungquist et al., 2014). Nevertheless, both of the studies revealed that there is still a need to bridge the gap between knowledge and practice.

The literature review also identified different methods of utilizing the IPI. Alotaibi and Restrepo (2014) evaluated the clinical correlation between the Capnostream IPI and results from arterial blood gases obtained in the Intensive Care Unit (ICU) by prospectively recording the IPI from 21 patients who were mechanically ventilated in the ICU. A total of 64 patient ventilator events were selected for their analysis as these events were the only ones that contained both the IPI and arterial blood gas (ABG) values (Alotaibi & Restrepo, 2014). The results indicated that
the mean IPI for the 64 events analyzed were consistent with the interpretation of the respiratory status reflected by the ABG values (Alotaibi & Restrepo, 2014). This study provides clinicians the opportunity to use the IPI as a more dynamic measure of the patient’s overall respiratory status. Kumar, Taft, Herrington, Whiddon, and Castresana (2013), determined the specificity of the IPI when weaning obese patients from mechanical ventilation after cardiac bypass surgery. They hypothesized that the IPI would be higher during successful spontaneous breathing trials (SBT) than unsuccessful SBT. The observational test was performed on mechanically ventilated patients in the surgical intensive care unit. All subjects were evaluated for weaning per hospital protocol, and the clinicians were blinded to the IPI. The researchers recorded data that was averaged over the first 30 minutes of SBT and analyzed the ability of the IPI to predict weaning evaluation outcomes. They concluded that the IPI values were indeed higher in successful SBTs, but larger sample sizes were needed to clearly define the value of the IPI (Kumar et al., 2013).

Voscopoulos, Theos, Hein, and George (2017) conducted a study to analyze the implementation of a postoperative non-invasive respiratory volume monitoring (RVM) tool to improve the detection of OIRD. They believed that SpO2 is a lagging indicator of respiratory depression and EtCO2 to be unreliable in non-intubated patients (Voscopoulos et al., 2017). In this study, all monitoring and clinical data were collected preoperatively, during surgery, and throughout the entirety of the PACU stay. Perioperative patient care was provided according to standard practice by clinical staff that were blinded to the measurements (Kumar et al., 2013). They found that the RVM tool was able to identify patients at risk for OIRD and may serve as a guide for opioid dosing.

The purpose of this capstone was to determine whether IPI or SpO2 has a greater specificity in detecting OIRD for postoperative patients undergoing orthopedic surgical
procedures. Various studies have reported that opioid-related adverse events are potentially preventable with improvements in the assessment. The use of the IPI has been reported to be consistent with respiratory status reflected by the ABG values, and continuous pulse oximetry has improved outcomes on a postoperative orthopedic unit. The implementation of adequate respiratory monitoring along with an appropriate theoretical basis could potentially improve outcomes, enhance patient safety, and improve the efficiency of care.

**Theoretical Framework**

Human beings constantly interact with environmental stimuli, which can either threaten or enhance an individual’s ability to adapt (Phillips & Harris, 2014). Roy’s Adaptation Model (RAM) provides an effective framework for addressing the adaptive needs of postoperative orthopedic patients. The RAM seeks better methods and tools for assessing and promoting adaptation. The tools utilized in this capstone were the IPI and SpO₂. The detection of OIRD can serve as a guide for administering postoperative analgesics and to allow patient adaptation to pain. The postoperative environment is a source of various of stimuli that can either threaten or promote an individual's well-being.

According to Roy, an individual does not respond passively to environmental stimuli and adaptation is modulated by his/her coping mechanisms and control processes (Phillips & Harris, 2014). Roy proposed that coping can be observed in any of the four adaptive modes: physiological, self-concept, role function, and interdependence adaptive modes. In this capstone, the investigators primarily examined the physiological adaptive mode, which refers to the way a person responds as a physical being to the environmental stimuli (Phillips & Harris, 2014).

The utilization of RAM in this study will help the participants survive, grow, and master adaptation. The nursing process is a goal-oriented, problem-solving approach to guide the
provision of comprehensive, competent nursing care to a person or a group of individuals (Phillips & Harris, 2014). Roy has conceptualized the nursing process to comprise the following six simultaneous, ongoing, and dynamic steps: assessment of behavior, assessment of stimuli, nursing diagnosis, goal setting, intervention, and evaluation (Phillips & Harris, 2014).

Assessment of Behavior

The exploration and assessment of behaviors allow the nurse to achieve an understanding of the patient’s current adaptation level and to plan interventions that will promote adaptation (Phillips & Harris, 2014). In this capstone, the reaction to the stimulus of opioid analgesics would be an observable physiological change in respiratory status. At the beginning of the nurse-patient relationship, a thorough assessment of behavior must be performed, and the assessment must be ongoing (Phillips & Harris, 2014). As mentioned in the study methods, the investigators will establish the participants’ baseline physiological respiratory status using the IPI and SpO2. After the individuals have undergone their orthopedic surgery, the participants will continue to be monitored on the IPI and SpO2.

Assessment of Stimuli

When assessing stimuli, the investigators are looking for variables that either threaten or promote the person’s well-being. Stimuli that arise from the environment can be classified as focal, contextual, or residual (Phillips & Harris, 2014). Focal stimulus is defined as the internal or external stimulus most immediately challenging the individual’s adaptation. In this capstone, it would be the postoperative pain felt by the participants that would be most challenging to the person’s adaptation. Contextual stimuli are all other stimuli existing in a situation that strengthen the effect of the focal stimulus (Phillips & Harris, 2014). With orthopedic surgery, a variety of anesthetic techniques can be used to manage the case. General anesthesia alone, without the use
of a peripheral nerve block, can contribute to the focal stimulus of postoperative pain. Residual stimuli would be any other phenomena arising from a person’s internal or external environment that may affect the focal stimulus but whose effects are unclear (Roy & Andrews, 1999). The residual stimulus in this study would be the patient’s medical history, perception of pain, administration of postoperative opioids, respiratory depression and the data obtained from respiratory monitoring. The three types of stimulus act together and influence the adaptation level, which is the individual’s ability to respond positively in a situation (Phillips & Harris, 2014).

**Nursing Diagnosis**

A nurse’s education and experience enable him/her to make an expert judgment regarding healthcare and the adaptive needs of the patient (Phillips & Harris, 2014). This judgment is expressed in a diagnostic statement that indicates an actual or a potential problem related to adaptation (Phillips & Harris, 2014). The nursing diagnosis most pertinent to the capstone would be acute pain related to tissue injury secondary to surgical intervention. A secondary nursing diagnosis would be impaired gas exchange related to treatment secondary to sedating effects of opioid analgesics.

**Goal Setting**

Goal setting focuses on promoting adaptive behaviors. Together the nurse and the postoperative patient will agree on desired behavioral outcomes of nursing care (Phillips & Harris, 2014). The outcome should be a balance of adequate pain management, opioid administration, and patient respiratory status.

**Intervention**
According to Roy, interventions focus on the manner in which goals are attained (Phillips & Harris, 2014). A nursing intervention is any action taken by a professional nurse, which he/she believes will promote adaptive behavior by an individual (Phillips & Harris, 2014). The nurse utilizing the IPI will be able to enhance adaptation by evaluating a patient’s respiratory status before treating the focal stimulus of postoperative pain.

Evaluation

In RAM, evaluation consists of determining whether those behavioral changes stated in the goal statement have been achieved by the recipient of nursing care (Roy & Andrews, 1999). In the evaluation phase, the investigators evaluated whether adequate postoperative pain management was achieved when simultaneously monitoring for OIRD.

Methods

Study Design

A quasi-experimental design was used in this proposal. The study took place at a hospital in Buffalo, NY. Thirty elective orthopedic postoperative patients receiving total knee and/or hip replacements received care as usual in addition to being monitoring with the Capnostream IPI and SpO₂ during recovery in the postanesthesia care unit (PACU). The subjects served as their own controls and they were measured with multiple instruments at the same time.

The investigators obtained IPI baselines from the subjects in the preoperative holding area. The baseline IPI value was be defined by an average of 10 consecutive one-minute interval recordings of the IPI. The subjects then proceeded to have their orthopedic surgery. The investigator did not follow or monitor the subjects during their time in the operating room. Following the subject’s operation and arrival in the PACU, IPI, and SpO₂ were recorded at a one-minute interval for an average of one hour or until discharge, whichever occurs first. If the
patient received a dose of opioids, the patient then received an additional 30 minutes of monitoring at a one-minute interval from when the dose was given. During the PACU data collection, the investigators only monitored the number of instances where OIRD was detected.

**Study Population**

Thirty patients over the age of 18 and undergoing elective orthopedic total knee and/or total hip replacement surgery were recruited in the preoperative area. Their age ranged from 44 to 82 years, with 10 males and 20 females. Their comorbidities included chronic-obstructive pulmonary disease, asthma, postoperative nausea/vomiting, chronic opioid use, and home oxygen usage. Exclusion criteria were defined as age less than 18 years old, refusal to participate, and/or the inability to understand and provide informed consent. This also included patients who did speak or read English. Exclusion of non-English speaking individuals was necessary to accurately obtain informed consent with minimal potential for miscommunication or misunderstanding.

**Variables**

The data points captured were from the Capnostream monitor during preoperative assessment for baseline measurements and postoperative assessment in the PACU, as well as narcotic medications and dosages administered within the PACU. Measurements captured by the Capnostream included EtCO₂, SpO₂, heart rate, respiratory rate, and IPI.

Typically, the IPI scores are divided into 3 groups: high IPI (score level 7–10) indicating that the patient was in a normal range, medium IPI (score level 4–6) signifying that the patient required attention, and low IPI (score level 1–3) representing that the patient required immediate intervention (Vaessen & Knappe, 2016). In this study, a 20% decrease from baseline indicated mild OIRD, a 30% decrease from baseline indicated moderate OIRD, and a 50% decrease from
baseline indicated severe OIRD. Normal pulse oximetry saturation ranges are between 97% and 99%, although some people, especially long-term smokers, may have a SpO₂ between 93% and 95% (DeMeulenaere, 2007). Readings of 90% or less may indicate that the patient may need supplemental oxygen and further tests as confirmation of hypoxia (DeMeulenaere, 2007). In this study, a 3% decrease from baseline measures indicated mild OIRD, a 5% decrease from baseline indicated moderate OIRD, and a 7% decrease from baseline indicated severe OIRD. This study examined the total number of OIRD instances detected with the Capnostream IPI compared with SpO₂.

**Data Analysis**

The study utilized Spearman’s Rank-Order correlation to measure the strength and direction of association that existed between the sample characteristics. When using Spearman’s correlation, the data set must fulfill two assumptions. First, the variables must be measured on at least an ordinal scale (Laerd, 2013); the IPI is measured on an interval scale, while the SpO₂ is measured on a ratio scale. The second assumption is that there is a monotonic relationship between the two variables—a monotonic relationship exists when the variables increase in value together, or when one variable value increases, the other variable value decreases (Laerd, 2013). To confirm this relationship, IPI was compared to SpO₂ on a scatterplot. The results revealed a positive monotonic relationship.

The data was also analyzed using the Friedman’s test and the Wilcoxon Signed Rank test. Friedman’s test is the non-parametric alternative to the one-way ANOVA with repeated measures and is utilized to test for differences between variables (Laerd, 2013). To correctly employ Friedman’s test, our data must follow four assumptions. First, one group must be measured on three or more different occasions (Laerd, 2013); for this study, both the IPI and SpO₂ on average
were measured 60 times postoperatively. Second, the group is a random sample from the population; our study participants were randomized and not individually selected. The third assumption is that the dependent variables should be measured at least on an ordinal level (Laerd, 2013); as stated earlier, this assumption has been met. The last assumption is that the variables do not need to be normally distributed (Laerd, 2013); both the IPI and SpO2 were plotted on histograms showing a non-normal distribution.

Lastly, the Wilcoxon Signed-Rank test was utilized to understand whether there was a difference between two sets of variables that came from the same participants (Laerd, 2013). Using the Wilcoxon Signed-Rank test required three assumptions. First, the dependent variables need to be at least measured on an ordinal scale; this assumption has been met with the previous two statistical measures. Second, the same subjects are present in both groups (Laerd, 2013); the study incorporated 30 participants, and each participant’s IPI was compared to the SpO2 from the same patient. The third assumption requires a symmetrical distribution between the two related groups (Laerd, 2013); the histograms from the IPI and SpO2 data both showed a symmetrical positive skew and were read as non-normal.

Results

There were a total of 30 participants without missing data measures. Age ranged from 44 to 82 years, with a total of 10 males and 20 females. Comorbidities included chronic-obstructive pulmonary disease, asthma, postoperative nausea/vomiting, chronic opioid use, and home oxygen usage. OIRD events were defined by IPI less than 7 and SpO2 less than or equal to 93%. The mean preoperative IPI was 8.93, sd=0.785 (Table 1). All of the patients scored greater than seven on their preoperative indicating a normal respiratory status and not OIRD. Ten of the 30 (33%) of the postoperative patients did not have measures indicative of OIRD, IPI less than 7.
Neither the SpO₂ (Table 2) nor the IPI (Table 3) showed a normal distribution; they both showed a positive skew and were read as non-normal.

Spearman’s Correlation

A Spearman's rank-order correlation was run to determine if a relationship exists between the IPI, and SpO₂ values. There was an intermediate, positive correlation between IPI and SpO₂, which was statistically significant \( r=.519, p=0.003 \) (Table 4).

Friedman’s Test

A Friedman’s test was run to utilized to analyze the specificity between IPI, and SpO₂ in detecting OIRD. There was a statistically significant difference between the specificity of IPI, SpO₂, & EtCO₂ for OIRD incident counts, \( \chi^2(2)=14.894, p<0.001 \). While the analysis showed a statistical difference, the findings did not pinpoint which groups in particular differed from each other.

Wilcoxon Signed-Rank Test

To examine where the differences actually occurred, the Wilcoxon signed-rank test was run on different combinations of related groups. The following combinations were compared: SpO₂ to EtCO₂, SpO₂ to IPI and EtCO₂ to IPI. A Bonferroni adjustment was made on the results we obtained from the Wilcoxon test because there were multiple comparisons, which made it more likely to falsely declare a result significant (Type I error). The Bonferroni adjustment was calculated by taking the significance level (0.05) and dividing it by the number of tests ran. In this case, we achieved a new significance level of \( 0.05/3 = 0.017 \). In Table 5, we can see that at
the $p<0.017$ significance level, the comparison between $\text{SpO}_2$ and $\text{EtCO}_2$ ($p=0.003$) and that between $\text{EtCO}_2$ and IPI ($p = 0.001$) were both significantly different.

[Insert Tables 5 here]

**Discussion**

Preoperative IPI data was obtained from all participants undergoing elective orthopedic surgery. The participants presented with comorbidities ranging from chronic-obstructive pulmonary disease, asthma, postoperative nausea/vomiting, chronic opioid use, and home oxygen usage. Despite comorbidities that may indicate a greater risk for OIRD, none of the patients scored less than seven on their preoperative IPI. The data collected on this variable provides weak support of the IPI as a predictor for postoperative OIRD.

The investigators also compared the sensitivity of the IPI to $\text{SpO}_2$ for detecting OIRD in the immediate postoperative period. OIRD measurements were defined prior to the study utilizing a thorough literature search on each monitoring instrument. These parameters were defined as an $\text{SpO}_2$ less than or equal to 93%, and an IPI score less than seven. IPI and $\text{SpO}_2$ demonstrated a positive correlation and statistical sensitivity for detecting OIRD. They recorded a total of 1,131 OIRD incidences, with the IPI identifying 42% and $\text{SpO}_2$ 50%. Spearman’s rank-order correlation was used to compare the IPI and $\text{SpO}_2$ measurements; the resulting correlation between IPI and $\text{SpO}_2$ was strong and positive, as well as statistically significant. This variable resulted in statistical significance based on the similarity of OIRD detection with either IPI or $\text{SpO}_2$. The data collected on this variable provides strong support for the use of IPI or $\text{SpO}_2$ in detecting postoperative OIRD.

To further confirm our findings, the Friedman’s test was utilized to verify that there was a statistically significant difference among the specificity of IPI, $\text{SpO}_2$, and $\text{EtCO}_2$ in detecting
OIRD. The monitoring devices were found to be different for OIRD incident counts. Although the analysis showed there is a difference in monitoring precision, the findings did not pinpoint which monitoring tools in particular differed from each other. The Wilcoxon signed-rank test was then applied to examine where these differences occurred. We compared the specificity of SpO$_2$ to EtCO$_2$, SpO$_2$ to IPI and EtCO$_2$ to IPI. The comparison indicated that there was a significant difference in detection between SpO$_2$ and EtCO$_2$ ($p=0.003$), and between EtCO$_2$ and IPI ($p=0.001$). The Wilcoxon signed-rank test did not find a statistically significant difference in precision between SpO$_2$ and IPI. The data collected on this variable also provides strong support for the use of IPI or SpO$_2$ in detecting postoperative OIRD.

Opioid-related adverse events are multifactorial and potentially preventable with improvements in the assessment of sedation levels, monitoring of oxygenation and ventilation (Lee et al., 2015). Postoperative monitoring with the IPI and SpO$_2$ are variables that greatly contribute to the detection of OIRD after a surgical procedure. Research with substantial clinical significance, as this project has, should be communicated to various facilities and used to facilitate the incorporation of postoperative IPI or SpO$_2$ monitoring into clinical practice.

**Implications for Nursing**

Despite study participants presenting comorbidities that would place them at a higher risk for postoperative OIRD, preoperative IPI testing did not detect respiratory depression. The potential implications for practice as a result of this study include the exclusion of preoperative IPI as a predictor for postoperative OIRD. The results showed that the use of SpO$_2$ has been a reliable method for monitoring patients in the PACU, despite the fact that current literature describes SpO$_2$ as a late indicator of respiratory depression (Voscopoulos et al., 2017). Surgical facilities may consider the use of the IPI as an additional monitoring instrument in the PACU to help
prevent patients from suffering adverse outcomes associated with OIRD. The study also identified zero incidences of OIRD as per IPI with the one patient who received a spinal anesthetic. Further investigation into spinal anesthesia and multimodal pain management for orthopedic procedures is warranted.

**Strengths and Limitations**

The tools used in this study to measure OIRD are the IPI and SpO$_2$. Ronen, Weissbrod, Overdyk, and Ajizian (2017) tested the strength of the IPI in a retrospective analysis obtained from 523 patients in a variety of clinical settings. The IPI correlated well with the expert interpretation of the continuous respiratory data ($R = 0.83$, $p < 0.001$), with an agreement of $-0.5 \pm 1.4$ (Ronen et al., 2017). The receiver operating curves analysis resulted in high levels of sensitivity (ranging from 0.83 to 1.00), with a corresponding specificity (ranging from 0.96 to 0.74) (Ronen et al., 2017). Ronen et al., 2017, concluded that the IPI reliably interpreted the respiratory status of patients in multiple areas of care. In addition, pulse oximetry has been a standard tool in the evaluation of a patient’s oxygenation status and has been routinely used in many areas of clinical practice (DeMeulenaere, 2007). Oxygen saturation that is calculated by pulse oximetry has a 95% confidence rate of ±4%, so oximetry is considered to be reliable at readings that range between 70% and 100% (DeMeulenaere, 2007).

While the results of the data analysis supported the use of IPI in detecting postoperative OIRD, it is important to mention the limitations of the study. An initial limitation of the study involves the data collection method. PACU staff member were aware of the investigators monitoring patients for OIRD, which may have influenced their guide postoperative analgesic regimens. The study was also limited by the sample size, the dominant postoperative orthopedic population and will need further testing to generalize results.
Ethical Considerations

To minimize ethical issues, this study was conducted following the approval from the University at Buffalo’s institutional review board, and written informed consent from each patient. To further ensure the protection of human subjects, each subject enrolled in this study will received standard care and the investigators did not perform any additional interventions. The consented subjects received the standard hospital protocol, and hospital clinicians were blinded to the IPI. This helped to ensure that there would be no deviation from the standard of care. During the data collection period, the investigators monitored the instances of OIRD and only intervened when a patient was in imminent danger as deemed by the investigators.

Conclusion

The preoperative baseline results from the study did not find the IPI as a reliable indicator for postoperative OIRD. All 30 participants in the study scored ≥7, despite having comorbidities that would indicate a higher level of risk. The postoperative results, however, revealed a statistically significant correlation between the IPI and SpO₂. When monitoring postoperative total knee and/or hip patient, 1,131 incidences of OIRD were recorded. Of these, 42% were recorded with using the IPI, 50% using SpO₂, and 8% using EtCO₂. All three aspects of the data analysis also correlated the specificity of the IPI with SpO₂. By providing additional data on the monitoring of postoperative OIRD, the results of this study are significantly beneficial to the hospital setting where the study was performed. The results could encourage the utilization of the IPI as a guide to postoperative analgesic regimens. The findings also serve as a valuable tool for educating surgical facilities regarding OIRD and for them to consider the IPI as an additional monitoring instrument in the PACU.
References


Table 1

*Frequency of Preoperative IPI*

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Table 2

*Postoperative Frequency of OIRD Measured with SpO₂*

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Table 3

*Postoperative Frequency of OIRD Measured with IPI*

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<tr>
<th>Frequency</th>
<th>Percent</th>
<th>Valid Percent</th>
<th>Cumulative Percent</th>
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Table 4

*Correlations for OIRD Incidents by Type of Measurement Device*

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<tr>
<th>Spearman’s Rho</th>
<th>SpO2 Incidents less than or equal to 93%</th>
<th>IPI Incidents less than 7</th>
<th>EtCO2 Incidents greater than 50mmHg</th>
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<tbody>
<tr>
<td></td>
<td>1.000</td>
<td>0.519**</td>
<td>0.310</td>
</tr>
<tr>
<td>SpO2 Incidents less than or equal to 93%</td>
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<td></td>
</tr>
<tr>
<td>IPI Incidents less than 7</td>
<td>0.519**</td>
<td></td>
<td></td>
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<tr>
<td>EtCO2 Incidents greater than 50mmHg</td>
<td>0.310</td>
<td>0.075</td>
<td>1.000</td>
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</table>
Table 5

*Comparing OIRD Specificity Between Paired Measurement Devices*

<table>
<thead>
<tr>
<th>Wilcoxon Signed Rank Test</th>
<th>SpO₂ Incidents less than or equal to 93% - EtCO₂ Incidents greater than 50mm Hg</th>
<th>IPI Incidents less than 7 – SpO₂ Incidents less than or equal to 93%</th>
<th>IPI Incidents less than 7 – EtCO₂ Incidents greater than 50mm Hg</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Z</td>
<td>-3.009</td>
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<tr>
<td>Asymp. Sig. (2-tailed)</td>
<td>0.003</td>
<td>0.492</td>
<td>0.001</td>
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Appendix I

October 3, 2017

Dear Gary Yam:

On 10/3/2017, the IRB reviewed the following submission:

<table>
<thead>
<tr>
<th>Type of Review:</th>
<th>Initial Study</th>
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<tbody>
<tr>
<td>Title of Study:</td>
<td>Comparing and Identifying Monitoring Devices for Efficacy in the Detection of Opioid Induced Respiratory Depression (OIRD)</td>
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<tr>
<td>Investigator:</td>
<td>Gary Yam</td>
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<tr>
<td>IRB ID:</td>
<td>STUDY00001793</td>
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<td>Funding:</td>
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<td>IND, IDE, or HDE:</td>
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| Documents Reviewed: | • HRP-503-Template%20Mullaney_Yam%202017%20Revision%20(4)%210-2-17-1.docx, Category: IRB Protocol;  
   • HRP-502-Template%20Consent%20Document%20Revision%20(2)%210-2-17.pdf, Category: Consent Form;  
   • datacollection.xlsx, Category: Other; |

The IRB approved the study from 10/3/2017 to 10/2/2018 inclusive. The Initial study materials for the project referenced above were reviewed and approved by the SUNY University at Buffalo IRB (UBIRB) by Non-committee Review. Before 10/2/2018 or within 30 days of study closure, whichever is earlier, you are to submit a continuing review application with required explanations. You can submit a continuing review application by navigating to the active study in Click IRB and selecting ‘Create Modification / CR’. Studies cannot be conducted beyond the expiration date without re-approval by the UBIRB.

In conducting this study, you are required to follow the requirements listed in the Investigator Manual (HRP-103), which can be found by navigating to the IRB Library within the IRB system.

HIPAA Authorization combined with consent document
The consent form document includes the HIPAA authorization for use/disclosure of personal health information and has met the required elements of the federal regulations of HIPAA.

UBIRB approval is given with the understanding that the most recently approved procedures will be followed and the most recently approved consent documents will be used. If modifications are needed, those changes may not be initiated until such modifications have been submitted to the UBIRB for review and have been granted approval.

As principal investigator for this study involving human participants, you have responsibilities to the SUNY University at Buffalo IRB (UBIRB) as follows:

1. Ensuring that no subjects are enrolled prior to the IRB approval date.
2. Ensuring that the study is not conducted beyond the expiration date without re-approval by the UBIRB.
3. Ensuring that the UBIRB is notified of:
   - All reportable information in accordance with the New Information SOP (HRP 024).
   - Project closure/completion by submitting a Continuing Review/Modification submission.
4. Ensuring that the protocol is followed as approved by UBIRB unless a protocol amendment is prospectively approved.
5. Ensuring that changes in research procedures, recruitment or consent processes are not initiated without prior UBIRB review and approval, except where necessary to eliminate apparent immediate hazards to subjects.
6. Ensuring that the study is conducted in compliance with all UBIRB decisions, conditions, and requirements.
7. Bearing responsibility for all actions of the staff and sub-investigators with regard to the protocol.
8. Bearing responsibility for securing any other required approvals before research begins.

If you have any questions, please contact the UBIRB at 716-888-4888 or ub-irb@buffalo.edu. Please include the project title and number in all correspondence with the UBIRB.
MONITORING FOR OPIOID INDUCED RESPIRATORY DEPRESSION
Comparing and Identifying Monitoring Devices for Efficacy in the Detection of Opioid Induced Respiratory Depression (OIRD)
Justin Mullaney RN, BSN, DNP-c & Gary Yam RN, BSN, DNP-c

Introduction
Opioid-induced respiratory depression (OIRD) is an issue that affects all postoperative patients, including major orthopedic patients such as those undergoing total hip or total knee replacements. Due to the invasiveness of these procedures, many patients require higher doses of opioids to control their pain effectively. As a result, these patients are at a greater risk for OIRD. Despite the frequent use of opioid analgesics administered throughout the perioperative period, there are no universally accepted protocols for monitoring patients receiving opioids for respiratory depression.

Purpose
To compare the effectiveness and sensitivity of the Integrated Pulmonary Index (IPI) with standard monitors such as capnography (EtCO2) and pulse oximetry (SpO2) in detecting opioid-induced respiratory depression.

Background
Opioid related adverse events and concerns over their occurrence have many negative consequences on hospitalized patients, including ineffective pain control, decreased quality of life, longer hospitalizations, increased hospital costs, and even death. Over the past five years, several professional organizations have published recommendations and clinical practice guidelines to specifically address opioid-induced respiratory depression and advancing sedation. Collectively, the guidelines recommended are increased monitoring of any procedures requiring sedation, two of these guidelines specifically recommend continuous monitoring of all patients on opioid medications.

Significance
Precise estimates for the incidence of failure to rescue from opioid-induced respiratory depression vary, and are confounded by the fact that they are often near miss events that are under-reported. According to The Joint Commission (TJC) there were 129 opioid-related sentinel events reported between the years 2004 and 2011. Of these events, root causes were found to be:
• 47 percent wrong dose medication errors
• 29 percent related to improper monitoring
• 11 percent related to other factors, such as excessive dosing and medication interactions.
The lack of evidence on which electronic monitoring systems (respiratory rate, pulse rate, ETCO2, SpO2, or IPI) perform best, and uncertainty over when patients are actually experiencing OIRD necessitates the need for more accurate monitoring devices in the Post-Anesthesia Care Unit (PACU).

Methods
A quasi-experimental design was used comprising of thirty patients undergoing elective orthopedic total knee or total hip replacement surgery in Buffalo, New York between October 2017 and December 2017. Measurement of IPI, EtCO2, respiratory rate (RR), pulse rate (PR) and SpO2 took place preoperatively and during recovery in the PACU using the Capnostream monitoring device. Following the patients operation and arrival to the PACU intraoperative medication amounts were documented and monitoring of IPI, SpO2, and EtCO2 was initiated and continued for an average of 50 minutes. If patients received an opioid during their recovery, the time, dose, and route of delivery was recorded until the patient was either discharged from the PACU or a duration of one hour recovery time was achieved.

Inclusion Criteria
• Adults age 18+
• English language
• Total hip or total knee replacement surgery
• PACU recovery
• Perioperative opioids

Results
SpO2 was found to be the most statistically reliable monitoring device to detect incidences of OIRD, followed closely by the IPI in the detection of OIRD within the PACU environment. EtCO2 was found to be the least reliable monitoring device.

Implications for Practice & Future Research
• IPI was an effective additional monitoring instrument to detect OIRD in the PACU setting.
• SpO2’s utility as a reliable method for monitoring patients for OIRD in PACU was supported.
• More research is needed to determine EtCO2’s efficacy for detecting OIRD in the PACU environment
• Multimodal analgesic approaches to pain management in the perioperative period should be implemented more frequently to decrease incidences of OIRD.

Discussion
The results of this capstone suggest that both the IPI, as well as SpO2, are acceptable monitoring devices for accurately detecting OIRD in postoperative orthopedic patients based on the statistical significance of the data collected. However, the results are inconclusive in regards to routine use of EtCO2 monitoring as no correlation between OIRD events and their detection using EtCO2 monitoring could be established. Also, only one patient in this study received a spinal anesthetist prior to undergoing orthopedic surgery and as a result required less narcotic analgesics postoperatively and exhibited fewer episodes of hypventilation when compared to a majority of the other patients monitored. This lends further merit to the need for further implementation of multimodal analgesic techniques to reduce the overall amount of opioid narcotics used during the perioperative period.

Significance
The impact related to OIRD on the overall healthcare system is especially relevant during the immediate postoperative period, such as when a patient arrives in the PACU following a surgical procedure. The use of more efficacious assessment systems, such as IPI monitoring in conjunction with the continued use of SpO2 monitoring in the PACU, as well as, increasing the use of multimodal analgesic techniques to decrease the overall amount of narcotics used perioperatively, are essential to prevent the adverse patient outcomes caused by OIRD.

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