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Acute Pain Symptom Assessment and Management in Nonverbal Puerto Rican Patients in the Early Postoperative Period

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**ACUTE PAIN SYMPTOM ASSESSMENT AND MANAGEMENT
IN NONVERBAL PUERTO RICAN PATIENTS IN THE EARLY
POSTOPERATIVE PERIOD**

A Dissertation Presented

by

SHERILY PEREIRA

Submitted to the Graduate School of the
University of Massachusetts Amherst in partial fulfillment
of the requirements for the degree of

DOCTOR OF PHILOSOPHY

September 2016

Nursing

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**ACUTE PAIN SYMPTOM ASSESSMENT AND MANAGEMENT
IN NONVERBAL PUERTORICAN PATIENTS IN THE EARLY
POSTOPERATIVE PERIOD**

A Dissertation Presented

by

Sherily Pereira

Approved as to style and content by:

Annette Wysocki, Chair

Donna Zucker, Member

Carol Bigelow, Member

Stephen Cavanagh, Dean
College of Nursing

DEDICATION

To my family; here stands our symbol of perseverance; we shall never forget its significance.

To surgical patients suffering from acute pain, because everyone has the right to receive the best quality care.

To nursing professionals and nurse anesthesia specialists, we have the power for patient advocacy and in research lies the key.

ACKNOWLEDGMENTS

First and foremost, I want to thank my husband and my children; Miguel, Enrique, Miguel Angel, Stephen, and Stephanie thank you for unwavering patience and understanding when often times I had to sacrifice time with you. To my children, I hope this journey shows you that you can achieve anything with hard work and commitment. Miguel, I love you. Thank you.

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ABSTRACT

ACUTE PAIN SYMPTOM ASSESSMENT IN NONVERBAL PUERTORICAN PATIENTS IN THE EARLY POSTOPERATIVE PERIOD

September 2016

SHERILY PEREIRA, BSN, PONTIFICAL CATHOLIC UNIVERSITY OF PR
MSNA, UPR MEDICAL SCIENCES CAMPUS
PH.D., UNIVERSITY OF MASSACHUSETTS AMHERST

Directed by: Professor Annette Wysocki

Acute pain is a symptom that represents significant concern for surgical patients during the early postoperative period. This is probably due to the use of ineffective instruments or protocols for assessment in patients with different levels of sedation after general anesthesia. This study described the relationships between the total scores obtained from two pain assessment instruments, the Non-verbal Pain Scale Revised (NVPS-R) and Critical Care Pain Observation Tool (CPOT), during the early postoperative period for non-verbal patients at Post Anesthesia Care Unit (PACU). After assessing patient's pain with both instruments simultaneously, we determined, and evaluated the relationships between the two behavioral instruments to assess acute pain in the early postoperative period. Recent literature confirmed the research gap in assessment of postoperative pain in nonverbal patients due to inadequate evidence to guide recommendations about which specific non-verbal pain instrument to use. The results of this study present a high correlation between total pain scores of both behavioral assessment instruments, CPOT and NVPS-R, for postoperative patients after abdomino-pelvic, gastrointestinal and

gynecological surgeries. Incidental findings suggest that CPOT vocalization indicator was consistently present in patients with significant pain. Increases in the NVPS-R vital signs and respiratory indicators were not seen consistently in patients with significant pain. The vital sign indicators included in the NVPS-R need to be further investigated to determine their validity for assuring pain assessment because our findings do not support their use exclusively. Physiologic indicators as heart rate, mean arterial pressure, respiratory rate and pulse oxygen saturation were not good indicators of acute pain. This study is important because pain assessment is the best way to initiate the most appropriate treatment to alleviate pain after surgery. Institutions where surgeries are performed need to standardize and provide clear policies and procedures for effective postoperative pain assessment and management. Healthcare providers are patient advocates and a clear vision in providing the most effective management contributes to decrease the worldwide problem of undertreatment of acute pain.

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CHAPTER 1

INTRODUCTION

Statement of the Problem

The National Institutes of Health has identified improved treatment of pain as a priority: *“the experience of pain and the challenge of treatment have remained uniquely individual and unsolved”* (U.S. DHHS, 2006). In 2010, the Joint Commission on Accreditation of Healthcare Organizations released the National Patient Safety Goals (NPSG) prioritizing pain management as a standard of care. The NPSG standards require organizations to acknowledge the rights of patients in order to assess and manage pain appropriately, screen patients for pain, and educate patients suffering from pain and their families (JCAHO, 2010). Acute pain is a common symptom after surgery and one of the most important postoperative physiological recovery domains (Lindqvist, Royse, Brattwall, Warrén-Stomberg, & Jakobsson, 2013). According to the National Center of Health Statistics (2010), the total number of inpatient surgical procedures was 51.4 million. After surgical procedures, acute pain is between moderate to severe. Data suggest 80% of patients experience pain postoperatively, with between 11-20% experiencing severe pain (Apfelbaum, Chen, Mehta, et al., 2003).

Despite the availability of analgesics and national guidelines to manage pain, the incidence of postoperative pain has remained stable over decades (Hutchinson, 2007). Acute pain associated with surgical procedures is common in the early postoperative period and remains inadequately assessed and managed. This is probably due to the use of ineffective instruments or protocols for pain assessment in patients under sedation due to general anesthesia. An extensive literature review identified a gap in the assessment and management of acute pain in the early postoperative period. This points to the need for an instrument that assesses acute pain in the

early postoperative period for patients with levels of sedation after general anesthesia and to establish a standard of care.

Definitions of pain have been refined to include the fact that a person's inability to verbally communicate does not preclude the possibility that pain is present or negate the responsibility of healthcare providers to treat it. Currently, post anesthesia care unit (PACU) nurses do not use an effective instrument for the assessment of acute pain in non-verbal adult patients after general anesthesia. During the early postoperative period a patient's state of consciousness changes from an unconscious level to wakefulness. The patient's level of consciousness should be considered when pain assessment is performed in this population.

The use of valid and reliable pain measurement instruments while patients are still under sedation in the PACU would lead to earlier and better pain assessment and management and a significant decrease in postoperative complications. The effects of unrelieved acute pain can have a significant impact on a patient's recovery from surgery and general anesthesia. Inadequate pain assessment and management have been linked to increased morbidity and mortality (Shannon & Bucknall, 2003). Poor treatment of acute pain may lead to the development of serious complications (Dunwoody et al., 2008), which can impact a patient's physical functioning, satisfaction, and well being after surgical procedures. In postoperative patients, functional goals include deep breathing, ambulating, and being able to participate in physical therapy (Carr & Goudas, 1999) and acute pain directly impacts those goals.

Background and Significance

Literature suggests that unrelieved pain can contribute to the development of several multisystem effects. These effects include an increase in physiological parameters such as heart rate and blood pressure (Payen, Bru, Bosson, Lagrasta, Novel, & Deschaux, 2001; Stotts et al.,

2004), atelectasis (Puntillo & Weiss, 1994), blood clots, pneumonia, vasoconstriction, decreased tissue-oxygen partial pressure (Akca et al., 1999), hyper-metabolism resulting in hyperglycemia, delay in wound healing and risks of wound infection (McGuire, Heffner, Glaser, Needleman, Malarkey, & Dickinson, 2006). These multisystem effects adversely affect postoperative outcomes.

Continuous post-operative assessment and management of pain by nurses is of utmost importance because it guides them in the process of providing analgesia before patients reach a maximum acute pain threshold. The postoperative pain management guideline and the pain, agitation, and delirium (PAD) guideline, both recommend providing continuous assessment of patient's pain (Bader et al. 2010; Barr, Fraser, Puntillo, Wesley, Gélinas, Dasta, 2013) to achieve early recognition and early treatment. Adequate acute pain assessment would help nurses identify objective measures for the development of new effective protocols for better acute pain management.

Current literature is directed at the use of different verbal pain scales during the postoperative period. However they have not been recommended for non-verbal patients in the PACU due to the lack of research in this area. In 2016, the American Pain Society, along with the American Society of Anesthesiologists, commissioned an interdisciplinary expert panel to develop a clinical practice guideline to promote evidence-based, effective, and safer postoperative pain management. The recommendations were based on the underlying premise that optimal management begins in the preoperative period to develop a plan of care tailored to the individual and the surgical procedure involved, and extends to the continuous pain assessment of the patient (Chou et al., 2016).

The most consistently used pain scales in the PACU are subdivided in three categories for pain assessment. The categories include 1) verbal pain scales, 2) multidimensional pain scales, and 3) behavioral pain scales. The verbal pain scales assess pain intensity while multidimensional pain scales assess the quality of pain. Both of these categories of scales require a patient's verbal self-report. Consequently, patients need to be able to verbally communicate for these assessments to be useful. The last category of scales is the behavioral pain scales. These instruments assess pain through a framework that usually consists of physiological changes, body language and behavioral changes (Stites, 2013)

Two previously validated behavioral pain scales for use in PACU were designed specifically to measure behaviors for patients with cognitive impairment and dementia, and both are for older adults (Kovach, Weissman, Griffie, Matson, & Muchka, 1999). Other types of behavioral pain scales used to assess acute pain in critical care units are the behavioral pain scale (BPS), the Critical Care Pain Observation Tool (CPOT), and the revised Nonverbal Pain Scale (NVPS-R). The limitation in the application of the BPS for acute pain assessment is the requirement for a level of consciousness because this instrument is limited to intubated patients (Barr et al., 2013). An adaptation of the BPS was designed for non-intubated critically ill patients (BPS-NI) (Chanques et al., 2009). However, the BPS- NI instrument needs more research to validate its psychometric properties.

So far, of the available observational pain scales, the CPOT has shown superior reliability and validity when used in nonverbal critically ill adults (Stites, 2013). The CPOT effectively measures acute pain in sedated non-intubated patients, but needs more research, as it has not been studied in PACU patients. NVPS-R contains behavioral dimensions and physiological dimensions that are graded in severity. Some authors concluded that the NVPS-R was a valid

observational pain scale (Stites, 2013), however a comparison between CPOT and NVPS-R in sedated patients at early postoperative period, has never been studied.

After reviewing the applicability of these nonverbal pain assessment instruments in patients under levels of sedation after general anesthesia, a recommended one cannot be found. The available instruments were designed and validated for used with conscious patients and other behavioral scales for those patients with cognitive impairment. Thus, there is a need for a pain assessment instrument for patients under sedation in the early postoperative period, which would aid in the early identification and anticipatory relief of pain.

The early postoperative period is the time immediately after the patient arrives at the PACU and extends for approximately two hours. During this early postoperative period, significant pain from surgical procedure is expected and acute pain can sometimes be difficult to assess because residual effects of general anesthesia are particularly high.

The most commonly used instrument for the assessment of acute pain in the PACU is the self-reported Numeric Rating Scale (NRS), which is considered the gold standard for the assessment of pain (Li, Puntillo, Miaskowski, 2008). However, the NRS instrument was designed and validated to evaluate pain intensity in verbal, conscious patients and is not an adequate instrument to evaluate patients unable to self-report their pain. The sole use in the PACU of the NRS for the assessment of acute pain can delay early assessment, which can lead to a poor pain management. Pain assessment using appropriate instruments to measure pain in non-verbal adult patients under sedation is currently not a standard protocol in PACU's in Puerto Rico and other countries.

Nurses routinely begin the assessment of acute postoperative pain when patients are able to report pain verbally. The delay of acute pain assessment is significant in nonverbal patients

because it leads to an increase in the time that the patient needs to recover physiologically and psychologically to attain their health status. This delay increases the risk for postoperative complications, the length of patient's stay in the PACU, and in the hospital, and medical costs.

The American Society for Pain Management Nursing (ASPMN), the American Pain Society (APS), the American Society of Anesthesiologists (ASA), and the Centers for Disease Control and Prevention, all emphasize the importance of pain assessment for better pain management. The recommendation for pain assessment is the use of the most valid and reliable behavioral pain scales for monitoring pain in medical, postoperative, or trauma settings. Because adult intensive care unit (ICU) patients are sometimes unable to self-report pain, the use of valid and reliable bedside assessment instruments continues to be an important part of pain management. The ability to reliably assess a patient's pain is the foundation of effective pain treatment (Barr et al., 2013).

Pain assessment is essential for appropriate treatment, especially as part of a comprehensive pain management protocol. The PAD and management of postoperative pain guidelines presents two behavioral pain assessment instruments as the most valid and reliable scales, the BPS and CPOT. Those instruments have been validated for monitoring pain in medical, postoperative, and trauma ICU patients. The quality of evidence is moderate (Barr et al., 2013; Chou et al., 2016) showing the need for more research, especially during the postoperative period. The use of the CPOT during the early post-operative period in patients after general anesthesia under levels of sedation has never been studied.

A systematic review that tested pain assessment instruments for use with sedated patients states that the CPOT may also prove to be useful in assessing pain among sedated patients (Cade, 2008). During the nociceptive exposure of postoperative cardiac patients, the CPOT had a

sensitivity of 86%, a specificity of 78% and was effective for the screening of pain. The CPOT seems to be a useful instrument to detect pain in intubated postoperative cardiac adults, especially during nociceptive procedures (Gélinas, 2009). However, to date no specific nonverbal pain assessment instrument has emerged that is superior to other instruments and has been tested for reliability and validity in nonverbal patients after surgery.

To facilitate the effectiveness of acute pain management after surgery and general anesthesia there is a need to establish clear protocols and a systematic routine including the most effective measurement instruments for the assessment of acute pain in nonverbal patients under sedation. The effective measurement instrument selection must include the initial evaluation of the level of sedation of the patient to select the appropriate pain assessment instrument for verbal and non-verbal patients. The use of the Richmond Agitation Sedation Scale (RASS) is necessary to establish a patient's level of sedation before using the CPOT. In patients at the deepest level of sedation, the pain behaviors are decreased to -4 RASS (Li, Puntillo, & Miaskowski, 2008). The CPOT could be a predictive measure of acute pain in patients under sedation, after general anesthesia.

An early assessment during the postoperative period can promote pain relief, such that all patients receive the most effective acute pain management following general anesthesia. The advantage of this early intervention is the identification and management of pain before the patient reaches an acute pain threshold.

Purpose of the study

This study assessed the relationship between the CPOT and the NVPS-R for acute pain assessment in the early postoperative period after general anesthesia in sedated patients. The specific purpose of this research study was to compare the use of two behavioral acute pain

assessment instruments during the early postoperative period for non-verbal sedated patients to enhance anticipatory assessment and management of pain. One behavioral instrument was the adult NVPS-R, and the second was the CPOT behavioral pain scale. Both instruments were used simultaneously, to determine and evaluate relationships between both nonverbal instruments to assess acute pain in the early postoperative period for patients under sedation. Knowledge derived from this research is expected to help in the development of protocols that would allow for better pain identification and management during the early post-operative period.

The use of the behavioral instruments CPOT and NVPS-R in the PACU provides a new alternative in the process of early acute pain assessment to improve post-operative acute pain management. These research data could be useful for continuing education of nurses working in the PACU to increase their knowledge of pain manifestations, pain assessment and pain management. It is hoped that through this type of exploratory research, behavioral pain assessment instruments can be used as part of a systematic routine during the early postoperative period in the PACU to decrease omissions in effective acute pain assessment in patients under sedation.

Theoretical Framework

The incidence of postoperative acute pain suggests that symptom management research is a priority for adults. The symptom management theory (SMT) is a middle range theory depicting symptom management as a multidimensional process (Linder, 2010). In Harver and Mahler (1990), a symptom was defined as a subjective experience, reflecting changes in bio-psycho-social functioning. Research addressing symptom management is recognized as a priority (Berger, Cochrane, & Mitchell, 2009; Hockenberry, 2004).

The SMT model of the theory, illustrates a multidimensional process of symptom

management. Three essential concepts include symptom experience, components of symptom management strategies and outcomes. The concepts are framed within the dimensions of nursing science: person, environment and health and illness, to serve as a reminder of the contextual considerations of nursing research. The model provides a conceptual framework for understanding relationships between factors influencing the symptom experience as well as the larger contextual factors influencing symptom management. Additionally, the model includes the patient's role in self-care. With regards to postoperative acute pain in adult patients, it can guide nursing interventions aimed at influencing the context in which intense acute pain is occurring as well as the development of symptom management strategies. The goal is to eliminate the symptom or minimize the distress of the symptom experience.

The method of this study was contained within the model as part of the component of symptom management strategies, because it incorporates who, what, and how the strategies are implemented. The early decrease in pain is the expected symptom status defined in the context of outcome in the framework. The symptom management theory (SMT), guides pain symptom assessment and treatment management in practice and research. The theory is applicable to a variety of symptoms and patient populations in different settings and provides the perfect framework to develop an improvement in acute pain assessment and management. The model of the theory focused on three factors: the symptom experience, that is acute pain; symptom management strategies, that is an early acute pain assessment; and outcome/symptom status, which is acute pain early identification and/or pain relief (Figure 1).

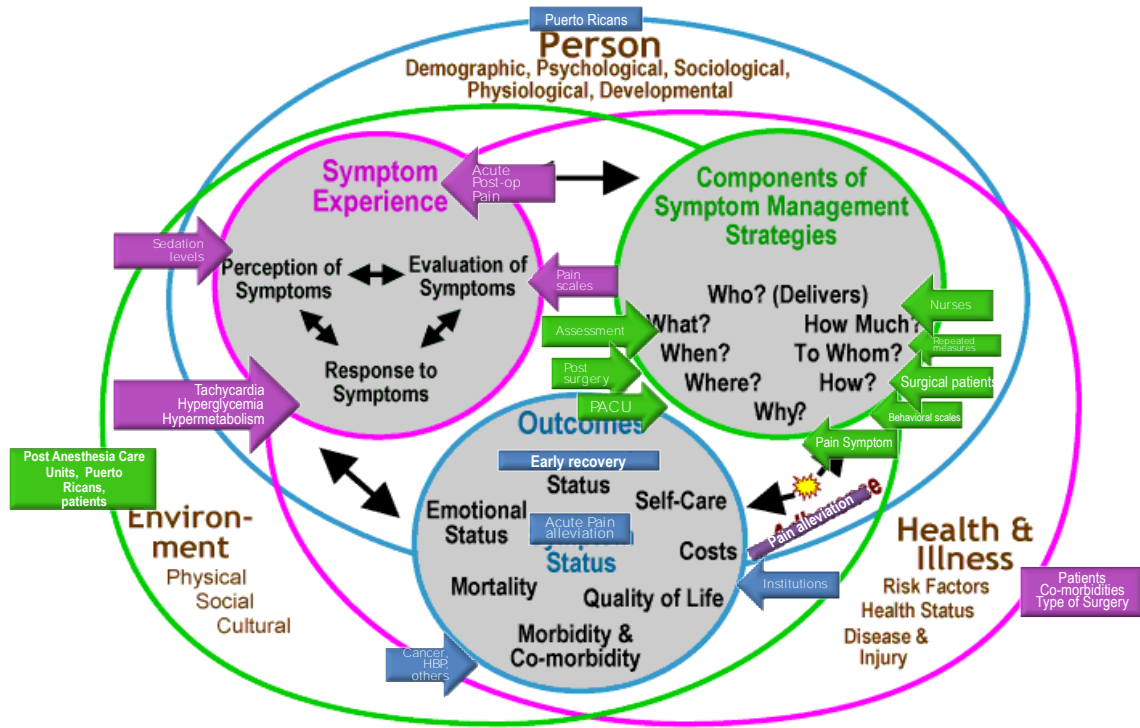


Figure 1. Symptom Management Theory Model application to the study

To achieve the proposed outcome of early identification of acute pain symptom and hence, acute pain relief in postoperative patients, three factors were considered including patient’s experience of acute pain symptom (behaviors, perception, and response of pain), type of analgesia (medications and doses), and assessment and management strategies (assessment instruments: CPOT, NVPS-R). To achieve acute pain relief, nurses need to use appropriate assessment and management strategies and an important component for effective postoperative acute pain management is early pain assessment. Patients, who receive general anesthesia during surgery, arrive to the PACU under sedation; therefore pain behaviors could be decreased. If nurses use appropriate instruments to assess pain before patients become conscious, early management can be given to achieve acute pain relief. Early identification of acute pain is extremely important for proper management, before patients achieve or exceed the maximum acute pain threshold.

Definition of Terms and Operational Definitions

- 1) *Pain*: an unpleasant sensory and emotional experience associated with actual (surgery) or potential tissue damage or described in terms of such damage (International Association for the Study of Pain, 1979).
- 2) *Acute pain*: is an expected physiologic experience to noxious stimuli (surgery) that can become pathologic, is normally sudden in onset, time limited, and motivates behaviors to avoid actual or potential tissue injuries. Pain that can be either brief, lasting moments or hours, or it can be persistent, lasting weeks/several months until the disease or injury. The condition has a predictable beginning, middle and end. For research purposes, acute significant pain is defined by behavioral pain scales as CPOT ≥ 3 and NVPS-R ≥ 3 .
- 3) *PACU*: post anesthesia care unit, also known as recovery room.
- 4) *General Anesthesia*: A drug-induced loss of consciousness during which patients are not arousal, even by painful stimulation (ASA, 1999).
- 5) *RASS*: Richmond Agitation Sedation Scale is a measurement scale with values ranging from -5 to 4. Those values from -5 to -1 correspond to sedation, values of 0 to alert and calm, and 1 to 4 is agitation. For research purposes, RASS measure of sedation was between -4 to -2. Levels of sedation are -4 = deep sedation, -3= moderate sedation, and -2 = light sedation.
- 6) *Early Postoperative period*: is the immediate postoperative period in the PACU. For the purposes of this research study, the early post-operative period is the time period from 1 to 120 minutes after patient arrived from operating room (OR) to PACU.
- 7) *Postoperative outcomes*: patient satisfaction, decrease in medication consumption (opioids, non-opioids), decrease in secondary effects (nauseas/vomitus), decrease in pain behaviors.
- 8) *NVPS-R*: Non-verbal pain scale. A behavioral pain instrument for the assessment of acute

pain. Measures contain behavioral categories (facial expression, activity, and guarding) and physiological categories (heart rate, blood pressure) and respiratory component (respiratory rate and pulse oximetry). Items in each category are scored from 0 to 2 with a possible total score ranging from 0 to 10 (Rochester, 2004). The revised version (NVPS-R) was used in this study.

9) *CPOT*: Critical Care Pain Observation Tool. Measures behaviors in non-verbal patients. It includes four behavioral indicators: 1) facial expression, 2) body movements, 3) muscle tension, and 4) compliance with the ventilator for intubated patients or vocalization for non-intubated patients. For this study, the vocalization indicator was used because all participants were non-intubated patients. Items in each category are scored from 0 to 2 with a possible total score ranging from 0 to 8 (Gélinas et al., 2009).

10. *Sedation*: drug-induced state of consciousness depression during which patients may respond purposefully to verbal commands, either alone or accompanied by light or repeated tactile stimulation (Naguelhout & Plaus, 2014). No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

Summary

Early assessment of pain in nonverbal patients provides the framework for a process that can be used to manage pain. Studies suggest that observational instruments help to determine the presence of pain early and can be used to evaluate the effectiveness of interventions and decrease pain symptoms before the threshold of pain is reached. A behavioral score is not a pain intensity score, but the benefits for early pain intervention with the patients are greater.

Symptom management theory clearly establishes that the assessment of acute pain is a component of the symptom management process. The early assessment of acute pain directly improves and guides nursing interventions, as well as the development of symptom management

strategies. The most important goal is the early elimination of acute pain symptoms to minimize distress, which affects optimal recovery from surgery.

Early assessment and management will improve the relief of acute pain achieving the needed level of comfort for the patient to function adequately. In postoperative patients, a decrease in complications, morbidity, mortality and achievement of functional goals means early discharge and less costs for the patient and the institution.

CHAPTER 2

REVIEW OF THE LITERATURE

Introduction

Acute pain is an expected symptom that represents significant concern for surgical patients during the postoperative period. The ultimate goal when dealing with acute pain is the quality of pain management. For many years, studies devoted to the assessment of pain during the postoperative period have focused on pain intensity instruments. In 1997, Puntillo and others addressed the need for reliable and valid instruments for patients unable to verbally report the level of pain (Puntillo, Miaskowski, Kehrl, et al. 1997). Despite these efforts, guidelines, standards of practice, and research over the past decades, the undertreatment of pain continues to be present.

Many factors contribute to poor pain management, but the lack of assessment and inadequate management are the primary modifiable factors (McCaffery, 2002). The Post Anesthesia Care Unit (PACU) is the most common hospital setting where patients experience acute pain. An important part of the recovery period after surgery is the appropriate control of pain during rest and with activity (Barr et al., 2013). Appropriate postoperative pain alleviation helps patients return to satisfactory functional status.

This review of the literature addresses the topics of pain, acute pain, postoperative acute pain, pain nociception, neuroendocrine response, and pain assessment and management during the early postoperative period. The emphasis of this review is acute pain symptom assessment in adult non-verbal patients during the early postoperative period. Postoperative pain can be effectively managed, but in many cases it is not well assessed. Early assessment is an essential instrument for the adequate management of pain and could increase the adequate administration

of analgesics during the early postoperative period. It is important to highlight that inadequate postoperative pain assessment and management, directly affects the patient's recovery and satisfaction.

Search for Review of the Literature

A search was initiated in October 2012 and throughout the process. Databases used for this review of the literature included Cumulative Index of Nursing and Allied Health Literature (CINAHL), Pub Med, Cochrane Library, Academic Search Premier, Google Scholar, Medline, and ProQuest. The databases were searched using the key words, alone and in combination, including: pain, acute pain, pain physiology, surgery stress, postoperative pain, acute pain assessment, acute pain management, behavioral pain scales, pain assessment instruments, non-verbal pain scales, symptom management, non verbal pain scales, nursing and pain assessment, critical care pain observation tool (CPOT), nonverbal pain scale revised (NVPS-R), and early postoperative period. Inclusion criteria included these terms: qualitative or quantitative studies, systematic reviews, and literature reviews pertaining to pain assessment, reference of care from a nursing and health care provider that included nurses, and written in the English language. The goal of this review was to integrate findings on pain assessment and non-verbal patients. All abstracts were; excluded were articles not written in English, and studies in pediatric population, because pain behaviors in this population differ from those of adults. A review of reference lists of all selected articles was also conducted.

Pain

In 1968, McCaffery defined pain as "whatever the person experiencing says it is, existing whenever he says it does" (Pasero & McCaffery, 2011; Sipos & Karapas, 2010). This definition allowed healthcare providers to intervene and treat patients on the basis of the self-report of the

pain experience. Over time, the definitions of pain have been further refined to include the fact that a person's inability to verbally communicate does not eliminate the possibility that pain is present or that healthcare providers have a responsibility for treating it (Pasero & McCaffery, 2011). The definition of pain endorsed by the International Association for the Study of Pain and the American Pain Society both define pain as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage” (IASP, 1979). This definition describes pain as a phenomenon with multiple components that makes an impact on a person’s psychosocial and physical functioning (McCaffery & Pasero, 1999). Pain is often classified as acute or chronic, based on duration and origin. Acute pain includes postoperative pain that subsides as healing takes place. Chronic pain is persistent and is subdivided into cancer-related pain and nonmalignant pain, such as arthritis, low-back pain, and peripheral neuropathy (McCaffery & Pasero, 1999). Pain is classified by its pathophysiology into two major types: nociceptive and neuropathic. Nociceptive pain involves the normal neural processing of pain that occurs when free nerve endings are activated by tissue damage or inflammation (Pasero & McCaffery, 2011). Neuropathic pain is a persistent, chronic pain that arises as consequence of central and peripheral nerve damage (Pace, Mazzariello, Passavanti, Sansone, Barbarisi, & Aurilio, 2006).

Acute pain

Acute pain results from activation of the pain receptors (nociceptors) at the site of tissue damage. This type of pain is nociceptive and generally accompanies surgery, traumatic injury, tissue damage, and inflammatory processes. Acute pain is typically self-limiting and resolves in a short period of time (less than four weeks), alerts the body that it has been injured, and is the result of tissue injury that corresponds to a healing process. It is a sharp, localized pain of rapid

onset (IASP, 1979; Barr, 2013), and implies tissue damage that is usually from identifiable causes such as burns, trauma, surgery, disease and several medical conditions such as myocardial infarction (Courtenay & Carey, 2008). For the purpose of this review, acute pain will be defined as pain that is present in a surgical patient after a procedure (ASA, 2012).

Patients can perceive acute pain during any activity or procedure in acute care settings, intensive care units (ICU), or long-term care settings (Plante & Van Itallie, 2010). Acute pain includes other physical and psychological symptoms that create distress and stimulate the sympathetic nervous system creating a disruption to homeostasis (Barr, 2013). The transmission of acute pain is very complex with many different types of substances produced and utilized to help or block pain transmission (D'Arcy, 2011).

Physiology of Pain Nociception

The transmission of the sensation of pain requires the activation of different mechanisms within the peripheral nervous system and central nervous system (Argoff, 2001). To transmit and facilitate pain sensation, a series of complicated inhibitory and excitatory process occur, including the production and utilization of neurotransmitters, cytokines, glutamate, and substance P (American Society for Pain Management Nursing (ASPMN), 2010; Sorkin, 2005).

Between tissue damage and pain perception, lie a complex of electromechanical events called nociception. Nociception involves physiologic processes of transduction, transmission, modulation, and perception of pain. Transduction implies the translation of noxious stimuli into electric activity at the sensory endings of the nerves. Transmission is the impulse propagation through the sensory nervous system. Modulation is the process where nociceptive transmission is modified through neural influences and perception is the final process where the other three processes interact with the person's psychology to create the final individual experience of pain.

In visceral tissue the transduction process of nociception is supplied by afferent sympathetic nerve fibers. The nociceptive signal is transmitted from the surgical site to the central nervous system. After incision and surgical injury, nociceptors become hypersensitive to noxious stimuli, a process called sensitization. The transmission takes place at the spinal cord, ascending via tracts to the thalamus, hypothalamus and brain stem to the somatosensory cortex for the sensory, discriminative, affective, and motivational aspects of the pain perception. Finally the modulation occurs at the central nervous system in which descending antinociceptive pathways can be activated by pain.

Tissue damage from the surgical incision releases chemical mediators, such as prostaglandins, bradykinin, serotonin, substance P, and histamine. These substances then activate nociceptors, resulting in transduction, or the generation of an action potential (an electrical impulse). In the second process, the transmission, action potential moves from the site of injury along afferent nerve fibers to nociceptors at the spinal cord. Release of substance P and other neurotransmitters carry the action potential across the cleft to the dorsal horn of the spinal cord, from where it ascends the spinothalamic tract to the thalamus and the midbrain. Finally, from the thalamus, fibers send the nociceptive message to the somatosensory cortex, parietal lobe, frontal lobe, and the limbic system, where the third nociceptive and perception process occurs (Sipos & Karapas, 2010). Perception, the conscious experience of pain, involves both the sensory and affective components of pain.

Neuroendocrine Stress Response to Surgery and Acute Postoperative Pain

Physiologic responses related to surgery and pain includes marked catabolism, increased cardiac work and arrhythmogenesis, hypercoagulability, and immunosuppression. Local mediators released from injured tissue stimulate global inflammatory responses contributing to

the stress response. These include interleukins, prostaglandins, bradykinin, and substance P. This is the characteristic hypothalamic activation of the initial endocrine response to surgery.

Vasopressin also is elevated in plasma during stress. Prolonged elevation of vasopressin levels is seen after major surgery (Ferrante & VadeBoncouver, 1993).

The surgical stress response is an endocrine, metabolic, and inflammatory response to surgical injury and is composed of a variety of physiologic changes (Kehlet, 1982). In 1993, Kehlet defined postoperative pain as a neural stimulus and release mechanism for the surgical stress response. The correlation between the site and extent of surgery and the magnitude of the resultant hormonal stress response presumably reflects the graded actions of neural pathways. Thoracic procedures or those involving deep tissue in the abdomen evoke quantitatively greater responses (Ferrante & VadeBoncouver, 1993).

Peak concentrations of thromboxane B₂ and serotonin occur 1-2 hours after skin incisions. Mediators released from injured tissue directly contribute to the stress response by traveling through the circulation to influence distant target organs. Mediators indirectly contribute to the stress response by augmenting afferent nociceptive transmission (Ferrante & VadeBoncouver, 1993), and the early phase of the stress response within the first 24 hours following surgery. Pain induced reflexes can increase cardiac oxygen demand, vulnerability to fibrillation, impair respiratory function, and increase the risk of postoperative thromboembolism.

Other adverse effects of uncontrolled postoperative pain include slow recovery from surgery, increased morbidity in the postoperative period, delayed resumption of normal pulmonary function, restriction on mobility contributing to thromboembolic complications, nausea and vomiting, increased systemic vascular resistance, cardiac work and myocardial oxygen consumption due to excessive catecholamine excretion (Rawal, 1982).

In general, tissue injury due to surgery causes acute pain and the release of inflammatory mediators such as substance P, cytokines, eicosanoids, and bradykinin, that contributes to the initiation and maintenance of the stress response.

Acute Postoperative Pain

Data suggest that, in the United States, 80 percent of patients experience pain postoperatively (Apfelbaum, Che, Mehta et al., 2003) and have a 50% to 80% chance of experiencing unrelieved pain (Curtiss, 2001, Warfield C, & Kahn C., 1995). These statistical data provide relevant information that clearly establishes the need to continue to develop new strategies for the assessment of pain. Such statistics demonstrate a large number of patients could potentially be suffering from inadequate postoperative pain assessment and management in the early postoperative period.

Acute pain management during general anesthesia begins in the operating room during induction and maintenance of anesthesia and surgery. General anesthesia involves combining medications from several different drug classes and encompasses five components: unconsciousness, amnesia, analgesia, immobility, and attenuation of autonomic nervous system responses to noxious stimuli (Morgan, Mikhail, & Murray, 2006). During general anesthesia, opioids are used to provide primary or supplemental analgesia in combination with other anesthetic agents. When inhalation agents are used as the primary anesthetics for general anesthesia, opioids are commonly employed to provide supplemental analgesia (Heltemes, 2007). All of these medications affect the postoperative recovery from sedation and result in patients having to stay under moderate sedation during the early post operative period.

Post-surgical patients develop acute pain that triggers a number of physiological responses in the human body. The physiological responses that activate the sympathetic nervous

system increase those responses, and the patients develop other symptoms associated with acute pain that make it more difficult to regain cardiac, pulmonary, gastrointestinal, musculoskeletal and cognitive function. Associated symptoms include increase in endogenous hormones such as epinephrine, cortisol, and renin, and increases in heart rate, hypertension, fatigue, muscle spasms, sleeplessness, anxiety and depression (Mc Caffery & Pasero, 1999).

Unrelieved pain produces a state of heightened sympathetic tone and a resetting of the baroreceptor reflex. Heart rate and blood pressure are both elevated. Cardiac work and myocardial oxygen consumption increase, predisposing to myocardial ischemia. Pain also produces a reflex reduction in parasympathetic outflow. The distorted balance of sympathetic and parasympathetic tone that accompanies pain alters the normal relationship between heart rate and arterial blood pressure (baroreceptor reflex). This resetting of the baroreceptor reflex yields an abnormally high heart rate for a given blood pressure.

The goal of the acute pain management after surgery is to prevent complications and improve postoperative outcomes. Postoperative acute pain in the post anesthesia care unit (PACU) is an expected symptom after surgery and is estimated to be present continuously during the first 24–48 hours after surgery (Gordon, Pellino, Miaskowski, et al. 2002). The patient first becomes aware of surgical pain in the PACU. Pain levels are measured frequently and most PACU policies require that patients attain a specific level of comfort before the patient is transferred to another unit.

Acute Pain Management

It is clear that acute pain requires a number of complex and physiologically based interventions to inhibit the transmission of pain impulses and achieve pain alleviation, however the basic standard for management includes accurate assessment and administration of opioid

and non-opioid medications as the most important management intervention. It is important that acute pain be effectively treated because if it persists, a number of physiological responses can limit patient recovery and cause physiologic stress.

With careful planning, multimodal analgesic techniques, and accurate assessment of the characteristics of pain, the appropriate selection of drugs at the precise timing minimize the patient's side effects (Ganhdi, Baratta, Heitz, Schwenk, Vaghari & Viscusi, 2012). Major areas of concern regarding postoperative pain management are safety, cost, and concern over side effects (Ferrante & VadeBoncouver, 1993). For pain inhibition, enkephalin, serotonin, norepinephrine, and gamma-amino butyric acid must be activated (American Society for Pain Management Nursing (ASPMN), 2010; Sorkin, 2005). Fear of drug addiction and the side effects of pain medications (especially respiratory depression) has led nursing staff to withhold medication, which is an absolute error. The aim of postoperative analgesia is to dissociate tissue injury and mediator release from their usual hormonal sequelae (Ferrante & VadeBoncouver, 1993). Adverse outcomes that may result from the undertreatment of acute pain include thromboembolic and pulmonary complications, additional time spent in an intensive care unit, PACU or hospital, needless suffering, and impairment of health related quality of life.

Acute Pain Measurement

The patient's self-report is the most reliable indicator of pain and the sole indicator of pain intensity (Herr, Coyne, Key, et al., 2006; Pasero & Mc Caffery, 2011). If a reliable self-report of pain cannot be elicited, the next step is to consider whether the patient has a condition associated with pain or is undergoing procedures that are generally considered painful. In such cases, the nurse should "assume that pain is present" (Pasero & Mc Caffery, 2011). The assumption that a patient who is unresponsive or nonverbal is not feeling pain is completely

erroneous.

The difficulty in measuring acute pain in postoperative patients under moderate sedation points to the need for accurate and reliable instruments that provide better evaluations and pain control. Despite the inherent difficulties in assessment, routine quantification of postoperative pain is of utmost importance for the quality of pain management. Unfortunately, most of the existing assessment scales are designed for use with patients who can respond verbally to assessment commands (Odhner, Wegman, Freeland, Steinmetz, & Ingersoll, 2004) including postoperative patients after general anesthesia.

The patient's individual pain trajectories, assessment of pain modulating processes, and the patient's psychological status (Davis, Billings, & Ryland, 1994) improve acute pain management. When medications are administered, nurses need to establish a baseline of pain. Appropriate pain assessment is the most reliable instrument and foundation for effective pain management. During the postoperative period, pain assessment must be brief and simple to complete (Carr, Jacox, Chapman, et al. 1992).

Each healthcare setting needs to establish a clear and effective procedure for evaluating acute pain symptom presence and the treatment response in sedated or awake patients in the PACU. The ASA recommends that healthcare providers use standardized, validated instruments to facilitate the regular evaluation and documentation of pain intensity, the effects of treatment, and treatment side effects. The ASA also strongly suggests/recommends that patients who are critically ill, cognitively impaired, or have communication difficulties due to sedation may require additional interventions to ensure optimal acute pain management (ASA, 2012). Generally in the PACU, when patients that do not have a verbal response arrive, the nurses assume that pain isn't present. Current literature isn't sufficient to evaluate the application of

pain assessment methods or pain management techniques specific to this population. This area of assessment needs more research and development.

The ability to reliably assess patient's pain is the foundation for effective pain treatment. As the International Association for the Study of Pain (2010) states, "the inability to communicate verbally does not negate the possibility that an individual is experiencing pain and is in need of appropriate pain-relieving treatment". Therefore, clinicians must be able to reliably detect pain, using assessment methods adapted to a patient's diminished communication capabilities. In such situations, clinicians should consider patients' behavioral reactions as surrogate measures of pain, as long as their motor function is intact (Anand & Craig , 1996). Detection, quantification, and management of pain in critically ill adults are major priorities and have been the subject of research for over 20 years (Puntillo, 1990). Despite this fact, the incidence of significant pain is still 50% or higher in both medical and surgical ICU patients (Chanques, Sebbane, Barbotte, et al., 2007; Payen, Chanques, Mantz, et al. (2007).

Unfortunately during the postoperative period in first hours post anesthesia during the postoperative period, many factors such as the administration of sedatives, hypnotics, and adjuvants may alter the level of consciousness which impacts communication of healthcare providers with patients. These obstacles make pain assessment more complex. The use of appropriate communication methods may reduce patients distress associated with the presence of pain. When the patient is unable to communicate in any way, observable behavioral indicators become unique indices for pain assessment.

Acute Pain Assessment in Non-verbal Patients

Appropriate pain assessment is the foundation of effective pain treatment. Because pain is recognized as a subjective experience, the patient's self report is considered the most valid

measure for pain and should be obtained as often as possible (Loeser & Treede, 2008). During the perianesthesia period, especially during the first hours of the postoperative period, the administration of anesthetics and sedative agents interfere with the level of consciousness. This alteration in the patient's ability to communicate makes pain assessment difficult.

Recognizing that certain behaviors may indicate pain, researchers have developed behavioral pain assessment instruments for use in patients who cannot self-report. Many of these instruments yield a behavioral score that can help determine the presence of pain, and when changes are noted, can be used to evaluate the effectiveness of interventions; however, a behavioral score is not a pain intensity score. If the patient cannot report the intensity of his or her pain, then the intensity is unknown (APS, 2008; Herr, 2011; Barr et al., 2013).

For sedated and postoperative non verbal patients the ASPMN published a position statement that recommends a comprehensive, hierarchical approach to the assessment of pain (Herr, Coyne, Key et al., 2006), which provides the framework for a decision-making process that can be used to manage pain (Pasero & McCaffery, 2011; Herr, Coyne, & Key, 2006). A complete pain assessment is vital and difficult for patients who are nonverbal, sedated, cognitively impaired, or unable to provide a self-report of pain. Unfortunately, most of the existing assessment scales are designed for use with patients who can respond verbally to assessment commands. Consequently, medication management in nonverbal patients is often guided by less precise and wholly untested methods of medication impact (Odhner, Wegman, Freeland, Steinmetz, & Ingersoll, 2004).

Behavioral scales are available and highly recommended by the Critical Care Medicine Association, American Society of Perianesthesia Nurses, American Society of Anesthesiologists, and American Pain Society among others, for the assessment of acute pain in nonverbal patients.

Observational behavioral ratings scales were not equivalent to self-reported intensity ratings. The most validated behavioral rating scales for non-verbal adult patients include five pain scales: Behavioral Pain Scale (BPS); Critical-Care Pain Observation Instrument (CPOT); Non-Verbal Pain Scale (NVPS-R); Pain Behavioral Assessment Instrument (PBAT); and the Pain Assessment, Intervention, and Notation (PAIN) Algorithm (Stites, 2014; Barr et al. 2013).

Although the literature presents the BPS and the CPOT as the most valid and reliable behavioral pain scales for monitoring pain in medical, postoperative and adult ICU trauma (except for brain injury) patients who are unable to self-report (Barr et al., 2013), the evidence does not suggest their applicability for patients in the early post operative period. For purposes of this study, the BPS instrument will not be considered since it was designed for intubated patients; our interest resides on patients under moderate sedation who are not intubated.

Behavioral Pain Scales

Pain algorithm (PAIN)

The PAIN algorithm was developed in 2001 and is divided into the components of pain assessment, the patient's ability to tolerate opioids, and guidelines for analgesic treatment decisions and documentation (Puntillo, Stannard, Miakowski, Kehrlé, & Gleeson, 2002). The pain assessment section of the instrument contains behavioral (movement, facial cues, posturing) and physiological (increased heart rate, respiratory rate, and blood pressure and perspiration or pallor) dimensions, which are similar to the NVPS-R instrument, with differences in the second and third components of the instrument.

Although this instrument was tested in postoperative patients, there are some disadvantages that affect the decision to consider this instrument as a comparative one for acute pain assessment in this study. The first is the insufficiency of data to establish its reliability and

validity. Another reason is the inclusion of analgesic treatment decisions and documentation, which is not a criteria included in the CPOT as a comparable instrument. Finally and most importantly, the extensiveness of the instrument, for it does not facilitate an early assessment, which is the focus of this study.

Non-verbal pain assessment instrument (NPAT)

The NPAT nonverbal pain scale consists of five observational subscales of behavioral indicators for pain: emotion, movement, verbal cues, facial cues, and positioning/guarding (Klein, Dumpe, Katz, & Bena, 2010). Two separate scoring systems are provided on the instrument for use in both verbal and nonverbal patients, each one with a score from 0 to 10 points.

Validity results were moderately strong when the NPAT was compared with the standard self-report in the third phase. The instrument was designed for nonverbal critical care patients, however has not been validated in this population. The scale testing was conducted with verbal medical-surgical patients, so it was not be considered for use in this study.

Non-verbal pain scale revised (NVPS-R)

The original NVPS was based initially based on the Faces, Legs, Activity, Cry, Consolability (FLACC) pediatric scale (Odhner, Wegman, Freeland, Steinmetz, & Ingersoll, 2004). Like the PAIN algorithm and the NPAT, the original NVPS contained behavioral categories (facial expression, activity, and guarding) and physiological categories (heart rate, blood pressure, and respiratory rate) that are graded in severity, and a final category physiologic II included autonomic indicators such as dilated pupils, diaphoresis, flushing, or pallor. The NVPS was revised on 2003 and autonomic indicators was substituted with respiratory category (respiratory rate, pulse oxygen saturation), and was renamed NVPS-R. Each domain is ranked

from 0 to 2, with a total score between 0-2 (no pain) and 3-10 (significant pain presence).

The original NVPS rated facial expression, activity, guarding, change in vital signs (physiologic I), and other physiological signs (physiologic II). NVPS-R was most valid and reliable assessment instrument than the original NVPS for sedated ICU patients receiving mechanical ventilation. In 2009, Kabes, Graves & Norris conducted a further validation of the revised NVPS-R in comparison with the original version. The revised version shows the validity and reliability of the observational instrument for assessing pain in an ICU population of patients who are sedated and receiving mechanical ventilation but are not paralyzed. Furthermore, The revised NVPS-R includes a new “respiratory” category that replaces the physiological II dimension of the original scale (Wegman, 2005). The dimension includes an assessment of the amount of deviation from the baseline respiratory rate, as well as oxygen saturation as measured by pulse oximetry and level of compliance with the ventilator. Using a non-experimental design, nurses in a trauma-surgical ICU assessed patients before, during, and at rest after a painful nursing procedure.

In 2010, Marmo and Fowler used a repeated-measures study design to examine the validity of the NVPS-R in a sample of 25 critically ill patients after open-heart surgery. The NVPS-R, CPOT, and FLACC were administered for a total of 300 paired, independent observations before, during, and after a painful procedure. This study included postoperative patients in critical care unit.

In 2011, Wibbenmeyer et al., in a sample of 38 burn patients, conducted a similar study. A total of 225 paired assessments were completed by nursing staff who were “briefly educated” on use of the CPOT and the NVPS-R. This study was similar to the proposed study. Due to the characteristics of the NVPS-R this instrument could be used for the assessment of pain in

patients in the PACU, however validation is needed in this specific setting.

Critical care pain observation tool (CPOT)

Behavioral indicators are strongly recommended for pain assessment in nonverbal patients and several instruments have been developed and tested in critically ill adults including the Critical Care Pain Observation Tool (CPOT) (Gélinas et al., 2006). The CPOT was tested in verbal and non-verbal patients (Gélinas & Jonhston, 2007; Gélinas & Arbour, 2009; Gélinas et al., 2006). Content validity was supported by critical care unit expert clinicians, including nurses and physicians (IASPN, 2007).

The CPOT was designed for use in both intubated and non-intubated critical care patients. Four indicators are scored from 0 to 2: facial expressions, movements, muscle tension, and ventilator compliance for intubated patients or vocalization for non-intubated patients; total scores range from 0-2 (no pain presence), 3 to 8 (significant pain presence). Content validity index of all indicators was 0.88 to 1.0, according to an analysis of the results of a questionnaire provided to physicians and critical care nurses. The CPOT was originally developed in French and was tested in a convenience sample of 105 cardiac surgery patients. Those patients were admitted to an ICU.

In 2006, Gélinas and Johnson used a repeated-measures design and trained data collectors to obtain the CPOT score of 105 patients at 3 times: at rest, immediately after repositioning (nociceptive procedure), and at recovery (20 minutes after repositioning). After completion of the assessment by 2 observers, the patient was asked to indicate the presence or absence of pain by nodding the head yes or no. Inter rater reliability was moderate to high (weighted κ coefficient = 0.52-0.88) when tested between the same 2 data collectors.

Discriminate validity was established by detection of elevations in heart rate and blood

pressure that occurred in accordance with elevated CPOT scores. Yet, physical motion is known to increase heart rate and blood pressure to compensate for increased oxygen demand, making this method of establishing validity problematic. However, when patients' self-reported pain values were compared with the observer-derived CPOT scores, the positive predictive value of the CPOT was high (85.7%).

The majority of the nurses also reported that the CPOT was quick to use (78%) and that they would recommend use of the CPOT routinely in practice (72.7%)(Gélinas, 2010). Also, in 2010, Marmo and Fowler tested the CPOT in patients after heart surgery and found that the instrument had high reliability ($\alpha = 0.89$). These researchers were also the first to report the internal consistency of the CPOT (56%-100% agreement). The CPOT was also included in the previously discussed study by Wibbenmeyer et al., 2011 who reported a high internal consistency (Cronbach α , 0.71) and good discriminate validity (mean scale scores = 0.27 at rest to 0.56 after noxious stimulation).

Vázquez et al., 2011 conducted a prospective, repeated-measures study in a 12-bed general ICU in Spain. A total of 330-paired observations were completed in a study sample of 96 critically ill patients. Observations were conducted before, during, and after a repositioning procedure. Inter-rater reliability of the CPOT was excellent ($\kappa = 0.79$), and discriminate validity was good; mean scores were 0.27 (SD, 0.64) at rest and 1.93 (SD, 1.41) during the procedure.

When pain assessment practices were analyzed by using descriptive statistics, reports of pain assessments were 3 to 4 times more frequent after implementation than they were before implementation. Interestingly, implementation of the CPOT was associated with decreased frequency of administration of sedatives and analgesics. Gélinas et al. (2011) provided 2 possible explanations: increased ability of nursing staff to discern pain from other symptoms (such as

anxiety) or decreased number of trauma patients in the group after implementation due to a change in the center's trauma designation.

The PAIN algorithm and NPAT have each been used in only a single study, and the findings in both studies were of limited value. The original testing of the NVPS-R is of limited value because of the study's non-experimental design and the use of the FLACC pediatric scale as the gold standard for comparison.

The NVPS-R is the only instrument that includes dimensions of physiological data; these indicators have been some of the least sensitive markers for the presence of pain (Pasero & McCaffery, 2005).

An overwhelming majority of the studies provide support for the reliability and validity of both the BPS and the CPOT in detecting pain in nonverbal critically ill adults. Of the available observational pain scales, the CPOT has shown superior reliability and validity when used in nonverbal critically ill adults. Thus far, the validation of observational pain scales has been for use in cognitively impaired patients and critically ill patients in the intensive care units, who are sedated (Kabes, Graves, & Norris, 2009) but not for sedated patients in the PACU.

A group of Canadian nurse investigators described observable physiological and behavioral indicators of pain (Gélinas, Fortier, Viens, Fillion, & Puntillo, 2004). In 2005 Pasero and McCaffery pointed out that heavily sedated patients might have severe pain but be unable to move. The BPS focuses on behavioral observations only (facial expression, cry, and movements), whereas the NVPS-R includes behavioral and physiological indicators. However, physiological indicators should not be used as the sole indicators of pain level.

The NVPS-R is similar to the CPOT pain scale (ASPMN, 2010). The CPOT appears to be a better instrument to detect pain in intubated post open-heart surgery adults compared with

the NVPS-R, as evidenced by better agreement between nurse raters. Further research is necessary to assess the reliability of the CPOT in other patient populations, including non-intubated, non-verbal patients. Nurses require an easy pain assessment instrument to use with clear descriptors for each item of the instrument and takes limited time to complete the assessment. The implementation of a new practice in any setting requires careful planning, staff involvement, motivation, training, and resources.

Richmond Agitation Sedation Scale (RASS)

The RASS is the most valid and a reliable instrument for assessing depth of sedation (Barr et al., 2013) and to quantify agitation severity in patients receiving sedative medications (Martínez-Castillo et al., 2013) in various settings. The RASS assesses the level of consciousness and agitated behavior of patients. The scale has a single-item numerical structure that involves the description of four levels of agitation (from 1- restless, to 4 - combative) and five levels of sedation (from -1- somnolence, to -5 - unarousable)

The original psychometric analysis of the RASS included in the 2013 Pain, Agitation, and Delirium guidelines included eight studies with over 1,600 ICU patients (Sessler et al., (2002). Six additional RASS studies have been published since 2010, for a total of over 3,400 ICU patients studied using RASS (Wessley et al., 2003). The validity and reliability of the scale has been established in intensive care unit patients (Sessler et al., 2002).

Sedative medications are commonly administered to patients before and during surgery. To measure sedation levels, the RASS scale is applicable in postoperative patients after surgery and general anesthesia. Postoperative patients can suffer reduced awareness resulting from the use of medications used to induce and maintain a state of general anesthesia. In these clinical situations, the RASS is a useful instrument for evaluating patients' reduced awareness due to sedation and

to establish if a verbal or non-verbal instrument is adequate to assess acute pain.

The literature states that objective measures of brain function, such as auditory evoked potentials or bi-spectral index, are not to be used to assess depth of sedation as a primary source in *non-comatose*, adult patients (Barr et al., 2013). The RASS presented the highest psychometric scores, high degree of inter-rater reliability, convergent or discriminant validation when compared to other similar scales and had a robust number of study participants (Brandl, Langley, Riker, et al., 2001; Ryder-Lewis & Nelson 2008). The scale discriminates different sedation levels in many clinical situations, including with postoperative patients (Ely, Truman, Shintani, et al., 2003).

Summary

Literature suggests that existing validated instruments for use in the assessment of acute pain in the early post operative period and the pain management for patients under moderate sedation are lacking and research is warranted. Pain needs to be assessed beginning at admission to hospital and at regular intervals. Based on the principle of justice, all patients have the right to receive comparable care, including those who cannot report acute pain.

Unfortunately, acute pain remains prevalent. Pain measurement is complex, however, the basis for quality pain management is assessment using of reliable and valid instruments (Ferrante & VadeBoncouver, 1993). There is also a requirement that pain be reassessed after patients are medicated for pain to determine if the medication has relieved the pain (Barr et al., 2013). There is ample evidence that the appropriate use of analgesics at the right intervals can provide good pain relief for patients (Dolin, Cashman & Bland, 2002). The issue is the selection of the appropriate instrument to measure pain in the early postoperative period.

Health care organizations have the responsibility to develop processes to help support

improvements in pain management, including methods to ensure the recognition of patients' rights for suitable pain assessment and management, appropriate assessment of the severity of pain; regular pain assessment, recording, and follow-up; and establishment of policies and procedures that supports the appropriate prescription of pain medications (JCAHO, 2000). Pain scales need to be appropriately and consistently used for individual patients. Nurses need to be educated on the use of pain scales with special attention to the interpretation of each behavior or item on the instrument for accurate assessment and subsequent interventions.

Adequate pain management requires interdisciplinary evaluation and management. Well-documented pain assessments and interventions are essential to maintain effective communication between healthcare providers and monitor patients responses to acute pain management. The quality of acute pain management needs to emphasize the importance of the continual assessment to effectively improve pain treatment.

Currently, the literature is insufficient to evaluate the application of pain assessment methods or pain management techniques in nonverbal patients in the early post-operative period. This group of patients includes the critically ill, cognitively impaired, or patients with communication difficulties, such as patients after surgery. These patients require additional assessment and management considerations. Regular pain assessments and documentation of pain scores are an important component of an acute pain service program as it increases the likelihood that patients' pain remains below an acceptable threshold (Sinatra, 2010) to prevent and/or decrease postsurgical complications.

CHAPTER 3

METHODS

Background

Unrelieved postsurgical pain can lead to multiple complications that can delay recovery and lead to increased morbidity and mortality. The efforts of this study are directed at developing the scientific underpinnings to provide anticipatory pain management in the PACU for patients to promote faster recovery. One critical gap in developing this knowledge is the ability of nurses to evaluate pain in sedated non-verbal patients to provide better pain management before critical pain thresholds are exceeded.

Research Question

Two non-verbal instruments to evaluate pain in adults have been identified in the literature, but neither of these instruments has been previously tested in sedated, non-verbal patients in the post anesthesia care unit during the immediate postoperative period. Thus, the proposed research aimed to develop baseline measures of pain with these instruments that might subsequently be used to provide anticipatory pain management. Thus, this study addressed the following question: What is the relationship between the Critical-Care Pain Observation Instrument (CPOT) and the Non-Verbal Pain Scale (NVPS-R) when used during the assessment of acute pain for patients under sedation in the PACU?

Specific Aims

- **Aim 1** -To describe the relationship between pain scores obtained using the NVPS-R and CPOT assessment instruments, when administered upon arrival to the PACU, among patients undergoing major abdomino-pelvic, gynecologic, or gastrointestinal surgery.

- **Aim 2** - To describe the relationship between pain scores obtained using the NVPS-R and CPOT assessment instruments, when administered 120 minutes after arrival to the PACU, among patients undergoing major abdomino-pelvic, gynecologic, or gastrointestinal surgery.
- **Rationale Specific Aim 1 and Aim 2** - This study used the CPOT and the NVPS-R, to determine whether one instrument is best when assessing this population because it will describe the extent to which of the two scores is more predictive of pain. If one is found to be more predictive than the other, under those circumstances, the instrument that is simpler or faster for use by clinicians will be best.
- **Aim 3** - To describe the change in pain scores over time obtained using the NVPS-R assessment instrument, when administered to patients undergoing major abdomino-pelvic, gynecologic, or gastrointestinal surgery at the following time points (minutes) following arrival to the PACU: 0, 15, 30, 45, 60, 90 and 120.
- **Aim 4** - To describe the change in pain scores over time obtained using the CPOT assessment instrument, when administered to patients undergoing major abdomino-pelvic, gynecologic, or gastrointestinal surgery at the following time points (minutes) following arrival to the PACU: 0, 15, 30, 45, 60, 90 and 120.
- **Rationale Aim 3 and Aim 4** – The rationale for this research is to contribute to the literature additional knowledge of the course of pain over time among non-verbal sedated patients. The usefulness of this information is that it might guide the development of new and better protocols for providing anticipatory pain relief.
- **Aim 5** - To describe the relationship between the change over time in pain scores obtained using the CPOT assessment instrument and the NVPS-R assessment instrument,

when administered to patients undergoing major abdomino-pelvic, gynecologic, or gastrointestinal surgery at the following time points (minutes) following arrival to the PACU: 0, 15, 30, 45, 60, 90 and 120.

- **Rationale Aim 5**-The rationale is to describe if the two assessment instrument scores over time are predictive of one another. If the predictive significance of one assessment instrument is sufficiently high, then the two instruments are equivalent. Under those circumstances, the simpler or faster instrument is best for use.

Study Design

This exploratory study used an observational cohort, correlational, single-group, repeated measures design to compare and describe the relationships between the Critical-Care Pain Observation Instrument (CPOT) (APPENDIX C) and the revised Non Verbal Pain Scale (NVPS-R) (APPENDIX D), to evaluate acute pain during the early postoperative period.

Behavioral pain assessment was conducted in non-verbal patients after major abdomino-pelvic, gynecologic or gastrointestinal surgery under general anesthesia. These types of surgeries were associated with moderate to severe postoperative acute pain due to the involved dermatomes (neural pathways) that share the same sensorial innervation from sympathetic nerves from tenth thoracic to the first lumbar spinal cord segments (Ferrante and VadeBoncouer, 1993).

Setting

The Post Anesthesia Care Unit (PACU), at the Medical Services Administration (ASEM) in the Puerto Rico Medical Center was used for the recruitment of subjects (APPENDIX B). ASEM's PACU is an 18-bed acute care facility providing supra tertiary surgical services to adult patients admitted for management of acute care and trauma surgeries. The PACU is staffed by 35 nurses on average, 6-8 nurses in each eight (8) hour shift turn in 24 hours. On an average day 20-

35 patients were received daily in the PACU, with an average length of stay of two hours.

Study Population

The study population was comprised of adult male and female patients undergoing abdomino-pelvic, gynecologic, or gastrointestinal major surgeries who provided consent to be enrolled in the study. These patients had the expected symptom of acute pain after surgery and were unable to self-report the level of pain due to the level of sedation. The number of patients with abdomino-pelvic, gynecologic, or gastrointestinal surgery in the setting ranged from 8-10 per week. The sample included all patients that had previously consented to enroll in the study during a pre-operative visit. These pre-operative visits usually occurred from 7 days to a few hours before the surgery. The admitted participant subjects who had major abdomino-pelvic, gynecologic or gastrointestinal surgeries were enrolled from those individuals who had their surgery performed by multiple surgeons. Subjects admitted to the PACU after surgery were unable to self-report the level of pain due to a level of sedation.

In order to be eligible the subject had to be: an adult scheduled for selected surgeries, under sedation following surgery, with a RASS level of -4 to -2 (APPENDIX E). Subjects who had consented were included in the study in the post anesthesia care unit of the Medical Services Administration (ASEM).

Sample Size and Calculations

Sample size calculations were not performed. Because this is an exploratory study, we reason that enrolling 40 consenting participants afforded us sufficient precision for confidence interval estimation of the relationships of interest. Subjects scheduled for abdomino-pelvic, gynecologic, or gastrointestinal surgeries were identified during their pre-operative visit. Once identified, subjects were informed and invited to participate in the study. Those who agreed

were asked to read and sign a consent form and then enrolled in the study.

Inclusion criteria

- Adult 21 years or older.
- Able to provide informed consent.
- Consenting to abdomino-pelvic, gynecologic or gastrointestinal surgery.
- Unable to verbalize or indicate pain by using a traditional verbal scale such as the numeric rating scale (NRS) upon arrival in the PACU.
- RASS = -4 to -2 (deep, moderate and light sedation)

Exclusion criteria

- Patients able to self-report acute pain, with an initial sedation scale (RASS) = -1, and 0 to 4.
- Patients with history of chronic pain, or moderate to high acute pain previous to surgery.
- Patients with a previous diagnosis of chronic cognitive impairment (Dementia, Alzheimer) or neurologic impairment (paraplegia, quadriplegia, upper limbs amputations, or stroke), due to the variability in behaviors presented. This would disrupt patient's motor functions and the behaviors evaluated with the non-verbal pain instruments (NVPS-R and CPOT) couldn't be observable (Barr et al., 2013).

Recruitment

The potential participants were chosen during the preoperative visit by the investigator. A preoperative schedule at Surgery and OB GYN clinics was evaluated for inclusion and exclusion criteria of potential participants. A request for a waiver of authorization for the release of health information form (Appendix F) from the UPR RCM IRB was used for the purposes of accessing to personal health information (PHI) prior to consent of participants.

The investigator made the initial contact with the potential participants, informed them

about the study and asked if they were interested in participating. Upon agreeing to participate in the study, they were asked to read and sign the informed consent form previously approved by the Institutional Review Board (APPENDIX F) so that they had the opportunity to review it and ask any questions regarding participation. They were given a copy of the consent form for their records, the investigator retained the original, and a copy was placed in the subject's chart if required by the medical center. The investigator made note of the date of the surgical procedure following consent so that the patient could be visited in the PACU following surgery.

Informed Consent

Potential participants were informed that their participation was voluntary and that they could withdraw at any time before or after the study. Participants were informed that the study was confidential to comply with ethical and HIPAA guidelines. Each element of the consent form was reviewed with the subject prior to consent. Two copies of the original informed consent were printed; one for the PI to keep; one for the participant to keep; and one for the medical record, if required by the medical center. Approval to use human subjects in this research was granted by the University of Massachusetts Amherst Human Research Protection Office (HRPO) and the University of Puerto Rico Institutional Review Board (IRB). Written consent was required from each participant (APPENDIX F). This was a low risk study because it involved non-invasive measurements; there was no intervention and no alteration of received care. Thus, recruitment of the participants took place after an anticipated expedited review from Institutional Review Board and received approval from the UMASS-HRPO and UPR-IRB.

Data Collection Procedures

Pre-operative visit surgery day

The data collection procedure began during the preoperative visit, 0 to 7 days prior to the scheduled surgery (APPENDICES H & J). The PI evaluated the inclusion and exclusion criteria for each possible participant (APPENDIX K). When it was found that a potential participant met the inclusion criteria, the PI discussed the study purpose, risks, benefits and confidentiality. If the potential participant agreed to participate, they were asked to sign a consent form for study participation (APPENDIX F). We also determined if the participant had any pain at this visit before their surgery.

Surgery day

A socio demographic data instrument was completed with information during the pre-operative visit, in the holding area upon admission for surgery or before arrival to the PACU (APPENDIX G). Additionally, vital signs including blood pressure, heart rate, respiratory rate, and oxygen saturation were measured and recorded, before the participant's arrival to the operating room.

At PACU arrival

After surgery, upon the participant's arrival at PACU, the RASS was applied to measure the level of sedation. If the participant showed a RASS between -2 to -4, indicating a level of sedation from light to deep, then both non-verbal instruments, the Critical Care Pain Observation Tool (CPOT) (Gélinas, 2006), and the NVPS-R (Rochester University, 2004) was applied (APPENDICES C & D). The acute pain assessment with nonverbal instruments was applied at 0, 15, 30, 45, 60, 90, and 120-minute intervals. The order of the assessment instruments application

was used for randomization between patients. The randomization schedule was identified in advance.

There was the possibility of some subjects being excluded from the study after having provided consent due to level of consciousness upon arrival to the PACU. This occurred if a participant's RASS score was -5 (unarousable), -1 (drowsy) or the RASS score was 0, +1 to +4, which indicated a level of wakefulness (Sessler et al., 2008), thus the participant would have been able to self-report pain.

For documentation purposes, the PI nurse had a demographic data sheet and the assessment of acute pain instruments. Each bedside pain assessment was performed by the PI nurse using a data collection form (APPENDIX L) The form included the pain assessment instruments (CPOT and NVPS-R), for acute pain assessment for each patient. At established time intervals, the PI nurse rated each patient's level of pain and recorded their assessments on the data collection form.

In summary, after all participants were confirmed to have a RASS sedation level between -2 to -4, they were assessed with both non-verbal pain instruments during the early postoperative period, immediately after arrival to PACU. After that initial pain assessment, patients were assessed every 15 minutes until an hour had passed, then every 30 minutes until another hour had passed, for a total of seven (7) assessments with each instrument during a 2-hour period. The number and type of pain medications administered throughout the early postoperative period were also recorded.

Data Collection instruments

Personal and health information (PHI) that we used or disclosed (released) from medical records for this research included: Age, gender, and medical record number, discharge time from

PACU; and health information including American Society of Anesthesiologists (ASA) physical status, diagnoses, medications used, vital signs, type and length of surgery, anesthesia administered, lab results, pain assessments, pain presence at discharge, medications administered and side effects during PACU stay.

To protect the confidentiality of PHI in the records of the study, the following procedures were used:

PHI was protected through the assignment of a case number. The researchers kept all study records, including data codes, in the PI's office. The records were protected according to HIPAA regulations. A master key that linked names and codes remained separate and in a safe place. The master key will be destroyed three (3) years after the end of the study.

Electronic files (REDCAP database, spreadsheets), containing all personally identifiable information was password protected (Harris, Taylor, Thielke, Payne, Gonzalez, Conde, 2009). Any computers that host files were password protected to prevent access by unauthorized users. Only the researchers had access to passwords. At the conclusion of this study, researchers will publish their findings. The PHI is to be presented in a summary and participants will not be identified in publications or presentations.

A socio-demographic instrument (APPENDIX G) was used to collect data on age, ethnicity, sex, education, and weight. Other important data to be included was diagnoses and the level of pain during the pre-operative visit and during the day of the surgery before the procedure. All of this information is important to analyze results and establish relationships amongst the variables. As stated earlier, the RASS instrument was first used to establish sedation level (APPENDIX E), then two behavioral pain assessment instruments were used for this study, CPOT (APPENDIX C) and NVPS-R (APPENDIX D). Each instrument was applied for the selected nonverbal

patients, both instruments at a same time. Permission to use CPOT and NVPS-R instruments was obtained from the developers of the original scales via e-mail (APPENDIX A).

A data collection form was designed to include the socio-demographic data, pain assessment score, pain medication administered and other important data (APPENDIX L). At the end the results of significant acute pain presence measured with each instrument was compared to established relationships. These instruments have been described earlier in this manuscript.

Richmond Agitation and Sedation Scale (RASS)

The RASS is the instrument used to measure the level of sedation at this study. The instrument ranged from -5 (unarousable) to +4 (combative). If the RASS score range equaled -1 (drowsy) or higher, the patient sustained awakening or agitation, then they were either not enrolled in the study or data collection was stopped. If the score was -2 (light sedation), -3 (moderated sedation) or -4 (deep sedation), then data collection began immediately in the PACU.

Critical Care Pain Observation Tool (CPOT)

The CPOT has four behavioral indicators that include facial expression, body movement, and compliance with ventilator for intubated patients or vocalization for non-intubated, and muscle tension. Each indicator is valued is from 0-2 points, for a maximum total score of 8 points. In this study, the vocalization indicator was used because patients were expected to be breathing spontaneously. The presence of significant acute pain was defined by a total score equal to 3 or more (Barr et al., 2013). Subjects who were intubated on a ventilator were not included to increase the reliability and validity of measures.

Non-verbal Pain Scale Revised (NVPS-R)

NVPS-R includes behavioral and physiological categories. It contains five categories classified as three behavioral dimensions (facial expression, activity, and guarding), two

physiological dimensions (heart rate and blood pressure), and a respiratory dimension (respiratory rate and oxygen saturation) that was graded in severity. Each category is ranked from 0 to 2, with a total score between 0 (no pain) and 10 (maximum pain). The score from 0-2 indicate no pain, 3-10 indicates significant pain (University of Rochester Medical Center, 2004).

Data Analysis

Description of the study cohort

Prior to analyses to address the specific aims, the study cohort was described using means, standard deviations and percentiles for continuous variables and frequencies and relative frequencies for discrete variables. Variables considered included: demographics, medical history, plus selected surgery indices (type of surgery, duration of surgery, general anesthesia proposed), pain presence. Separate descriptive statistics were obtained for discrete and continuous variables of the population.

Data Analysis

Data Analysis (Appendix I) to Address Specific Aim #1 - To describe the relationship between pain scores obtained using the NVPS-R and CPOT assessment instruments, when administered upon arrival to the PACU, among patients undergoing either abdomino-pelvic, gynecologic, or gastrointestinal surgery.

The nature and strength of the relationship between NVPS-R and CPOT scores was explored using standard description approaches, Pearson correlation, and linear regression. Descriptive relationships were assessed through scatter plots. Simple linear regression models were then fitted to obtain estimates of the correlation in NVPS-R and CPOT scores and a prediction equation. The dependent variable in these analyses was the NVPS-R score. Thus, we considered the CPOT for the prediction of the NVPS-R.

Data Analysis to Address Specific Aim #2 - To describe the relationship between pain scores obtained using the NVPS-R and CPOT assessment instruments, when administered 120 minutes after arrival to the PACU, among patients undergoing major surgery that is either abdomino-

pelvic, gynecologic, or gastrointestinal.

Analyses to address Specific Aim #2 will be the same as those for Specific Aim #1.

Data Analysis to Address Specific Aim #3 - To describe the change over time in pain score obtained using the NVPS-R assessment instrument, when administered to patients undergoing major surgery that is either abdomino-pelvic, gynecologic, or gastrointestinal and at the following time points (minutes) following arrival to the PACU: 0, 15, 30, 45, 60, 90 and 120.

Change over time in the NVPS-R score was explored using descriptive statistics, mean, standard deviation (SD), range of values, and graphs. Because it was expected that pain would decline with time, the focus of these analyses was a description of the pattern of reduction and not a test of the null hypothesis of zero change. Descriptive statistics included, for each time point, regression models fitted to obtain estimates of the mean profile, overall and separately for sub-groups defined by key variables (eg – type of surgery, type of medications administered, dose per kilograms, time of administration)

Data Analysis to Address Specific Aim #4-To describe the change over time in pain score obtained using the CPOT assessment instrument, when administered to patients undergoing major surgery that is either abdomino-pelvic, gynecologic, or gastrointestinal and at the following time points (minutes) following arrival to the PACU: 0, 15, 30, 45, 60, 90 and 120.

Analyses to address Specific Aim #4 will be the same as those for Specific Aim #3.

Data Analysis to Address Specific Aim #5 -To describe the relationship between the change over time in pain score obtained using the CPOT assessment instrument and the change over time in pain score using the NVPS-R assessment instrument, when administered to patients undergoing major surgery that is either abdomino-pelvic, gynecologic, or gastrointestinal and at the following time points (minutes) following arrival to the PACU: 0, 15, 30, 45, 60, 90 and 120.

Data analysis to address Specific Aim #5- We considered an appropriately defined response to help us determine any change in scores from one time point to another. To evaluate the change over time using each one of the assessment tools, we calculated the Wilcoxon Signed Rank for the difference of the following time points in minutes (0 to 15, 15 to 30, 15 to 45, 15 to 60, 15 to 120). The differences in score for CPOT and NVPS-R were calculated as: change score = score at 120 minutes – score at 0 minutes, 2). For each patient, this will yield a pair of response features, summarizing the CPOT and NVPS-R profiles, respectively. Differences reached statistical significance if $p \leq 0.05$.

Sociodemographic data

Descriptive statistics were utilized to describe the demographic characteristics of the sample. Demographic data included age, type of surgery, general anesthesia administered and diagnoses. This data provided important information to establish inferences, relationships and correlations between the studied variables (APPENDIX G).

CHAPTER 4

RESULTS

Introduction

The purpose of this study was to determine the relationship between the CPOT and the NVPS-R for acute pain assessment in the early postoperative period in non-verbal sedated patients. We performed an exploratory study of 40 patients who underwent major abdomino-pelvic, gynecologic or gastrointestinal surgery and were in a non-verbal state of sedation in the early postoperative period. Seven repeated assessments of pain were conducted using both CPOT and NVPS-R instruments, in minutes post arrival to the PACU at 0, 15, 30, 45, 60, 90, and 120 minutes. A total of 246 assessments were measured with each instrument. Statistical methods used to explore the relationship between CPOT and NVPS-R pain scores included descriptive statistics and normal theory regression.

To address and account for the possibility that order of pain assessment (CPOT first or NVPS-R first) might influence the subsequent pain assessment (NVPS-R second or CPOT second), our study design also incorporated randomization of the order in which the CPOT and NVPS-R assessments were performed. Study participants were randomized to group 1 (CPOT first, NVPS-R second) or group 2 (NVPS-R first, CPOT second). Preliminary analyses of the data at each time point of measurement included a test of the null hypothesis of zero effect of group on CPOT and zero effect of group on NVPS-R.

REDCap a research electronic data capture is a secure, web-based application designed to support data capture for research studies (Harris, Taylor, Thielke, Payne, Gonzalez, Conde, 2009), was used to collect and categorize data. STATA version 14.0 was used to analyze data. Results from the major study findings are described in this chapter.

Subject Recruitment

This study was conducted in a Post Anesthesia Care Unit (PACU) located in Medical Services Administration (ASEM) in the Puerto Rico Medical Center. Fifty- nine patients, 22 to 87 years old, who were scheduled for abdomino-pelvic, gynecologic, or gastrointestinal surgery between October 20, 2015 and December 7, 2015 were consented for the study. Of these, 19 subjects were excluded. One subject was unable to sign the informed consent form, due to chronic cognitive impairment. The other 18 patients were excluded because their surgeries were cancelled (n=8), they received regional anesthesia during surgery (n=5), or because they were verbal (RASS -1, 0) upon arrival to the PACU (n=5). Thus, the final sample consisted of 40 subjects.

Characteristics of Study Participants

The characteristics of the study participants are shown in Table 1 (discrete variables) and Table 2 (continuous variables). Both demographics and surgical summaries are reported. The mean age of the study participants was 49.3 ± 17.1 years. The youngest participant was 22 years of age, and the oldest was 87 years of age. The mean weight was 79.8 ± 29.4 kilograms. Slightly over half (52.5%) of the participants had completed secondary education. Participants were classified using the American Society of Anesthesiologist's (ASA) physical status classification system (ASA). The ASA scale varies from 1= healthy patient, 2= mild systemic disease, 3= severe systemic disease, 4=incapacitating disease, 5=dying patient (Naguelhout & Plaus, 2014). Ten percent of the patients were healthy (ASA 1) whereas that 67.5% had a mild systemic disease (ASA 2). The majority of participants 72.5% were female. About 85% were white and 100% were of Hispanic origin.

Table 1. Characteristics of Study Participants for discrete variables, n=40

| Characteristics | Total n (%) |
|--|--------------------|
| Discrete variables | |
| Randomization | |
| Group 1: CPOT administered first | 20 (50.0%) |
| Group 2: NVPS-R administered first | 20 (50.0%) |
| Gender | |
| Male | 11 (27.5%) |
| Female | 29 (72.5%) |
| Hispanic origin | |
| Yes | 40 (100.0%) |
| No | 0 (0.0%) |
| Race | |
| White | 34 (85.0%) |
| Black/African | 6 (15.0%) |
| Education | |
| Primary | 5 (12.5%) |
| Secondary | 21 (52.5%) |
| Post Secondary | 5 (12.5%) |
| Bachelor | 6 (15.0%) |
| Master | 3 (7.5%) |
| American Society of Anesthesiologists (ASA) Physical Status Classification System | |
| 1 Healthy patient | 4 (10.0%) |
| 2 Mild Systemic Disease | 27 (67.5%) |
| 3 Severe Systemic Disease | 8 (20.0%) |
| 4 Incapacitating Systemic Disease | 1 (2.5%) |
| Pre op Analgesic/medications treatment | |
| Yes | 17 (42.5%) |
| No | 23 (57.5%) |
| Pre op Analgesic/medications | |
| Acetaminophen | 6.0 (15.0%) |
| Other pain med | 13.0 (32.5%) |
| No medication | 23.0 (57.5%) |
| Surgery Category | |
| Abdominal-pelvic | 7 (17.5%) |
| Gastrointestinal | 15 (37.5%) |
| Gynecologic | 18 (45%) |

| Characteristics | Total n (%) |
|--------------------------|--------------------|
| Primary Diagnoses | |
| Uterine Myoma | 5(12.5%) |
| Hernia | 5(12.5%) |
| Gynecologic Carcinoma | 10(25%) |
| Colon Carcinoma | 6(15.0%) |
| Ureter Carcinoma | 1(2.5%) |
| Other diagnoses | 13(32.5%) |
| Cancer Diagnosis | |
| Yes | 17 (42.5%) |
| No | 23(57.5%) |
| Intraop Opioids* | |
| Fentanyl | 40 (100.0%) |
| Morphine | 21(52.5%) |
| Other | 0 (0.0%) |

*Not mutually exclusive

The surgical categories for the participants included gynecologic surgeries (45%), followed by gastrointestinal surgery (37.5%), and abdomino-pelvic surgery (17.5%). Many participants had a cancer diagnosis (42.5%). Of all cancer diagnoses, the most prevalent was gynecologic carcinoma (25%), with colon carcinoma being the second most frequent diagnosis (15%), and ureter carcinoma (2.5%) the third. Other common primary diagnoses included uterine myoma (12.5%), hernia (12.5%), and other diverse diagnoses (32.5%), including, Crohn's disease, ulcerative colitis, enteric fistula, cystocele, intestinal obstruction, spleen cyst, pelvic mass, left upper quadrant mass, and vesicovaginal fistula.

The use of pre-operative opioid and non-opioid medication(s) for pain management, one day before surgery, was reported by 42.5% of participants. The primary non-opioid medication used alone was acetaminophen by 15% of participants. Other non-opioid medications given include, gabapentin 10%, and aspirin 2.5%, which accounted for another 12.5% of the participants who received medication pre-operatively. As for the pre-operative opioid

medication, 7.5% of the patients received morphine, 5% received tramadol, and 2.5% were given ultracet, which accounted for another 15% of the participants who received medication.

Intraoperative pain management included opioid administration, specifically fentanyl that was administered to 100% of participants. Morphine was administered intraoperatively; closest to the end of the surgery, to 52.5% of participants.

Pre-operative vital signs measurements of heart rate (HR), mean arterial pressure (MAP), respiratory rate (RR) and pulse oxygen saturation (SpO₂) were recorded and averaged, patients reported a HR of 78.3 ± 16.6 beats/mins, MAP of 97.3 ± 13.6 mmHG, SpO₂ $99.5 \pm 0.8\%$, and RR 17.7 ± 2.3 R/min.

Pain intensity was assessed using the numeric rating scale (NRS) prior to surgery, to establish a baseline measurement of pain. The NRS is a gold standard instrument used to measure pain intensity in verbal patients (Dhile, 2006). NRS scale intensity varies from 0 (no pain) to 10 (maximum pain intensity). Participants reported a pain intensity mean of 3.2 ± 3.4 . On average, the intraoperative duration of general anesthesia in the patients of this study was 9.86 ± 2.38 hours (mean \pm SD).

Table 2. Characteristics of Study Participants for continuous variables, n=40

| Characteristics | Mean (SD) |
|--|---------------------------|
| Continuous variables | Range |
| Age | 49.3 (17.1) 22.0-87.0 |
| Weight (kgs) | 79.8 (29.4) 38.6-167.7 |
| Pre-op Heart Rate (HR), l/min | 78.3 (16.6) 55.0-120.0 |
| Pre-op Mean Arterial Pressure (MAP), mmHg | 97.3 (13.6) 68-124.3 |
| Pre-op Oxygen Saturation (SpO₂), % | 99.5 (0.8) 97.0-100.0 |
| Pre-op Respiratory Rate (RR), r/min | 17.7 (2.3) 12.0-22.0 |
| Pre-op Pain Score Numeric Rating Scale (NRS) (0-10) | 3.2 (3.4) 0.0-10.0 |
| Anesthesia Time (in hours) | 9.86 (2.38) 7-15.25 |

Results: Analyses of Randomization (“Order Effect”)

Randomization yielded groups that were similar with regards to demographics and surgical experience, see Appendix Table 3. The Fisher Exact test and Mann-Whitney tests were each performed for the CPOT and NVPS-R. With the exception of the primary diagnosis, gynecologic carcinoma, no statistically differences were observed. There was a higher number of patients diagnosed with gynecologic carcinoma (n=9) in the group where the CPOT was administered first (p=0.008). However, when the demographic profile and characteristics for

discrete and continuous variables between the two groups were evaluated, the randomization of the two groups was similar and there were no significant differences ($p\text{-value} \geq 0.05$) in the distribution of the two groups.

Analyses of Study Aims

Results Aim 1

The first aim was to describe the relationship between pain scores obtained using the NVPS-R and CPOT assessment tools, when administered upon arrival (time 0) to the PACU, among patients undergoing major abdominal, pelvic, or gastrointestinal surgery. We assessed this relationship using a scatter plot, Pearson's correlation and a simple linear regression model at baseline (time 0) with a 95% Confidence Interval (CI). Results from the Pearson's correlation for Aim 1 (Figure 2) showed that the CPOT and NVPS-R pain scores were positively correlated (correlation coefficient, $r = 0.88$). The final prediction equation was $NVPS\text{-}R_0 = 0.3345383 + 0.8081036 * CPOT_0$, meaning that for each one-point increase in CPOT at time 0, NVPS-R at time 0 increased by 0.81. Results showed that the two-tail p-values were statistically significant ($p\text{-value} \leq 0.05$). In other words, CPOT at time 0 was statistically significant in explaining NVPS-R at time 0.

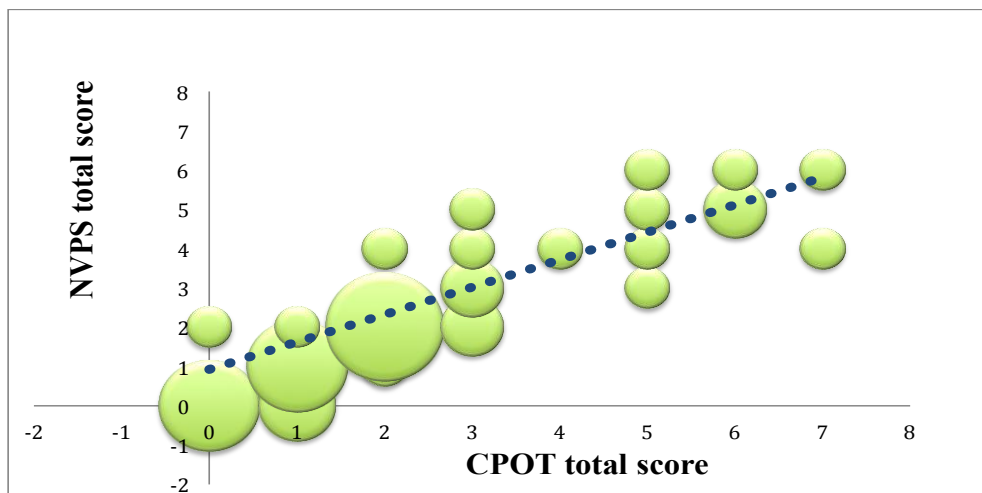


Figure 2. Scatter plot of CPOT at time 0 vs. NVPS-R at time 0
(The size of the dot visually represents the amount of possible (x,y) pairs in the same coordinate. The bigger the dot the more cases that reported the same scores on both scales).

Results Aim 2

The relationship between pain scores obtained using the NVPS-R and CPOT assessment tools, when administered 120 minutes after arrival to the PACU was assessed through a scatter plot with a 95% CI (Figure 3). Results showed CPOT and NVPS-R pain scores were positively correlated ($r = 0.89$). The final prediction equation is $NVPS-R_{120} = 0.8669332 + 0.2689891 * CPOT_{120}$, meaning that for each one-point increase in CPOT, NVPS-R minutes increased by 0.87. Results showed CPOT at 120 minutes explains 80% of the variation in NVPS-R at time 120 minutes and the two-tail p-values were statistically significant ($p\text{-value} \leq 0.05$).

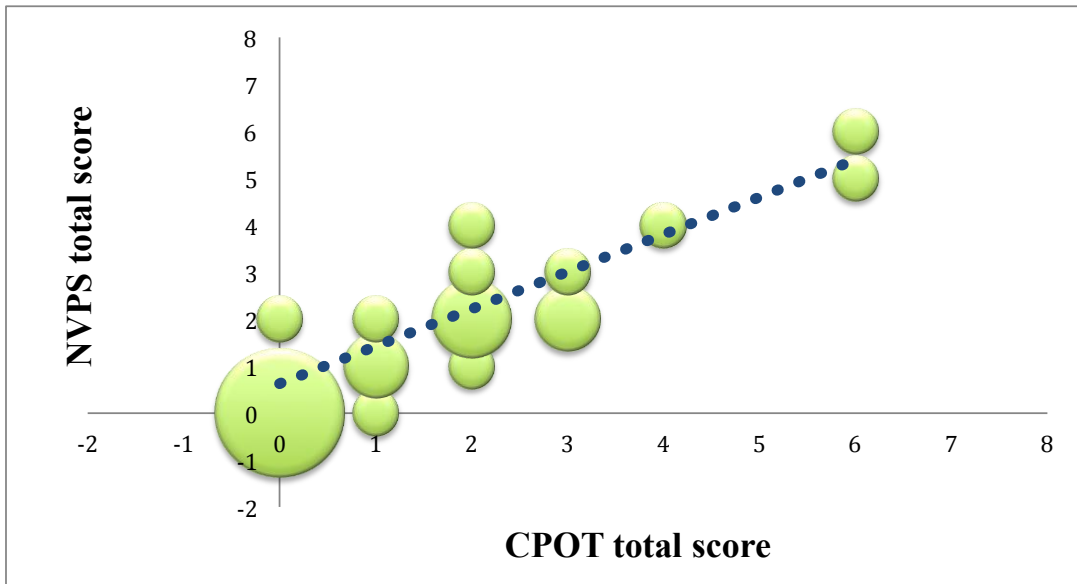


Figure 3. Scatter Plot of CPOT at time 120 vs. NVPS-R at time 120

(The size of the dot visually represents the amount of possible (x,y) pairs in the same coordinate. The bigger the dot the more cases that reported the same scores on both scales)

Results Aim 3

To describe the change in pain scores over time obtained using the NVPS-R assessment tool following arrival to the PACU at the following time points 0, 15, 30, 45, 60, 90 and 120

minutes. We created a table to evaluate the means, standard deviations (SD) and range of each time point values of NVPS-R (Table 3).

Table 3: Mean and Range of NVPS-R Scores at Different Times (in minutes)

| Time (minutes) | Mean \pm SD | Range (max - min) |
|----------------|-----------------|-------------------|
| 0 | 2.37 \pm 1.89 | 6 - 0 |
| 15 | 2.55 \pm 1.55 | 7 - 0 |
| 30 | 2.49 \pm 1.50 | 7 - 0 |
| 45 | 2.55 \pm 1.67 | 6 - 0 |
| 60 | 2.11 \pm 1.63 | 6 - 0 |
| 90 | 2.12 \pm 1.60 | 6 - 0 |
| 120 | 1.75 \pm 1.73 | 6 - 0 |

Figure 4 depicts the values for the means of NVPS-R pain scores over time. Results of the average NVPS-R scores showed that for all subjects the scores remained more or less constant during the first 45 minutes and gradually decrease (Figure 4).

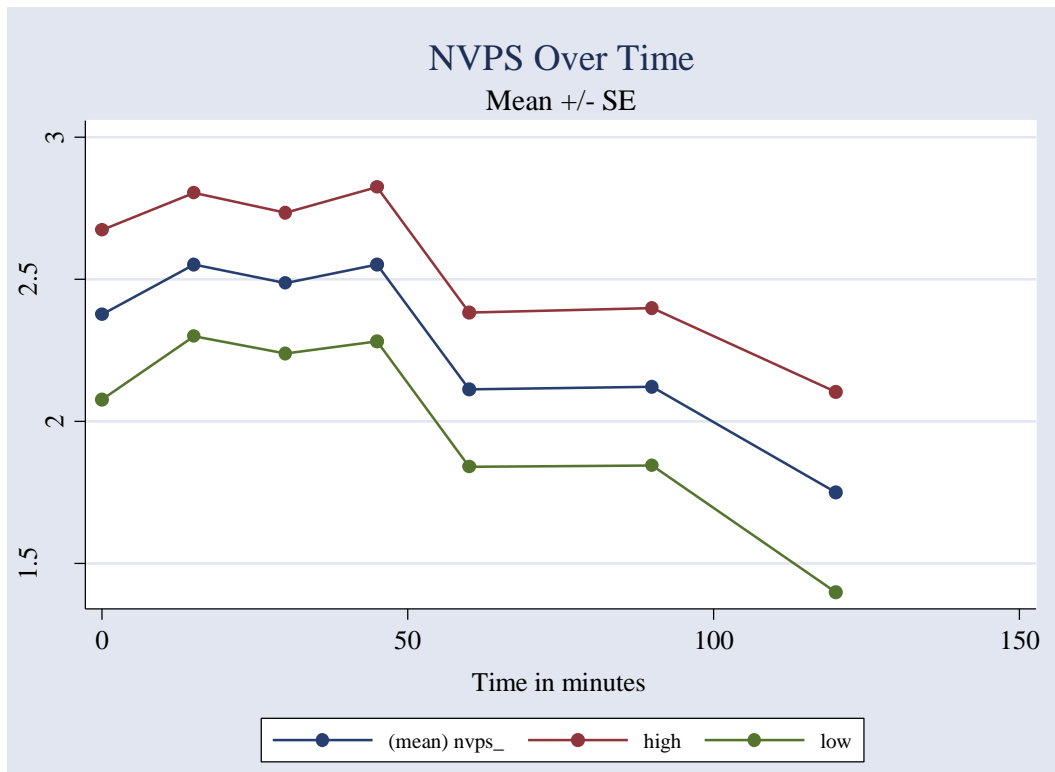


Figure 4. NVPS –R Mean Average Scores Over Time

Results Aim 4

To describe the change in pain scores over time obtained using the CPOT assessment tool at the following time points (minutes) following arrival to the PACU: 0, 15, 30, 45, 60, 90 and 120, we created a table in order to evaluate the mean, standard deviation (SD) and range of each time point values for CPOT (Table 4).

Table 4: Mean and Range of CPOT Scores at Different Times (in minutes)

| Time Points (minutes) | Mean \pm SD | Range (max - min) |
|-----------------------|-----------------|-------------------|
| 0 | 2.55 \pm 2.06 | 7 - 0 |
| 15 | 2.87 \pm 1.74 | 7 - 0 |
| 30 | 2.70 \pm 1.71 | 6 - 0 |
| 45 | 2.66 \pm 1.76 | 6 - 0 |
| 60 | 2.28 \pm 1.81 | 6 - 0 |
| 90 | 2.03 \pm 1.51 | 6 - 0 |
| 120 | 1.71 \pm 1.78 | 6 - 0 |

Figure 5 depicts the values for CPOT mean pain scores over time. Results of the average CPOT pain scores showed an increase in the first 15 minutes, where afterwards they seem to be slowly decreased (Figure 5).

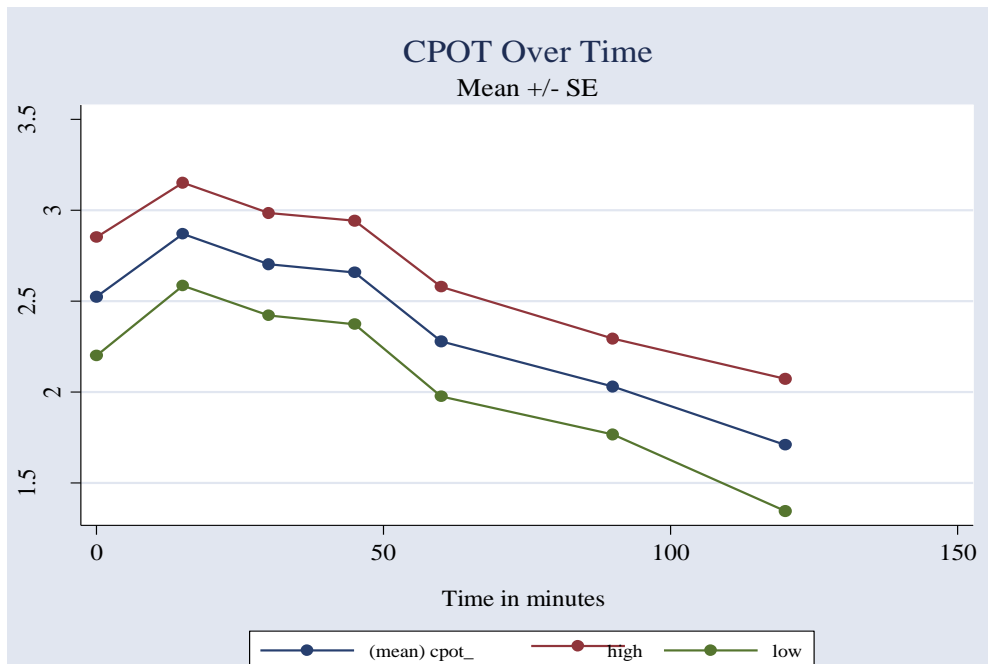


Figure 5. CPOT Average Scores Over Time

Figures 6 and 7 show each patient's NVPS-R and CPOT scores, respectively over time. Overall, both graphs resulted in different patterns when examining change in pain scores over time for each individual patient.

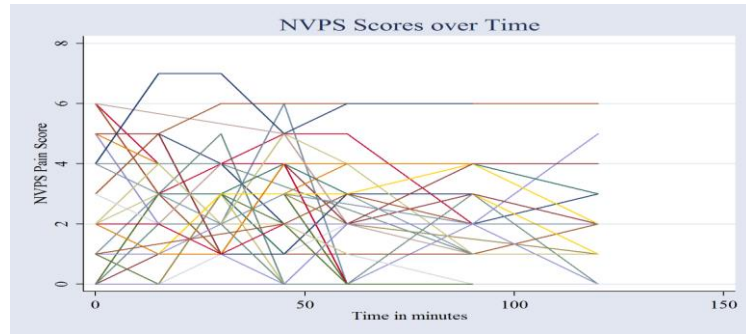


Figure 6. NVPS-R Scores over time for each patient

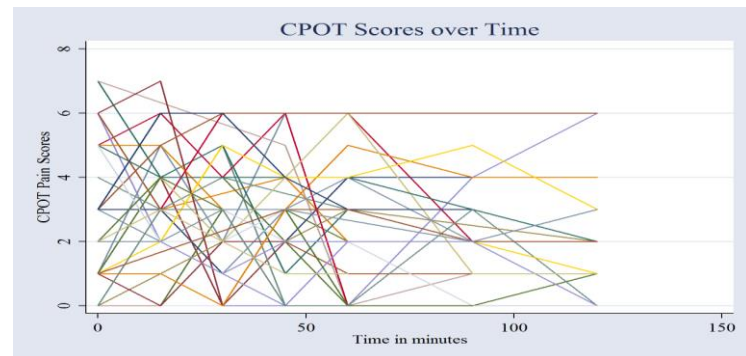


Figure 7. CPOT Scores Over Time for each patient

Figure 8 show repeated measures used to compare changes in pain scores over time using the NVPS-R and CPOT across the seven time points for all 40 subjects from arrival to the end of early postoperative period at PACU. A total of 246 repeated measures were achieved among the patients with each instrument.

Overall, a comparison over time between NVPS-R total scores and CPOT total scores showed total pain scores correlations between instruments at each time point and doses of pain medication doses administration across time points.

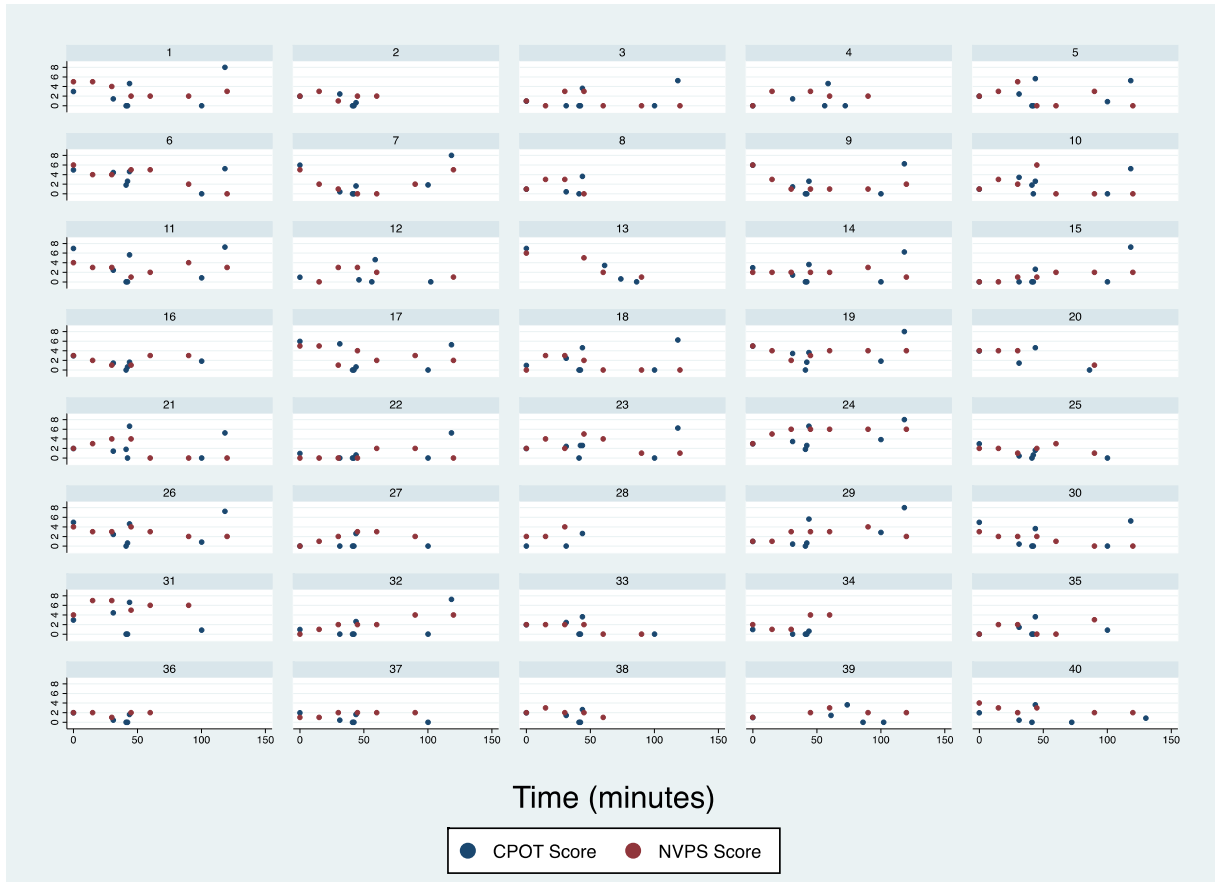


Figure 8: CPOT and NVPS-R total scores profile comparison

Comparison of CPOT and NVPS-R Scores Plots at Different Times

Figure 9 shows pain assessment scores using CPOT and NVPS-R scales at six time points; 0, 30, 45, 60, 90, and 120 (minutes), had similar mean pain scores. It was noted that at most times there were no differences with the administration of one or another instrument, except for the measurements taken during time 15 (minutes) upon arrival to the PACU (Table 4). The plot, at this time point, showed a slight increase in CPOT mean score (mean/SE 2.87 ± 1.74) when compared with the NVPS-R mean score (mean/SE 2.55 ± 1.55) (Table 3). The p-value showed a statistically significant difference ($p \leq 0.05$) at this time point (15 minutes).

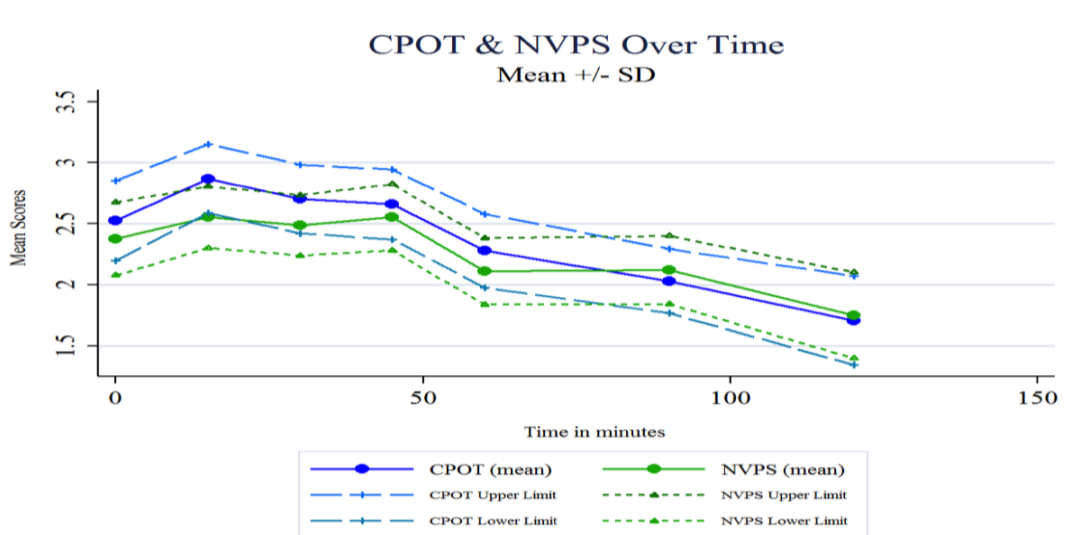


Figure 9. Comparison of CPOT vs NVPS-R Scores Plots at Different Time points

Results Aim 5

To address aim 5 we performed a Wilcoxon Signed Rank test analysis (Table 5) to describe if the change over time between the CPOT and NVPS assessment tool was the same or not. For this assessment the changes from 0 to 120, 0 to 15, 15 to 30, 15 to 45, 15 to 60, and 15-120 minutes were calculated because they are clinically important points.

Table 5: Summary p-values for changes in different time points

| Time differences (minutes) among CPOT and NVPS-R | P value* |
|---|-----------------|
| 0-120 | 0.3558 |
| 0-15 | 0.2270 |
| 15-30 | 0.7767 |
| 15-45 | 0.1558 |
| 15-60 | 0.2132 |
| 15-120 | 0.0496 |

*p values were obtained using Wilcoxon Signed Rank analysis

Change over time from time 0 min to 120 minutes

For this difference (scores at 120 min – scores at 0 min) only 24 patients were used for the analysis because the other 16 patients were awake at time 120 (minutes). There is no statistically significant difference between the score change of CPOT from time 0 to time 120 and the change of NVPS from time 0 to time 120.

Prob > |z| = 0.3558.

Change in time from time 0 min to time 15 mins

There are no statistically significant differences between the change of CPOT from time 0 to 15 minutes and NVPS from time 0 to 15 minutes.

Prob > |z| = 0.2270

Change in time from time 15 min to time 30 mins

There are no statistically significant differences between the change of CPOT from time 15 to 30 minutes and NVPS from time 15 to 30 minutes.

$$\text{Prob} > |z| = 0.7767$$

Change in time from time 15 minutes to time 45 minutes

There are no statistically significant differences between the change of CPOT from time 15 to 45 minutes and NVPS from time 15 to 45 minutes.

$$\text{Prob} > |z| = 0.1558$$

Change in time from time 15 min to time 60 mins

There are no statistically significant differences between the change of CPOT from time 15 to 60 minutes and NVPS from time 15 to 60 minutes.

$$\text{Prob} > |z| = 0.2132$$

Change in time from time 15 min to time 120 mins

For this difference (scores at 120 min – scores at 15 min) there were statistically significant differences between the score change of CPOT from time 15 to 120 minutes and the score change in NVPS from time 15 to 120 minutes.

$$\text{Prob} > |z| = 0.0496.$$

Ancillary Analyses: Relationship of CPOT and NVPS-R Scores to Vital Signs

In ancillary analyses, the relationship between CPOT and NVPS-R was investigated at three different time points with selected physiologic parameters (vital signs and respiratory): heart rate (HR), mean arterial pressure (MAP), respiratory rate (RR), and oxygen saturation (SpO₂). The three time points include time 0 at arrival to the PACU, time 15 after arrival to the PACU which was one important time point in behavioral pain scores differences between instruments, and at 120 minutes the end of early postoperative period.

For these analyses, three (3) groups of patients were hypothesized *a priori* as clinically distinct: Group A) CPOT total ≤ 2 **and** NVPS total ≤ 2 ; Group B) CPOT total ≥ 3 **or** NVPS total ≥ 3 ; and Group C) CPOT total ≥ 3 **and** NVPS total ≥ 3 . Patients were grouped using these criteria at each time point.

Vital signs at baseline (time 0)

Table 6 shows means and standard deviations for each vital sign at time 0 for all 40 participants, by groups A (n=23), B (n=3), and C (n=14). Results show an average heart rate (HR) of 79 beats (b)/min for group A, 97 b/min for group B, and 85 b/min for group C. In Group A, patients with no significant pain showed a lower average HR (79.0 ± 12.5 b/min) than those patients in Group B with significant pain on the CPOT or NVPS-R scale (97.0 ± 6.2), or those patients in Group C with significant pain in both CPOT and NVPS-R scales (85.4 ± 19.8).

The mean of the mean arterial pressure (MAP) was 93.7 mmHg for Group A, 100.0 mmHg for group B, 95.3 mmHg for group C. The MAP results showed that patients in Group A, without significant pain, presented a lower average MAP (93.7 ± 12.2 mmHg) than those patients in Group B, who had one assessment of significant pain on the CPOT or NVPS-R scale (100.3 ± 33.7). However, those patients in Group C, who had significant pain in both CPOT and NVPS-R scales, presented an average MAP of 95.3 ± 13.1 between the three groups (A,B, and C).

In the Group A, the average oxygen saturation (SpO₂) was (99.2 ± 1.3) %, in Group B it was (100 ± 0.0) %, and in Group C it was (98.1 ± 2.6) %. The average SpO₂ between patients without significant pain, those in the Group A, and with significant pain, those in Groups B and C, was very similar.

Respiratory rate (RR) for Group A was (17.6± 5) R/min, for Group B it was (18.3 ± 0.6) R/min, and for Group C it was (17.8 ± 7.7) R/min. The RR among patients in Group A, B and C, generally maintained within the same average level.

Table 6: Summary Statistics of Vital Signs and CPOT and NVPS-R Assessments Meeting Clinical Threshold of Pain: Time 0

| Time 0 | Group A: Both CPOT total ≤ 2 and NVPS-R total ≤ 2 | Group B: Exactly one of CPOT total ≥ 3 or NVPS-R total ≥ 3 | Group C: Both CPOT total ≥ 3 and NVPS-R total ≥ 3 |
|--------------------------|--|---|--|
| Number, n | n=23 | n=3 | n=14 |
| Heart Rate, b/min | | | |
| Mean (sd) | 79.0 (12.5) | 97.0 (6.2) | 85.4 (19.8) |
| Range | 60-113 | 90-102 | 56-102 |
| MAP, mmHg | | | |
| Mean (sd) | 93.7 (12.2) | 100.3 (33.7) | 95.3 (13.1) |
| Range | 73.0-117.7 | 68-135.3 | 68.7-119 |
| SPO2, % | | | |
| Mean (sd) | 99.2 (1.3) | 100.0 (0.0) | 98.1 (2.6) |
| Range | 95-100 | 100-100 | 92.0-100 |
| RR, r/min | | | |
| Mean (sd) | 17.6 (5.0) | 18.3 (0.6) | 17.8 (7.7) |
| Range | 9-28 | 18-19 | 9-36 |

Group differences in vital signs at time 0 were tested for significance using the Kruskal-Wallis test (Table 7). No statistically significant differences were observed.

Table 7: Kruskal-Wallis of Vital Signs by groups of CPOT and NVPS-R Assessments Meeting Clinical Threshold of Pain at time 0 minutes

| Time 0 min | Chi-square | P value |
|-------------------|-------------------|----------------|
| Heart Rate, l/min | 4.444 | 0.108 |
| MAP, mmHg | 0.631 | 0.886 |
| SPO2, % | 1.227 | 0.208 |
| RR, r/min | 0.846 | 0.737 |

Vital signs at time 15 (minutes)

Table 8 shows means and standard deviations for each vital sign at time 15, separately for groups A (n=14), B (n=6), and C (n=20). Results showed an average heart rate (HR) of 73.1 ± 12.3 for Group A (n=14), 90.1 ± 0.0 for Group B (n=6), and 78.4 ± 18.3 for Group C (n=20). The HR among Groups A, B and C showed a mean increase.

In Group A, patients with no significant pain showed a lower average HR (73.1 ± 12.3 b/min) than those patients in Group B with significant pain on the CPOT or NVPS-R scale (90.1 ± 0.0), or those patients in Group C with significant pain in both CPOT and NVPS-R scales (78.4 ± 18.3).

The mean of the mean arterial pressure (MAP) was 93.5 mmHg for Group A, 100.0 mmHg for group B, 93.8 mmHg for group C. The MAP results showed that patients in Group A, without significant pain, presented a lower average MAP (93.5 ± 11.4 mmHg) than those patients in Group B, who had one assessment of significant pain on the CPOT or NVPS-R scale (100 ± 13.9). However, those patients in Group C, who had significant pain in both CPOT and NVPS-R scales, presented an MAP of 93.8 ± 15.2 , similar to the patients without significant pain in group A.

In the Group A, the average oxygen saturation (SpO₂) was (99.7 ± 0.47) %, in Group B it was (99.8 ± 0.41) %, and in Group C it was (99.5 ± 0.82) %. The average SpO₂ among patients in Group A, B and C was similar.

Respiratory rate (RR) for Group A was (18.6 ± 1.7) R/min, for Group B it was (17.3 ± 3.0) R/min, and for Group C it was (17.6 ± 2.5) R/min. The RR among patients in Group A, B and C, generally was maintained in the same average level.

Table 8: Summary Statistics of Vital Signs and CPOT and NVPS-R Assessments Meeting Clinical Threshold of Pain: Time 15

| Time 15 | Group A: Both CPOT total ≤ 2 and NVPS-R total ≤ 2 | Group B: Exactly one of CPOT total ≥ 3 or NVPS-R total ≥ 3 | Group C: Both CPOT total ≥ 3 and NVPS-R total ≥ 3 |
|--------------------------|--|---|--|
| Number, n | n=14 | n=6 | n=20 |
| Heart Rate, b/min | | | |
| Mean (sd) | 73.1 (12.3) | 90.1 (00.0) | 78.4 (18.3) |
| Range | 60-99 | 63-106 | 55-120 |
| MAP, mmHg | | | |
| Mean (sd) | 93.5 (11.4) | 100 (13.9) | 93.8 (15.2) |
| Range | 73-111 | 85-123 | 67.3-122.6 |
| SPO2, % | | | |
| Mean (sd) | 99.7 (0.47) | 99.8 (0.41) | 99.5 (0.82) |
| Range | 99-100 | 99-100 | 98.0-100 |
| RR, r/min | | | |
| Mean (sd) | 18.1 (1.7) | 17.3 (3.0) | 17.6 (2.5) |
| Range | 14-20 | 12-20 | 12-22 |

Group differences in vital signs at time 15 were tested for significance using the

Kruskal-Wallis Test (Table 9). No statistically significant differences were observed.

Table 9: Kruskal Wallis of vital signs by groups of CPOT and NVPS-R assessments meeting clinical threshold of pain at time 15 minutes

| Time 15 min | Chi-square | P value |
|--------------------|-------------------|----------------|
| Heart Rate, l/min | 4.18 | 0.12 |
| MAP, mmHg | 0.83 | 0.66 |
| SPO2, % | 0.61 | 0.73 |
| RR, r/min | 0.41 | 0.81 |

Vital signs at time 120

Table 10 shows means and standard deviations for each vital sign at time 120, separately for groups A (n=16), B (n=4), and C (n=4). Results showed an average heart rate (HR) of 76.9±15.7 for Group A (n=16), 85.5 ± 25.1 for Group B (n=4), and 76.0 ± 9.6 for Group C (n=4). The HR among Groups A, B and C showed a mean decrease.

The average MAP for Group A was 94.6 ± 11.6 mmHg, for the Group B it was 104.7 ± 7.7 mmHg, and for Group C was 93.9 ± 19.2 mmHg. There was a slight increase, approximately of 10.1 mmHg, in the average MAP of participants in the Group B. On the other hand, there was a slight decrease, approximately of 0.7 mmHg, in the average MAP in the Group C when compared with the average MAP of Group A. See Table 10.

Table 10: Summary Statistics of vital sign by groups of CPOT and NVPS-R assessments meeting clinical threshold of pain at time 120 minutes

| Time 120 min | Group A: Both CPOT total ≤ 2 and NVPS-R total ≤ 2 | Group B: Exactly one of CPOT total ≥ 3 or NVPS-R total ≥ 3 | Group C: Both CPOT total ≥ 3 and NVPS-R total ≥ 3 |
|--------------------------|--|---|--|
| Number, n | 16 | 4 | 4 |
| Heart Rate, l/min | | | |
| Mean (sd) | 76.9 (15.7) | 85.5 (25.1) | 76.0 (9.6) |
| Range | 53-110 | 58-115 | 66-88 |
| MAP, mmHg | | | |
| Mean (sd) | 94.6 (11.6) | 104.7 (7.7) | 93.9 (19.2) |
| Range | 69.7-112.7 | 97.3-112 | 66.3-109.3 |
| SPO2, % | | | |
| Mean (sd) | 99.7 (0.6) | 100 (0) | 97.7 (3.9) |
| Range | 98-100 | 100-100 | 92-100 |
| RR, r/min | | | |
| Mean (sd) | 17.1 (4.74) | 13.7 (3.9) | 20.0 (4.0) |
| Range | 8-27 | 10-18 | 18-26 |

The average oxygen saturation (SpO_2) for Group A was $99.7 \pm 11.6\%$, for Group B it was $100 \pm 0.0\%$, and for Group C it was $97.7 \pm 3.9\%$. In addition, the average RR for Group A was 17.0 ± 4.7 R/min, for Group B it was 13.7 ± 3.9 R/min, and for Group C it was 20 ± 4.0 R/min. There was a slight decrease approximately of 3.4 R/min, in the mean RR of participants in the Group B when compared with Group A. On the other hand, there was a slight increase in the

average RR, approximately of 6.3 R/min, in the Group C when compared with Group B.

Group differences in vital signs at time 120 were tested for significance using the Kruskal-Wallis Test (Table 11). No statistically significant differences were observed.

Table 11: Kruskal Wallis of vital signs by groups of CPOT and NVPS-R assessments meeting clinical threshold of pain at time 120 minutes

| Time 120 min | Chi-square | P value |
|---------------------|-------------------|----------------|
| Heart Rate, l/min | 0.338 | 0.845 |
| MAP, mmHg | 2.256 | 0.324 |
| SPO2, % | 1.634 | 0.442 |
| RR, r/min | 3.729 | 0.155 |

Incidental finding: Significant pain and relationships in changes for vocalization indicator for CPOT, and Physiologic I, and respiratory indicators for NVPS-R

Table 12 shows the frequency of patients with significant pain that showed a CPOT vocalization indicator ≥ 1 , and NVPS-R physiologic I, and respiratory indicators ≥ 1 .

It was found that over 70% of patients with significant pain across time points scored > 1 on the CPOT vocalization indicator, while less than 70% scored > 1 on the physiologic indicator of the NVPS-R and less than 30% scored > 1 on the NVPS respiratory indicator.

Also was also found that more patients with significant pain (NVPS-R or CPOT ≥ 3) or the NVPS-R (n=20) and CPOT (n=22) at time 15 (minutes) than for patients with a total score indicative of significant pain at the other time points. At time 15 were found in the indicators; for CPOT in vocalization and for NVPS-R in the physiologic I indicators. For the CPOT vocalization indicator, increases were shown in the partial score where 86% of patients (n=19) had significant pain at this time point and presented increases in vocalization. For NVPS-R physiologic indicator I, the total quantity of patients that showed increases in partial score was

(n= 4) which indicates that 20% of patients with significant pain at this time point presented physiologic I (MAP) increase. The same quantity of patients (n=6) presented significant pain at time 120 with both scales during assessment.

Table 12. Patients with significant pain that showed vocalization, physiologic I, and respiratory indicators ≥ 1

| Time points (minutes) | CPOT | | NVPS-R | | |
|--------------------------|-----------------------------|---|-------------------------------|---|--|
| | CPOT $\geq 3^*$ freq. | Vocalization ≥ 1 frequency (%) | NVPS-R $\geq 3^*$ freq. | Physiologic I ≥ 1 frequency (%) | Respiratory ≥ 1 frequency (%) |
| 0 | 16 | 14 (88%) | 15 | 5 (33%) | 2 (13%) |
| 15 | 22 | 19 (86%) | 20 | 5 (25%) | 0 (0%) |
| 30 | 19 | 18 (95%) | 15 | 7 (47%) | 2 (13%) |
| 45 | 19 | 14 (74%) | 17 | 4 (24%) | 2 (12%) |
| 60 | 15 | 12 (80%) | 12 | 3 (25%) | 0 (0%) |
| 90 | 10 | 9 (90%) | 11 | 6 (55%) | 3 (27%) |
| 120 | 6 | 6 (100%) | 6 | 4 (67%) | 0 (0%) |

*Total patients with significant pain per time points using CPOT and NVPS-R,

Summary

The use of two behavioral acute pain assessment instruments simultaneously in this study provided important information about the relationships between instruments to enhance anticipatory assessment and management of pain in the early post operative period. A goal is to recommend one of the instruments for the early pain assessment in PACU, based on comparisons and results.

For this study a total of fifty- nine patients, 22 to 87 years of age were initially consented. Of these, 19 subjects were excluded. The final sample was comprised of 40 subjects, who were divided into two groups. Group one included 20 participants that were assessed first with the CPOT and with the NVPS-R second. Group two consisted of 20 participants who were assessed with the NVPS-R tool first and with the CPOT second.

To assess the potential for selection bias the adequacy of randomization was evaluated. Randomization yielded groups that were similar with regards to demographics and surgical experience. Fisher's Exact test and Mann-Whitney tests were performed one for CPOT and one for NVPS. With the exception of the primary diagnosis gynecologic carcinoma, no statistically significant differences were observed. There was a higher number of patients diagnosed with gynecologic carcinoma (n=9) in the group where the CPOT was administered first (p=0.008). However, the demographic profile and characteristics for discrete and continuous variables between the two groups was evaluated and there were no significant differences (p-value \geq 0.05) in the distribution of the two groups.

The socio-demographic data showed the average age of the participants was 42.5 years with the youngest being 22 and the oldest being 87. Over half (52.5%) of the participants had achieved secondary school education. Most participants were ASA 1 and ASA 2 from the ASA physical status classification system, and only 10.0% of the patients were healthy (ASA 1) and 67.5% had a mild systemic disease (ASA 2). The majority of participants, 72.5%, were female, about 85% were white and 100% were of Hispanic origin.

The surgical categories included 45% gynecologic surgeries, followed by 37.5% gastrointestinal surgery, and 17.5% abdominal-pelvic surgery. Most of the participants had a cancer diagnosis (42.5%); 25% of these were diagnosed with gynecologic carcinoma 15% with colon carcinoma, and 15% with ureter carcinoma.

In terms of study aims a linear relationship was evaluated between CPOT and NVPS-R tool pain scores through a scatter plot using Pearson's correlation at time 0 (baseline) with a 95% CI. Results showed a positive correlation between CPOT and NVPS-R tool pain scores (r= 0.88;

$p \leq 0.05$). Results showed the two-tail p-values were statistically significant ($p\text{-value} \leq 0.05$). In other words, CPOT at time 0 was statistically significant in explaining NVPS at time 0.

The linear relationship between CPOT and NVPS-R tool pain scores were evaluated at 120 minutes through a scatter plot with a 95% CI. Results showed CPOT and NVPS-R tool pain scores were positively correlated ($r = 0.89$; $p\text{-value} \leq 0.05$). Results showed CPOT at 120 minutes explained 80% of the variation in NVPS-R at time 120 minutes and the two-tail p-values were statistically significant ($p\text{-value} \leq 0.05$). NVPS-R results showed that for all subjects, on average, the score remained more or less constant during the first 45 minutes and then gradually decreased. Additionally, CPOT results showed that for all subjects, on average, CPOT pain score increased in the first 15 minutes where afterwards they slowly decreased.

Overall, mean pain assessment scores using CPOT and NVPS-R scales at six time points, 0, 30, 45, 60, 90, and 120 minutes, were similar. It was noted that most times there were no differences with the administration of one or another instrument, except for the measurements taken during time 15 (minutes) upon arrival to the PACU (Table 4). The plot (Figure 4), at this time point, showed a higher CPOT mean score (mean/SE 2.87 ± 1.74) in comparison with the NVPS-R (mean/SE 2.55 ± 1.55). The p-value showed a statistically significant difference between scores ($p \leq 0.05$) at time 15 minutes. Overall the NVPS-R and CPOT score over time, resulted in different patterns changes among patients.

To describe the relationship between the change over time in pain scores obtained using the CPOT assessment tool and the NVPS-R assessment tool paired t-tests were performed. Time changes from 0 to 120, 0 to 15, 15 to 30, 15 to 45, 15 to 60, and 15-120 minutes seen as clinically important time points, were evaluated. No statistically significant difference was observed between the change in CPOT scores from time 0 to 120 minutes and the change in the

NVPS scores from time 0 to 120 minutes. The differences from time 0 to 15 minutes and from time 15 to 60 minutes also were not significant. Meanwhile, there was a statistically significant difference between the CPOP change scores from time 15 to 120 minutes and the NVPS-R change scores from time 15 to 120 minutes.

In ancillary analyses, at each time point, we investigated the relationship between CPOP and NVPS-R with selected vital signs: heart rate (HR), mean arterial pressure (MAP), respiratory rate (RR), and oxygen saturation (SpO₂). A Kruskal-Wallis test was conducted at time zero and we observed no statistical differences ($p\text{-value} > 0.05$) between the pain scores and the different categories of each vital sign (i.e. HR, MAP, RR, and SpO₂). Likewise, at 15 and 120 minutes, we observed no statistical differences ($p\text{-value} > 0.05$) between the pain scores and the different categories of each vital sign (i.e. HR, MAP, RR, and SpO₂).

With the exception of time point 15 minutes, and NVPS-R vital signs indicator, most of the statistical tests showed that both scales were significantly related at different time points.

CHAPTER 5

DISCUSSION

Introduction

Acute pain is an expected physiologic experience to noxious stimuli, and motivates behaviors (Hadjistavropoulos et al., 2011), such as in post-surgical patients. In 2010, 51.4 million Americans underwent a surgical procedure(s) (National Center for Health Statistics, 2010). Several studies provide evidence that more than 75% of surgical patients report pain after surgery (Gramke et al., 2007; Apfelbaum, Chen, Mehta, & Gan, 2003; Warfield & Khan, 1995). The most important clinical approach to ensure effective pain management is to perform an optimal pain assessment. Currently, the Numeric Rating Scale (NRS) is the gold standard instrument used to assess pain among verbal patients who can self report pain (Downie et al., 1978). However, in the early postoperative period, it is believed that the residual effects of general anesthesia and sedative medication interfere with cognitive functions, which often makes it difficult for patients to verbally self-report their pain (Chou et al., 2016). Furthermore, the use of sedation does not equate to an absence of pain or pain relief (Herr, Coyne, McCaffery, Manworren, & Merkel, 2011). During the early post-operative period the use of objective pain assessment instruments is the key to adequate pain management. Observation of behavior is a valid approach for pain assessment in the absence of self-report.

This chapter will discuss findings of the study on acute pain assessment in nonverbal sedated patients conducted in a teaching hospital in San Juan, Puerto Rico. Recently the APS panel provided a strong recommendation for the use of validated assessment tools on postoperative pain assessment. Although there is inadequate evidence, this study provided data for two selected behavioral instruments, CPOT and NVPS-R. These instruments, which measure

similar behavioral indicators, were selected because they were validated in other populations. The exception between instruments includes, for CPOT vocalization indicator and for NVPS-R physiological and respiratory indicators. The interpretations were based on investigator analysis and interpretation of these findings. Additionally, this chapter will discuss the limitations of the study, strengths, future research focus, and the implications for nursing practice.

Characteristics of study participants

This study included a patient population of forty participants; the majority were females, with mild systemic disease. The participants required abdomino-pelvic, gynecologic or gastrointestinal surgery, and general anesthesia. Prior to surgery, patients were assessed for pain intensity with the NRS. The NRS categorizes pain intensity on a scale of 0 to 10: no pain (0), mild (1-3), moderate (4-6), to severe (7-10)(Dihle, Helseth, Kongsgaard, Paul, & Miaskowski, 2006). This assessment was fundamental to establish that patients were not experiencing severe or chronic pain before the surgical procedure, because it could have an effect on physiological indicators and lead to persistent pain in the PACU. Findings indicated that the overall baseline preoperative pain intensity in patients was 3.2 (i.e. mild). Surgery is an expected triggering factor for acute pain in all patients. Patients arrive at the post anesthesia care unit (PACU) with an expected presence of acute pain due to surgery, yet pain cannot be self-reported by some because they arrive to the PACU in a nonverbal state due to sedation levels.

Two nonverbal pain instruments (NVPS-R and CPOT) were used to assess the presence of pain and evaluate the relationship between the two instruments, in order to recommend one to assess acute pain in nonverbal sedated patients in the PACU. Each instrument includes measures

of pain behaviors, defined as indicators in the CPOT and categories in the NVPS-R (Table 13). The CPOT has four indicators: facial expression, body movements, muscle tension, and vocalization for non-intubated patients. The NVPS-R is comprised of five categories: face, activity, guarding, physiological I (vital signs: blood pressure and heart rate), and respiratory (respiratory rate and SpO2). Differences between scales include the two physiological categories (vital signs and respiratory) included in the NVPS-R and the vocalization indicator included in the CPOT.

Table 13. Comparison of CPOT Behavioral Indicators vs. NVPS-R

| CPOT indicators | NVPS-R categories |
|--|---|
| Similarities | |
| Facial expression | Face |
| Body movements | Activity |
| Muscle tension | Guarding |
| Differences | |
| Vocalization (non-intubated patients) | Physiological I vital signs (blood pressure, heart rate) |
| | Respiratory (respiratory rate and SpO2) |

Relationships between pain instruments at time 0 and time 120

At time 0 minutes, pain was measured in sedated patients after surgery, using the total pain score from each patient to assess whether or not there were differences in pain scores between the instruments. A high positive correlation was observed, meaning that both instruments determined pain presence in the population of this study. Other studies with sedated, critical care patients (Cade, 2008; Kabes, Graves, & Norris, 2009) have found inter-rater and

behavior indicator reliability, which supports the observed correlation of pain behavior indicators found between CPOT and NVPS-R in this study.

When assessing the linear relationship between both instrument's pain scores at 120 minutes and the total pain scores, a strong positive correlation was found showing similarities between both instruments in behavioral indicators or categories. At time 120 minutes after arrival at PACU, pain was measured in sedated patients using the pain total score for each patient to assess whether or not there were differences in the recording of pain scores between the two instruments. In the study, CPOT explained 80% of the variation in the NVPS and a relationship exists between the two instruments to indicate pain presence.

Change in pain scores over time points in each instrument individually and between both instruments

Patients change in pain scores over time was obtained using the NVPS-R following arrival to the PACU at seven time points 0, 15, 30, 45, 60, 90 and 120 minutes. Because there is insufficient evidence to guide final recommendations on optimal timing or frequency of patient reassessments in the postoperative setting (Chou et al., 2016), the time points used in this study coincided with the established protocol for vital sign measurement in the PACU.

NVPS-R results showed, for all patients on average, an increased score in the first 15 minutes, which remained fairly constant up to the 45-minute time point, where it slowly decreased until 120 minutes. This assessment also was conducted using the CPOT at the same time points following arrival to PACU. CPOT mean score results showed that, on average, pain score increased in the first 15 minutes, whereas it slowly decreased from then on.

The results showed that the pain assessment scores using CPOT and NVPS-R at six of the seven time points; 0, 30, 45, 60, 90, and 120 minutes had a similar mean. It was noted that

there were no differences with the administration of either instrument; except for the measurements taken at the 15 minutes time point, after arrival to the PACU. At this time point, there was an increase in CPOT mean score in comparison with the NVPS-R. There was an increase in the frequency of vocalization indicator used only in the CPOT, which is one of the differences between both instruments. One reason for this change at this time point is that patients' sedation levels were between low to moderate (RASS -2, -3), and some patients were able to vocalize with sighs, moans, cries and/or sob behaviors, for example.

Repeated measures were used to compare changes in pain scores over time using the NVPS-R and CPOT across the seven time points from arrival to the PACU at time 0,15, 30, 45, 60, 90, and 120 minutes. Every patient had three to seven pain assessment measures. Thus, a total of 246 repeated measures were achieved among the forty patients with each instrument. When NVPS-R and CPOT scores were compared over time, different patterns resulted among patients. The comparison of repeated patient measures resulted in a single graph, where a specific pattern was not shown. These results reinforce the conclusion of several authors that more information is needed about the large individual variability in pain experience after surgical procedures (Lundblad, Kreicbergs, & Jansson, 2008; Werner, Duun, & Kehlet, 2004; Turk & Okifuji, 1999). In a clinical scenario, when assessing and managing pain, it is imperative to remember that every patient's pain experience is unique and individual.

In 1994 the International Association for the Study of Pain (IASP) stated that inability to communicate verbally does not negate the possibility that an individual is experiencing pain and is in need of appropriate pain-relieving treatment (International Association for the Study of Pain, 1994). Health care providers need to use objective criteria to assess individual patient behaviors to assess pain in nonverbal patients. Measures of pain assessment in non-verbal

patients must include an interplay of objective and subjective assessment components. The objective component includes observations made by nurses and healthcare providers through reliable instruments related with complex patients behaviors, which are individual and subjective in nature.

The symptom management theory (SMT) framework model used for this study helps us conceptualize relationships between symptom components (acute pain) to describe, predict, and explain the pain phenomena within the framework of nursing practice. The model focuses on three dimensions: symptom experience, symptom management strategies, and outcome/symptom status (Dood et al., 2001). The complexity of acute pain phenomena can be explained with the SMT framework because patient needs can be conceptualized while understanding why different patients pain behaviors were shown in nonlinear patterns. Each patient experiencing acute pain showed behaviors that are not totally predictable, but their behaviors are interconnected. Individual variability explains unpredictability and different acute pain patterns between patients. To adequately assess and manage patient's pain, nurses and healthcare providers need to accept and work with this complexity. Although pain is a subjective experience for patients, nurses and healthcare providers have to assess pain in an objective method in patients that cannot self-report pain. The SMT helps to understand and direct patient care considering individual symptom particularities.

Patient's pain was assessed to describe the relationship between the change in pain scores over time obtained using the CPOT and the NVPS-R, at seven clinically important time points following arrival to the PACU. Changes were measured at arrival and at discharge from PACU (0-120 minutes), at arrival and the first minutes after general anesthesia (0-15 minutes), at the first minutes after general anesthesia to the third time point (15-30 minutes), at the first minutes

after general anesthesia to fourth time point (15-45 minutes), at the first minutes after general anesthesia and at the first hour (15-60 minutes), and at first minutes after general anesthesia, and at the end of early postoperative period (15-120 minutes).

There were no statistically significant differences between the changes in CPOT and the changes in NVPS-R at time 0 to 120 minutes, at time 0 to time 15, at time 15 to 30 minutes, at time 15 to 45 minutes, and at time 15 to 60 minutes. There was a difference between the change in CPOT and NVPS-R at time 15 and 120 minutes. At the 15-120 minutes time points include; at the 15 minute time point, the time after patient arrival to the PACU and is the time when patients are generally waking from anesthesia making them more able to manifest and express pain behaviors. By the 120 minutes time point, many patients had either been discharged or had adequate pain management.

Ancillary analyses: Relationship of CPOT and NVPS-R scores to vital signs

In ancillary analyses at three different time points, the relationship between CPOT and NVPS-R was investigated with selected physiologic parameters (vital signs and respiratory): heart rate (HR), mean arterial pressure (MAP), respiratory rate (RR), and oxygen saturation (SpO₂).

Vital signs at baseline (Time 0)

Differences between pain scores and the different physiologic categories including vital signs and respiratory (i.e. HR, MAP, RR, and SpO₂) were not observed upon patient arrival to the PACU. Patients in the significant pain group, who had a score ≥ 3 , did not present an increase in physiologic or respiratory criteria (SaO₂) on the NVPS-R during pain assessment. This agrees with the findings of Puntillo, Miaskowski, Kehrle, Stannard, Gleeson, & Nye (1997) who stated that the absence of increased vital signs cannot be considered absence of pain. This

finding is also supported by Kapoustina, EcheGARAY & Gélinas, (2014), who indicated that vital signs might not be specific to pain. Arbour & Gélinas, 2010 conducted a study in 33 post-cardiac surgical patients where the results indicated that increases in vital sign parameters could be related to other physiologic processes. Physiologic indicators are not sensitive for assessed pain (Foster, Yucha, Zuk, & Vojir, 2003; Gélinas & Johnston, 2007). Absence of a change in vital signs does not indicate absence of pain.

Vital signs at Time 15

Differences between pain scores and the different physiologic categories including vital signs and respiratory (i.e. HR, MAP, RR, and SpO₂) were not observed at time 15 minutes after non-verbal patients arrival to the PACU. Patients with significant pain (group C), did not present an increase in physiologic or respiratory criteria (SaO₂) on the NVPS-R during pain assessment. This agrees with the findings of Puntillo, Miaskowski, Kehrle, Stannard, Gleeson, & Nye (1997), who stated that the absence of increased vital signs cannot be considered absence of pain. This finding also correlates with Kapoustina, EcheGARAY & Gélinas, (2014), who indicated that vital signs might not be specific to pain. Arbour & Gélinas, 2010 conducted a study in 33 post-cardiac surgical patients where the result indicate that increases in vital signs parameters could be related to other physiologic processes. Physiologic indicators are not sensitive for assessed pain (Foster, Yucha, Zuk, & Vojir, 2003; Gélinas & Johnston, 2007). Absence of a change in vital signs does not indicate absence of pain. As results suggest, the differences observed at 15 minutes in patients with significant pain do not show correlation with pain presence and changes in vital signs.

Vital signs at time 120

Similar to the baseline, we did not observe differences between the pain scores and the different categories of each vital sign (i.e. HR, MAP, RR, and SpO₂) at 120 minutes. Clinically, this means that the presence of significant pain in the participants of this study was not consistent with an increase in the mean of the HR, MAP, RR, and SpO₂. Overall statistical and clinical results show that patients with significant pain in this study did *not* present changes in physiologic or respiratory parameters of the NVPS-R immediately. However, increases in vital sign parameters are still considered a sign to begin further assessment of pain in non-verbal adults by experts, as published in the recent guideline for the management of postoperative pain of the Task Force of the American Pain Society and American Society of Regional Anesthesia and Pain Medicine, and the American Society of Anesthesiologists' Committee on Regional Anesthesia, Executive Committee, and Administrative Council (Chou et al., 2016). Thus, our results do not agree with current recommendations and indicate that further research is required to reconcile these differences.

At this time point we did observe one clinically important finding in a small group (n=4) of patients with significant pain on one of the instruments. When data were explored, two of the four patients presented an increase in MAP (NVPS-R physiologic parameter). This increase is itself clinically relevant because when those patients are tracked individually, significant pain was found through one or both instruments at two previous time points, 45 and 90 minutes. Pain medication administration was not registered during those time points in both cases. This finding correlates with a previous study where the validity of behaviors and fluctuations in vital signs for pain assessment in post-brain surgery adults (Kapoustina, Echegaray-Benites, & Gélinas, 2014) was examined and it was concluded that vital signs may suggest the presence of pain, although

their validity for such use is not standard.

NVPS-R and CPOT scores to vital signs overall findings

Most of the statistical tests show that both instruments are significantly related at different time points with the exception of time 15 (minutes), in which the CPOT was marginally significantly different from the NVPS-R. There is no correlation between physiologic indicators (vital signs and SpO₂) increase on the NVPS-R and the group of patients with significant pain, in both CPOT and NVPS-R measures. The impact of pain on physiologic parameter one of the NVPS-R was observed in two patients without medication administration and significant pain measures in previous time periods. Physiologic indicators in the NVPS-R were less frequent in identifying significant pain. In this study, it was found that the CPOT was more frequent in determining the significant presence of pain due to the observational behavior categories (facial expression, body movements, muscle tension, and vocalization) measured by the instrument. Thus, this study finding agree with Chanques et al. 2014, who considered 30 critical care patients conducting 258 paired assessments. They used the CPOT, BPS and NVPS-R instruments. The psychometric properties' findings suggested correlations for NVPS-R and CPOT behavioral indicators, but not for NVPS-R physiological indicator.

A study from Marmo and Fowler (2010) compared the NVPS-R, the CPOT, and Faces, Legs, Activity, Cry, Consolability (FLACC scale for children) pain instruments to determine each instruments' consistency and reliability. The study indicated that the CPOT was more reliable when evaluating pain in post-operative open-heart surgery intubated patients than the NVPS-R which included vital signs (Marmo & Fowler, 2010). Those results were consistent with what was observed in the post-operative patient group in the study reported here , although the patients in this study were not intubated. Additionally, the use of the NVPS-R and CPOT was

implemented in a study with verbal and non-verbal critical care patients. The patients were assessed before, during, and after painful and non-painful stimuli. Reliability of the CPOT instrument is evidenced by the consistent increase in pain scores (Topolovec-Vranic et al., 2013). In 2013, Gélinas, Barr, Puntillo, & Joffe described and analyzed the development and psychometric properties of eight behavioral pain assessment tools available for use in nonverbal critically ill adults. They concluded that the CPOT and BPS are considered the most valid and reliable, according to the available evidence. This study supports the use of the CPOT instrument, as suggested in our study.

Incidental finding: Significant pain and vocalization indicator for CPOT, and Physiologic I, and respiratory indicators for NVPS-R

The main differences in the results between the two instruments was the vocalization indicator of the CPOT because in patients with significant pain at all time points the vocalization indicator was more frequent in comparison with the physiologic I and respiratory indicators of NVPS-R.

When the overall data were explored to identify the possible reasons for the marginal differences between the instruments' indicators at different time points; especially at time points 15 and 120 minutes identified as clinically important time points, fewer patients demonstrated significant pain on the NVPS-R and CPOT at time 120 minutes in comparison with time 15 minutes. Data for those patients with significant pain at time 120 minutes reveal differences between the two scales. For the CPOT vocalization indicator, 100% (n= 6) of patients with significant pain at this time point presented this behavior. For the NVPS-R physiologic indicator I, 66% (n= 4), of patients with significant pain at this time point presented an increase in MAP. Both comparisons at time 15 and at time 120 minutes suggest that the vocalization measure

included in the CPOT is a better indicator of pain than the physiological indicators included in the NVPS-R.

Study Strengths and Limitations

The findings of this study denote the pain assessment performed by a single nurse investigator. The participants represent a Hispanic group of non-verbal sedated patients after major gastrointestinal, abdominal-pelvic and gynecologic surgeries. However, this study cannot generalize the experience of all patients receiving care from a nurse in a PACU at the Medical Center of PR. The findings of this study add to the nursing knowledge base of caring and the assessment and management of acute pain in the early postoperative period.

Strengths of this study include the researcher's experience as a nurse anesthetist who has knowledge about working with patients during and after general anesthesia, and patients with acute pain after surgery. This was helpful while conducting pain measurements and interacting with the nurses and patients in the study setting. Randomization was used to reduce the bias for order effect. The study participants were assigned randomly to one group; at the end both groups were homogenous in characteristics. The two objective instruments used for the assessment of acute postoperative pain in the study were previously tested and validated in other non-verbal patient populations.

Limitations to the study were present, and included the research procedure in which one research investigator assessed patients with both NVPS-R and CPOT instruments while the management of pain was the responsibility of the unit nurse in charge of patients. Pain assessment in the PACU of the Medical Center is based mainly on patient's self-report and the misconceptions of healthcare providers to manage pain after the nurse investigator reported behavioral pain assessment score was evident. This limitation made it difficult to manage pain

based on the objective measures of the instrument, as there was a delay or absence of medication administration after significant pain assessment was reported to PACU nurses by the investigator.

The progressive attrition of patients along the study may have reduced the likelihood of finding statistical differences. Another limitation of the study was the selection of patients with specific types of surgeries (abdomino-pelvic, gynecologic, and gastrointestinal), thus limiting the generalizability of results to other populations with different characteristics or types of surgery.

Implications for Nursing Practice

The major implication of this study for nursing practice is the clinically significant result which suggests that physiologic indicators of the NVPS-R, such as heart rate, mean arterial pressure, respiratory rate and oxygen saturation, are not consistent parameters for assessment of acute pain because in this study they did not show an immediate increase in patients with significant pain. These results are consistent with current literature that further stresses that vital signs should not be sole indicators for the presence of acute pain.

Using a valid, reliable, and feasible pain instrument (Wysong, 2014) is important when assessing pain in postoperative patients in the early postoperative period by the nurse and other health care providers. More studies are needed to establish new methods for communication between healthcare providers and patients who are unable to self-report pain. Sedation level that inhibits the possibility of self-report should not be a barrier for early assessment of acute pain.

Implications for Future Research

Although this area needs further study, the major contribution of this study to nursing knowledge was the consistency of the CPOT vocalization indicator for suggesting acute pain

presence in contrast with the physiologic indicators of the NVPS-R. Currently, the available research using CPOT and NVPS-R instruments includes participants from medical, cardiac and trauma ICUs, and applying those results to other populations is difficult. More research is needed to validate instruments for different populations, such as patients during the early postoperative period. Our preliminary findings suggest that the CPOT, with the use of the vocalization parameter, is a better acute pain indicator than the physiological parameters of the NVPS-R, but additional studies are needed to confirm this finding.

The main recommendation for future research is to identify valid, reliable and consistent measures of pain in non-verbal patients during the early postoperative period. Healthcare providers need tools to guide acute pain assessment and treatment because of the current frequent inadequate assessment in sedated patients. The decrease in physiologic responses to the acute pain symptom experience, pain alleviation, early discharge and complete recovery of patients are the main outcomes of the adequate symptom management. Improved communication between patients and healthcare providers can be achieved through research in postoperative acute pain to improve clinical protocols and include the acute pain phenomenon as a teaching priority for healthcare providers.

As stated by the American Pain Society (2016), there is low quality evidence to recommend a specific validated pain assessment instrument to track responses after postoperative pain treatments and adjust plans individually. There is insufficient evidence to guide recommendations in the immediate postoperative setting (Chou et al., 2016). We need to be committed to conduct further studies to contribute to the assessment and treatment of those at risk for suffering acute pain.

Conclusion

Finally, after evaluation of the results, we suggest that the CPOT may be the better tool to guide early actions in the management of acute pain to achieve better postoperative outcomes. The CPOT shows that the vocalization indicator is the most consistent criterion presented in PACU patients with acute pain over time. While this study's results present an overall high correlation between pain scores on both behavioral tools (CPOT and NVPS-R) in patients after general anesthesia and abdomino-pelvic, gastrointestinal and gynecological surgeries, incidental findings suggest that physiological indicators of NVPS-R in patients with acute pain are not consistent in their results. The vital sign indicators included in the NVPS-R need to be investigated further to determine their validity for assuring adequate pain assessment in postoperative patients because our findings do not support their use exclusively.

This study is important because pain assessment is the best way to initiate the most appropriate treatment to alleviate pain after surgery. Recent literature confirmed the research gap in assessment of postoperative pain in nonverbal patients leading to the release of the first guideline for the management of postoperative pain (APS, 2016). The APS expert panel recommends that clinicians use a validated pain assessment instrument, but there is inadequate evidence to guide recommendations about which specific non-verbal pain instrument to use. The communication barrier between clinicians and non-verbal patients limits the appropriate acute pain symptom assessment during the early postoperative period; however the use of behavioral instruments can lead to better pain management.

Findings of this study provide evidence to support relationships between CPOT and NVPS-R in certain behavioral pain indicators, including facial expressions, muscle tension, and

body movements. Both instruments showed a strong correlation in their assessment of acute pain in nonverbal sedated patients after general anesthesia during the early postoperative period. However, it was found that the vital sign parameters of the NVPS-R are not consistent indicators. On the other hand, the incidental finding that CPOT vocalization is a consistent indicator in patients with significant pain deserves further investigation. The study findings contribute to providing significant data needed to establish specific recommendations in the assessment of pain in postoperative patients. The absence of studies to support and recommend a specific behavioral pain instrument for nonverbal sedated postoperative adults in post anesthesia care units leads nurses to misuse existing instruments, undertreat patients' pain, and increase the gap in the standard of care for pain assessment and management. Patients who are evaluated early to identify the presence of acute pain and have early management have a lower rate of postoperative complications due to the stress response (Barr et al., 2013).

The 2010 Patient Protection and Affordable Care Act (PPACA), 111 Law, Section 4305, required the Human Health Secretary (HHS) to establish an agreement with the Institute of Medicine (IOM) for activities directed to increase the recognition of pain as a significant public health problem. The 2011 IOM report prompted the HHS to release a National Pain Strategy in 2016, which focused support on research to identify and reduce barriers to appropriate care, adequacy of assessment, diagnosis, treatment, and management of acute pain in all conditions in which it could be present. This mandate forces us to focus our own efforts as researchers to address pain symptom concerns.

The goal of nursing and anesthesia professionals is to contribute to the treatment of patients suffering from pain and to help in the process of early recovery of patients after anesthesia and surgery. For effective pain assessment and management we need to assess pain in

a systematic way. Pain assessment should be measured at regularly established intervals during the early postoperative period. As previously stated, assessment is the basis for adequate pain treatment and the achievement of positive postoperative outcomes.

As clinicians, we believe that vital signs alone are not good criteria to define pain presence during early pain assessment for all patients. PACU nurses need to agree on a set of measures used to assess pain that should be used to assess sedated patient's pain, in order to provide the best care. To improve the quality of pain assessment and management, healthcare providers must consistently use a reliable, validated instrument.

Institutions where surgeries are performed need to standardize and provide clear policies and procedures for effective postoperative pain assessment and management. Follow-up pain assessments provide an objective mechanism to decrease the number of patients who experience pain and decrease complications due to inadequate assessment and management of pain in daily practice. Healthcare providers are patient advocates and a clear vision in providing the most effective pain assessment and management will contribute to reducing the worldwide problem of undertreatment of acute pain.

APPENDIX A PERMISSION TO USE INSTRUMENTS

Universidad de Puerto Rico Mail - (no subject)

Page 3 of 3

Gracias!

Sent from my iPad
[Quoted text hidden]

Céline Gélinas, Dr. <celine.gelinas@mcgill.ca>
To: Sherily Pereira Morales <sherily.pereira@upr.edu>

Mon, Oct 21, 2013 at 4:01 PM

Dear Sherily,

Your project looks very exciting!

I have validated the COPT in early postop ICU patients who could have been to PACU as well. It's just that the ICU was used as the PACU for the cardiac surgery group.

So my feeling is that the CPOT would be a good fit to your study. When I initially developed the CPOT, I consulted PACU nurses who provided similar pain indicators than the ICU nurses. I think the use of the CPOT in your study would also be a nice addition to the literature and could support its use in its use in the PACU too.


I am attaching the CPOT directives of use for your information. If you decide to use it, let me know and I will forward you the agreement form to be completed and signed (no fees).

Sincerely,

Celine

From: Sherily Pereira Morales [sherily.pereira@upr.edu]
Sent: October 14, 2013 7:32 PM
To: Céline Gélinas, Dr.
Subject: Fwd:

[Quoted text hidden]

 CPOT description and directives_English_detailed_revised.pdf
362K

MEMORANDUM OF AGREEMENT

Agreement between the author Céline Gélinas who developed the Critical-Care Pain Observation Tool (CPOT), and Sherily Pereira «the User »who wish to use the CPOT for research purposes.

Céline Gélinas, who developed the CPOT, had transfered, assigned and conveyed all copyright rights and other rights incidental in the English version of the CPOT to the American Association of Critical-Care Nurses.

Subject to fair dealing provisions of copyright legislation and all the terms and conditions of this Agreement, the User shall share results from his research or from trial in clinical practice with the author Céline Gélinas and to inform her of the journal in which results will be published.

The User shall clearly identify the CPOT's source in the text and in the reference list of any document naming the CPOT as follows: "Gélinas, C., Fillion, L., Puntillo, K. A., Viens, C., & Fortier, M. (2006). Validation of the Critical-Care Pain Observation Tool in adult patients. *American Journal of Critical Care*, 15 (4), 420-427."

Any reproduction of the description of the CPOT (Gélinas et al., 2006, Table 1, p.421) in a manuscript to be published will require written permission from the American Journal of Critical Care (see <http://ajcc.aacnjournals.org/>).

The User acknowledges that copyright in the CPOT English version is owned by American Association of Critical-Care Nurses, and that no transfer of ownership of copyright is conveyed by this agreement. The User agrees that it will not, during the term of this Agreement or any time thereafter, contest directly or indirectly any copyright in the CPOT.

Please complete the following statements or questions:

1. The CPOT is intended to be used for a research purpose or clinical purpose. (Please check)
2. The CPOT is intended to be used for the following ICU population, please check when appropriate:
 Postoperative patients, specify types of surgery abdominal, pelvic and gastrointestinal
 Medical ICU patients
 Trauma ICU patients, please check include head injury patients
Other: _____

Use to translate according to fair dealing provisions :

1. The CPOT is intended to be translate into (specify) _____ language.
2. In no event shall Céline Gélinas or American Association of Critical-Care Nurses be liable for any translation whatsoever.
3. The CPOT translation shall be identified as follows: *Spanish* version executed by _____ of the CPOT "Gélinas, C., Fillion, L., Puntillo, K. A., Viens, C., & Fortier, M. (2006). Validation of the Critical-Care Pain Observation Tool in adult patients. *American Journal of Critical Care*, 15 (4), 420-427."
4. The translation shall be immediately sent to Céline Gélinas for archiving purpose.

SUBJECT TO FAIR DEALING PROVISIONS OF COPYRIGHT LEGISLATION CPOT IS MADE AVAILABLE AT NO CHARGE FOR TEACHING, SCHOLARSHIP, OR RESEARCH PURPOSES. ACCORDINGLY, THE CPOT IS PROVIDED "AS IS" WITHOUT WARRANTY OF ANY KIND. YOU ARE SOLELY RESPONSIBLE FOR THE USE OR TRANSLATION, BY YOU AND ANY OF YOUR AUTHORIZED USERS. THE ENTIRE RISK AS TO YOUR CPOT USE OR TRANSLATION IS BORNE BY YOU. YOU AGREE TO INDEMNIFY AND HOLD CÉLINE GÉLINAS AND AMERICAN ASSOCIATION OF CRITICAL-CARE NURSES HARMLESS FROM ANY CLAIMS ARISING FROM OR RELATING TO YOUR CPOT USE OR TRANSLATION.

IN NO EVENT SHALL CÉLINE GÉLINAS AND AMERICAN ASSOCIATION OF CRITICAL-CARE NURSES, OR THE CPOT CONTRIBUTING EDITORS, BE LIABLE FOR ANY INDIRECT, SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES, EVEN IF ADVISED OF THE POSSIBILITY THEREOF, AND REGARDLESS OF WHETHER ANY CLAIM IS BASED UPON ANY CONTRACT, TORT OR OTHER LEGAL OR EQUITABLE THEORY, RELATING OR ARISING FROM YOUR CPOT USE OR TRANSLATION.

All notices from one party to any other party shall be sent by mail to the addresses specified below unless prior notice shall have been given of any change of address.

Neither party shall be under any liability for any loss or for any failure to perform any obligation hereunder due to causes beyond their control including, but without limitation, industrial disputes of whatever nature, acts of God, hostilities, force majeure or any circumstances which they could not reasonably foresee and provide against.

The Agreement will be governed by the Canadian laws.

To complete if the CPOT is used for a research purpose :

Validation of any newly developed tool like the CPOT is a long process. Any research using the CPOT could include interesting data which may result in some modifications in the CPOT in order to improve its content for better patient's pain assessment in the non-verbal critically ill population. By sharing your research data, the CPOT could be revised or modified, and the validation could be enhanced.

Yes, I accept to share my data with the author of the CPOT.
 No, I refuse to share my data with the author of the CPOT.

By accepting to share your data with reference to the education/research and fair dealing provisions of copyright legislation, you agree that the author Céline Gélinas or American Association of Critical-Care Nurses has the right to publicly identify the source of the data in any published document.

Refusing to share your data doesn't interfere with the permission for you to use the CPOT as agreed above.

IN WITNESS WHEREOF, the parties hereto, who are authorized signatories, have executed this Agreement:

__01__ / __03__ / __2015__ (month-day-year)

Date



Céline Gélinas, RN, PhD
Assistant Professor
School of Nursing
McGill University
3506, University Street, Wilson Hall, Room 420
Montreal, Quebec
H3A 2A7, Canada
Tel: (514) 398-6157
Fax: (514) 398-8455
celine.gelinas@mcgill.ca

Sherily Pereira (electronic sign)

(signature)

Name : Sherily Pereira

Address

PMB #72 Box 70344 San Juan,
Puerto Rico, 00936

Email

Freeland, Nancy <Nancy_Freeland@urmc.rochester.edu>
To: Sheryly Pereira Morales <sheryly.pereira@upr.edu>

Mon, Jan 5, 2015 at 9:26 AM

Thank you for inquiring about the adult nonverbal pain scale (NVPS). Many institutions are now using the scale and you have our permission to use the scale. I have attached a copy of the scale and ask that you reference the copyright and any reproductions of the scale. Please contact me with any questions. We would appreciate your feedback and input as you continue your research on pain assessment on nonverbal patients.

Nancy Freeland RN, MS, CCRN

Senior Nurse Educator

Adult Critical Care Nursing

University of Rochester, Strong Memorial Hospital

601 Elmwood Avenue, Box 619-26

Rochester, NY 14642

(585) 275-6015

nancy_freeland@urmc.rochester.edu

APPENDIX B

LETTER OF AUTHORIZATION FROM THE ASEM SETTING



COMMONWEALTH OF
PUERTO RICO
Puerto Rico Medical
Services Administration
Office for Research and Development
in (Re)habilitation and Health

August 6, 2015

Sherily Pereira, PhD, RN
University of Massachusetts
Amherst, MA

Dear Mrs. Pereira:

I hereby authorized you to use ASEM as the setting to conduct the research study: *Acute Pain Symptom Assessment and Management in Nonverbal Puerto Rican Patients in the Early Postoperative Period*. I am pleased to have the opportunity to collaborate with you on this important project.

I am confident that you will abide by all IRB procedures. I am convinced that your research will continue to develop nursing science and improve practice. I will gladly work with you to meet the project's aims.

The nurses of our PACU and medical of Anesthesia Department very well accommodate your research sample. We have specialized human resources and equipment of high complexity and modern technology, which allow the provision of specialized care to the entire population of Puerto Rico.

On behalf of ASEM, we wish you much success in the completion of your research study. I'd like to express my support for this project and my conviction that this research will be worthwhile. We will be looking forward to the presentation of your findings.

Sincerely,

Nicolas Linares Orama, PhD
OIDRS Director, ASEM
San Juan, Puerto Rico



APPENDIX C

CRITICAL CARE PAIN OBSERVATION TOOL (CPOT)

| | | | | |
|---|--|---|---|-------------------|
| Facial expressions | Relaxed, neutral No muscle tension observed | Tense Presence of frowning, brow lowering, orbit tightening and levator contraction or any other change (e.g. opening eyes or tearing during nociceptive procedures) | Grimacing All previous facial movements plus eyelid tightly closed (the patient may present with mouth open or biting the endotracheal tube) | 0-2 |
| Body movements | Absence of movements or normal position. Does not move at all (doesn't necessarily mean absence of pain) or normal position (movements not aimed toward the pain site or not made for the purpose of protection) | Protection Slow, cautious movements, touching or rubbing the pain site, seeking attention through movements | Restlessness/Agitation Pulling tube, attempting to sit up, moving limbs/thrashing, not following commands, striking at staff, trying to climb out of bed | 0-2 |
| Compliance with the ventilator (intubated patients) OR Vocalization (extubated patients) | Talking in normal tone or no sound | Sighing, moaning | Crying out, sobbing | 0-2 |
| Muscle tension Evaluation by passive flexion and extension of upper limbs when patient is at rest or evaluation when patient is being turned | Relaxed No resistance to passive movements | Tense, rigid Resistance to passive movements | Very tense or rigid Strong resistance to passive movements or incapacity to complete them | 0-2 |
| Sub total score | 0 | 1 | 2 | Total score: 0 -8 |

Adapted from Gélinas, C., Fillion, L., Puntillo, K. A., Viens, C., & Fortier, M. (2006). Validation of the Critical-Care Pain Observation Tool in adult patients. *American Journal of*

Critical Care, 15 (4), 420-427. **Key: 0-2 points = No pain ≥ 3-8 = significant pain**

APPENDIX D

NON-VERBAL PAIN SCALE REVISED (NVPS-R)

| Categories | 0 | 1 | 2 |
|-----------------------------|--|---|---|
| Face | No particular expression or smile. | Occasional grimace, tearing, frowning, wrinkled forehead. | Frequent grimace, tearing, frowning, wrinkled forehead. |
| Activity | Lying quietly, normal position. | Seeking attention through movement or slow, cautious movement. | Restless, excessive activity and/or withdrawal reflexes. |
| Guarding | Lying quietly, no positioning of hands over areas of body. | Splinting areas of the body, tense. | Rigid, stiff. |
| Physiologic I (Vital signs) | Stable vital signs | Change over past 4 hours in any of the following: * SBP > 20 mm HG. * HR > 20/minute. | Change over past 4 hours in any of the following: * SBP > 30 mm HG. * HR > 25/minute. |
| Respiratory | Baseline RR/SpO2 Compliant with ventilator | RR > 10 above baseline, or 5% SpO2 or mild asynchrony with ventilator | RR > 20 above baseline, or 10% SpO2 or severe asynchrony with ventilator |
| Sub Total Score | 0 | 1 | 2 |

SBP= systolic blood pressure, HR= heart rate, RR= respiratory rate SpO2= pulse oximetry.
 Instructions: Each of the five categories is scored from 0-2, which results in a total score between zero and ten. Document total score by adding numbers from each of the five categories. **Key: Scores of 0-2 indicate no pain, 3-10 pain. Sepsis, hypovolemia, hypoxia need to be excluded prior to interventions.** © Strong Memorial Hospital, University of Rochester Medical Center, 2004. Used with permission

APPENDIX E

RICHMOND AGITATION AND SEDATION SCALE (RASS)

| Score | Term | Description |
|-------|--------------------------|--|
| +4 | Combative | Overtly combative, violent, immediate danger to staff |
| +3 | Very agitated | Pulls or removes tube(s) or catheter(s); aggressive |
| +2 | Agitated | Frequent non-purposeful movement, fights ventilator |
| +1 | Restless | Anxious but movements not aggressive vigorous |
| 0 | Alert and Calm | |
| -1 | Drowsy | Not fully alert, but has sustained awakening(eye opening/eye contact) to voice (≥ 10 seconds) |
| -2 | Light sedation | Briefly awakens with eye contact to voice (< seconds) |
| -3 | Moderate sedation | Movement or eye opening to voice (but no eye contact) |
| -4 | Deep sedation | No response to voice, but movement or eye opening to physical stimulation |
| -5 | Unarousable | No response to voice or physical stimulation |

Key: If RASS is -5, stop and Reassess patient at 15 minutes later.

If RASS is above -4 to -2 proceed to CPOT and NVPS-R Pain Assessment

*Sessler, et al. AJRCCM 2002; 166:1338-1344

*Ely, et al. JAMA 2003; 289:2983-2991.

APPENDIX F

CONSENT FORMS (ENGLISH AND SPANISH VERSION) AND REQUEST FOR WAIVER OF AUTHORIZATION

Consent Form for Participation in a Research Study (ENGLISH VERSION) *University of Massachusetts Amherst*

Researcher(s): Annette Wysocki, PhD- Professor, College of Nursing, UMASS-Amherst, *and* Sherily Pereira Morales RN, MSN- 5th year doctoral student, College of Nursing, University of Massachusetts (UMASS), Amherst

Study Title: *Acute Pain Symptom Assessment and Management in Nonverbal Puerto Rican Patients in the Early Postoperative Period*

1. WHAT IS THIS FORM?

This form is called a Consent Form. It will give you information about the study so you can make an informed decision about participation in this research.

This consent form will give you the information you will need to understand why this study is being done and why you are being invited to participate. It will also describe what you will need to do to participate and any known risks, inconveniences or discomforts that you may have while participating. We encourage you to take some time to think this over and ask questions now and at any other time. If you decide to participate, you will be asked to sign this form and you will be given a copy for your records.

2. WHO IS ELIGIBLE TO PARTICIPATE?

Subjects must be at least 21 years old and older to participate. You can take part in this study if you are undergoing to an abdominal, pelvic or gastrointestinal surgery; and be under sedation effects after surgery.

3. WHAT IS THE PURPOSE OF THIS STUDY?

Acute pain is a phenomenon commonly experienced by patients after surgery in post anesthesia care units (PACU). The purpose of this research study is to compare the use of two behavioral acute pain assessment instruments during the early postoperative period for non-verbal sedated patients to enhance early pain assessment and management.

4. WHERE WILL THE STUDY TAKE PLACE AND HOW LONG WILL IT LAST?

This study will take place at Post Anesthesia Care Unit (PACU) of the Medical Center of Puerto Rico (ASEM). You will participate in this study for a period of two hours in the early postoperative period in PACU.

There will be no communication with you after the discharge from PACU, nor in the future.

5. WHAT WILL I BE ASKED TO DO?

If you agree to take part in this study, you will not be prompted to do anything.

Data from this study will be obtained in two ways. Some information will be obtained directly from your medical record. Further information will be obtained directly using assessment instruments. The researcher estimates acute pain with the application of two observation instruments for the assessment of pain behaviors. The evaluation of acute pain will be held on arrival in the PACU, then every 15 minutes until complete one (1) hour and finally every 30 minutes to complete one (1) hour.

Major inclusion criteria include; consent for abdomino-pelvic, gynecologic, or gastrointestinal surgery, which cannot verbalize or indicate pain using a traditional verbal scale such as the numeric rating scale (NRS) upon his arrival in the PACU.

Exclusion criteria includes; patients able to self-report of pain, with an initial sedation scale score that show an awake state.

Patients with a chronic cognitive impairment as dementia, alzheimer's disease, or neurological weaknesses (paraplegia, quadriplegia, amputation of upper limbs or stroke).

6. WHAT ARE MY BENEFITS OF BEING IN THIS STUDY?

You may not directly benefit from this research. Your pain after procedure may improve as a result of your participation in this study. However, there is no guarantee of this.

We hope that the information from this research may lead to a better assessment and management of acute pain in the future.

7. WHAT ARE MY RISKS OF BEING IN THIS STUDY?

We hope that the information from this research may lead to a best estimate and management of acute pain in the future.

This research involves traditional nursing care procedures. Risk or physical, emotional or social discomfort are not anticipated by the assessment of acute pain with observation instruments. We believe that there are no known risks associated with this research study, however, a possible inconvenience that can happen is the time takes to complete study.

8. HOW WILL MY PERSONAL INFORMATION BE PROTECTED?

If you decide to participate in this study, the researchers will obtain personal information about you. This may include information that could identify you and includes: birth date, admission date, discharge date, and demographic data. The researchers can also get your health information, including your medical record data, diagnosis, vital signs, surgery, and medications administered.

The researchers may give information about you and your health, to:

- University of Massachusetts, Office for the protection of human subjects in research- HRPO (IRB)
- The University of Puerto Rico, Medical Sciences Campus, Institutional Review Board -(UPR MSC IRB)

To protect the confidentiality of your information in the records of the study, the following procedures shall be used:

Information about you and your health that could identify you will be protected through the assignment of a case number. The researchers will keep all records of study, including codes to your data, to a file locked in her office. The records shall be protected according to the HIPAA regulations. A master key that links names and codes will remain a separate and safe place. The master key will be destroyed three (3) years after the end of the study.

Electronic files (REDCAP database, spreadsheets), containing personally identifiable information will be protected with a password. Any computer that host files will also have protection by password to prevent access by unauthorized users. Only the researchers will have access to passwords. At the conclusion of this study, researchers will publish their findings. The information will be presented in summary and you will be not identified in publications or presentations.

The information can be reviewed by the University of Massachusetts - Amherst, Human Research Protection Office (HRPO) and/or the institutional review board of the Medical

Sciences Campus UPR, (IRB RCM UPR). It's a group of people who carried out an independent review of the investigation as required by the regulations. In addition, the researcher will review information with her dissertation Committee members at the University of Massachusetts-Amherst. But the information provided will be confidential.

If you cancel this authorization, the investigator will not use or disclose your personal information health authorization for this study, unless you need to use or disclose your personal health information part to preserve the scientific integrity of the study. Researchers may use submitted information before you cancel this authorization.

Authorization for use and disclosure for research purposes protected health information is completely voluntary. However, if you do not sign this document you cannot participate in this study. If this authorization is cancelled in the future, you will continue to not participate in this study.

9. WHAT IF I HAVE QUESTIONS?

Take as long as you like before you make a decision. We will be happy to answer any question you have about this study. If you have further questions about this project or if you have a research-related problem, you may contact the researcher(s), Sherily Pereira at (787) 234-5643 or sherily@nursing.umass.edu or sherily.pereira@upr.edu.

If you have any questions concerning your rights as a research subject, you may contact the University of Massachusetts Amherst Human Research Protection Office (HRPO) at (413) 545-3428 or humansubjects@ora.umass.edu.

11. CAN I STOP BEING IN THE STUDY?

Your participation is voluntary, and you do not have to be in this study if you do not want. If you agree to be in the study, but later change your mind, you may drop out at any time. There are no penalties or consequences of any kind if you decide that you do not want to participate.

You may cancel this authorization at any time by sending a written notice to the investigator at the following address:

Sherily Pereira Morales
University of Puerto Rico
Medical Sciences Campus

School of Nursing
PO Box 365067
San Juan, Puerto Rico 00936

or by email at sherily@nursing.umass.edu or sherily.pereira@upr.edu

12.WHAT IF I AM INJURED?

The University of Massachusetts does not have a program for compensating subjects for injury or complications related to human subjects research, but the study personnel will assist you in getting treatment.

13. SUBJECT STATEMENT OF VOLUNTARY CONSENT

When signing this form I am agreeing to voluntarily enter this study. I have had a chance to read this consent form, and it was explained to me in a language which I use and understand. I have had the opportunity to ask questions and have received satisfactory answers. I understand that I can withdraw at any time. A copy of this signed Informed Consent Form has been given to me.

Participant Signature: Print Name: Date:

By signing below I indicate that I has read and consenting to having the researchers obtain my personal health information. My personal health information will be obtained from the medical record.

Participant Signature: Print Name: Date:

By signing below I indicate that the participant has read and, to the best of my knowledge, understands the details contained in this document and has been given a copy.

Signature of Person
Obtaining Consent

Print Name:

Date:

Created by spereira/8/13/15

Rev.spereira/8/27/15

FORMULARIO DE CONSENTIMIENTO PARA PARTICIPACION EN UN ESTUDIO DE INVESTIGACION Y AUTORIZACIÓN PARA USO Y DIVULGACIÓN DE INFORMACIÓN DE SALUD (SPANISH VERSION)

Universidad de Massachusetts-Amherst y Universidad de Puerto Rico- Recinto de Ciencias Médicas

Investigador(as): Carmen Mabel Arroyo, PhD- Profesora, Universidad de Puerto Rico, Recinto de Ciencias Médicas, Escuela de Enfermería y a Sherily Pereira Morales RN, MSN- 5^{to} año estudiante doctoral, Escuela de Enfermería, Universidad de Massachusetts- Amherst (UMASS)

Título del Estudio: *Estimado y Manejo de Síntomas de Dolor Agudo en Pacientes Puertorriqueños que no verbalizan en el Período Postoperatorio Temprano.*

NÚMERO DE PROTOCOLO:

Patrocinador del Estudio: Ninguno

1. ¿Que es este formulario?

Usted está invitado para participar en un estudio de investigación. Este formulario de consentimiento le proveerá a usted la información acerca del estudio para que así pueda hacer una decisión informada sobre su participación. Antes de que usted decida participar en el estudio, por favor lea este formulario cuidadosamente.

Este formulario de consentimiento le dará la información necesaria para entender por qué se hace este estudio y por qué usted está siendo invitado a participar. También se describe lo que tendrá que hacer para participar y los riesgos conocidos, inconvenientes o molestias que pueda tener durante su participación. Le agradecemos tome algún tiempo para pensar y realizar preguntas en este momento y/o en cualquier otro momento para asegurarse que entienda los procedimientos del estudio, incluyendo riesgos y beneficios.

Si usted decide participar, se le pedirá que firme este formulario y se le dará una copia para su archivo.

2. ¿QUIÉN ES ELEGIBLE PARA PARTICIPAR?

Para ser elegible para participar usted debe tener 21 años o más. Usted puede participar de este estudio si está programado para realizarse una cirugía abdominal, pélvica o gastrointestinal; y se espera que los efectos de la sedación continúen en el periodo postoperatorio temprano (0-2 horas), después de la cirugía y que no pueda verbalizar o indicar dolor utilizando una escala verbal tradicional tales como la escala de calificación numérica (NRS) a su llegada a la Unidad de Cuidado Post Anestesia (PACU).

Usted no sera elegible si está alerta y es capaz de indicar verbalmente la intensidad de dolor agudo, con una escala de sedación inicial que indique que está alerta. Usted no puede participar además si tiene un diagnóstico previo de crónico deterioro cognitivo crónico como por ejemplo demencia o Alzheimer o debilidad neurológica (paraplejia, tetraplejia, amputaciones de miembros superiores o accidente cerebrovascular).

3. ¿Cuál es el propósito de este estudio?

El dolor agudo es un fenómeno comúnmente experimentado por pacientes luego de cirugía en unidades de cuidado post anestesia (PACU). El propósito de este estudio es comparar el uso de dos herramientas de estimado de síntomas de dolor agudo durante el período postoperatorio temprano para pacientes no verbales y dentro de niveles de sedación.

4. ¿DÓNDE SE LLEVARA A CABO EL ESTUDIO Y CUÁNTO DURARÁ?

Este estudio se llevará a cabo en la Unidad de Cuidado Post Anestesia (PACU) del Centro Médico de Puerto Rico (ASEM). Usted participará en este estudio por un periodo de dos horas mientras esté en PACU.

No habrá comunicación con usted después del alta de PACU, ni en el futuro.

5. ¿QUÉ SE LE SOLICITARÁ HACER?

Si usted acepta formar parte de este estudio se le solicitará permita al investigador obtenga los datos de este estudio de dos maneras. Algunos datos se obtendrán directamente de su expediente médico. Otros datos se obtendrán mediante la observación de conductas de dolor. El investigador le realizará el estimado del dolor agudo postoperatorio utilizando dos escalas diferentes que miden dolor mediante la observación de conductas. La observación del dolor agudo con las escalas se realizarán en diferentes tiempos; a su llegada a PACU, luego cada 15 minutos hasta completar una (1) hora y finalmente cada 30 minutos hasta completar una (1) hora adicional. El tiempo total de estimado de dolor son 2 horas.

6. ¿Cuáles son mis beneficios por participar en este estudio?

Usted no se beneficiará directamente por participar de esta investigación. Su dolor después del procedimiento puede mejorar como resultado de su participación en este estudio. Sin embargo, no hay ninguna garantía de ello.

Esperamos que la información de esta investigación puede conducir a un mejor estimado y manejo del dolor agudo en el futuro.

7. COSTOS

No se le cobrará a su familiar, a usted o su compañía de seguros por participar en este estudio.

No hay ningún costo por participar en este estudio.

8. INCENTIVO PARA EL PARTICIPANTE

A usted no se le pagará por ser parte de este estudio.

9. ¿CUÁLES SON MIS RIESGOS AL PARTICIPAR EN ESTE ESTUDIO?

Esta investigación involucra procedimientos tradicionales de cuidado de enfermería. No se anticipan riesgos ni molestias físicas, emocionales o sociales al realizarse el estimado de dolor agudo con los instrumentos de observación.

Creemos que no existen riesgos conocidos asociados con este estudio de investigación; sin embargo, un posible inconveniente puede ser el tiempo que tome el completar el estudio.

10. ¿CÓMO SE PROTEGE MI INFORMACIÓN PERSONAL?

Si usted elige participar en este estudio, la investigadora del estudio conseguirá información personal sobre usted. Esta puede incluir información que puede identificarle y puede también conseguir información sobre usted en el expediente clínico tales como: edad , sexo y número de expediente médico, hora de alta de PACU ; e información de salud que se limitan a: estado físico ASA , diagnósticos , los signos vitales , tipo y duración de la cirugía , la anestesia administrada , resultados de laboratorio , evaluaciones de dolor , presencia de dolor al momento del alta , los medicamentos administrados y los efectos secundarios durante estadia en PACU.

Para proteger la confidencialidad de su información en los registros de estudio, se utilizarán los siguientes procedimientos:

Información sobre usted y su salud que podría identificarle estarán protegidos mediante la asignación de un número de caso. Los investigadores mantendrán todos los registros de estudio, incluyendo los códigos a sus datos, en un archivo bajo llave en su oficina. Los registros serán protegidos según las regulaciones HIPAA. Una clave maestra que vincula nombres y códigos se mantendrá en un lugar separado y seguro. La clave maestra se destruirá a los tres (3) años después del cierre del estudio.

Los archivos electrónicos (base de datos de REDCAP, hojas de cálculo), que contengan información de identificación personal serán protegidos con una contraseña. Cualquier equipo que almacene tales archivos también contará con protección por contraseña para evitar el acceso a usuarios no autorizados. Sólo los investigadores tendrán acceso a las contraseñas. En la conclusión de este estudio, los investigadores podrán publicar sus hallazgos en revistas científicas o ser presentados en foros de investigación, pero la identidad de usted no será divulgada. La información se presentará en resumen y usted no será identificado en publicaciones o presentaciones.

La información puede ser revisada por la Universidad de Massachusetts - Amherst, Oficina de Protección de la Investigación Humana (HRPO) y / o la Junta de Revisión Institucional del

Recinto de Ciencias Médicas de la UPR, (IRB RCM UPR). Se trata de un grupo de personas que realizan una revisión independiente de la investigación según lo requerido por las regulaciones. Además, los miembros del Comité de disertación del investigador en la Universidad de Massachusetts-Amherst revisarán la información. Sin embargo la información provista será confidencial.

Si cancela esta autorización, el investigador principal no usará o divulgará su información personal de salud con la autorización para este estudio, a menos que necesite usar o divulgar parte de su información de salud personal para preservar la integridad científica del estudio. Los investigadores pueden usar información presentada antes de cancelar esta autorización.

La autorización para el uso y divulgación de información de salud protegida para propósitos de investigación es totalmente voluntaria. Sin embargo, si usted no firma este documento no podrá participar en este estudio. Si en el futuro se cancela esta autorización, usted no continuará participando en este estudio.

11. ¿QUÉ SUCEDE SI TENGO PREGUNTAS?

Tome el tiempo que usted necesite antes de hacer una decisión. Estaremos disponibles de responder cualquier pregunta que usted tenga acerca de este estudio o sobre su participación en el mismo, o si piensa que ha sufrido alguna lesión asociada al estudio, usted puede contactar a la investigadora principal: Dra. Carmen Arroyo al 787-758-2525 Ext. 2115 ó a Sherily Pereira Morales al (787)758-2525 Ext. 2115

Si usted tiene alguna pregunta sobre los derechos como participante del estudio, usted puede contactar a la:

Oficina de Protección de Participantes Humanos en Investigación

Teléfono (787) 758-2525 Exts. 2510 ó 2515

E-mail: opphi.rcm@upr.edu

12. ¿PUEDO DEJAR EL ESTUDIO?

Su participación es voluntaria, y usted no tiene que participar en este estudio si así lo desea. Si acepta participar en el estudio, pero más tarde cambia de opinión, se puede retirar en cualquier momento. No existen sanciones ni consecuencias de ningún tipo si usted decide no participar. Usted puede cancelar esta autorización en cualquier momento enviando una notificación por escrito a las investigadoras a una de las siguientes direcciones:

Investigadora Principal:

Dra. Carmen Mabel Arroyo

Universidad de Puerto Rico

Recinto de Ciencias Médicas

Escuela de Enfermería

Departamento Graduado

PO Box 365067

San Juan, Puerto Rico 00936

ó por correo electrónico a carmen.arroyo1@upr.edu

Sherily Pereira Morales

Universidad de Puerto Rico

Recinto de Ciencias Médicas

PO Box 365067

San Juan, Puerto Rico 00936

ó por correo electrónico a sherily@nursing.umass.edu ó sherily.pereira@upr.edu

13 ¿QUÉ PASA SI ME LESIONO?

En el caso de lesión física o mental, como resultado de este estudio de investigación, usted recibirá tratamiento médico libre de costo en el Hospital Universitario o cualquier otro hospital designado por el Rector del Recinto de Ciencias Médicas de la Universidad de Puerto Rico. La Universidad de Puerto Rico no prevé ofrecerle ninguna otra forma de compensación o remuneración directamente a usted. Sin embargo, por firmar este formulario de consentimiento, usted no renuncia a ningún derecho legal que pudiera tener.

14. DECLARACIÓN DE CONSENTIMIENTO VOLUNTARIO

Al firmar este formulario estoy de acuerdo en entrar voluntariamente en este estudio. He tenido oportunidad de leer este formulario de consentimiento, y me fue explicado en el lenguaje que utilizo y entiendo. He tenido la oportunidad de hacer preguntas y haber recibido respuestas satisfactorias. Entiendo que me puedo retirar del estudio en cualquier momento.

Autorizo el uso y la divulgación de mi información de salud a las entidades antes mencionadas en este consentimiento para los propósitos descritos anteriormente. Al firmar esta hoja de consentimiento, no he renunciado a ninguno de mis derechos legales. No firme este consentimiento a menos que haya tenido la oportunidad de hacer preguntas y recibir contestaciones satisfactorias para todas sus preguntas.

Si usted firma aceptando participar en este estudio, recibirá una copia firmada y fechada de este documento para usted, con el sello de aprobación del IRB en cada hoja.

Firma del Participante:

Nombre en letra de molde:

Fecha:

La firma en el siguiente espacio indica que el participante ha leído y en mi conocimiento, entiende la información contenida en este documento y se le ha entregado una copia.

Firma de la persona
que obtiene el consentimiento

Nombre en letra de molde:

Fecha:



COMITE DE DERECHOS HUMANOS (IRB)
INSTITUTIONAL REVIEW BOARD



Request for a waiver of authorization for the release of health information

Protocol #: H15535

Project Title: *Acute Pain Symptom Assessment and Management in Nonverbal Puerto Rican Patients in the Early Postoperative Period*

Principal Investigator: Dr. Carmen Mabel Arroyo

Date of Approval:

The Medical Sciences Campus Institutional Review Board (Federalwide Assurance Number 00005561) may waive or alter the requirement to obtain authorization from research subjects in order to use or disclose their protected health information (PHI*), provided that the investigator justifies, and the IRB agrees, that specific criteria have been met. Please explain how your research study meets the criteria by answering each of the following questions:

1. Explain why this research involves no more than minimal risk of loss of privacy to the subject. Include a detailed list of the PHI to be collected and a list of the sources(s) used/accessed for the PHI.

This research involves minimal risks because the assessment of acute pain will be conducted with observation instruments.

Personal and health information that we may use or disclose (release) from medical record for this research includes: Age, gender, and medical record number, discharge time from PACU; and health information including ASA physical status, diagnoses, medications used, vital signs, type and length of surgery, anesthesia administered, lab results, pain assessments, pain presence at discharge, medications administered and side effects during hospital stay.

- a. Describe the plan for protecting the identifiers from improper use and disclosure and indicate where PHI will be stored and who will have access to the study's PHI. (IRB, Sponsor, FDA, DSMB)

To protect the confidentiality of PHI in the records of the study, the following procedures shall be used:

PHI will be protected through the assignment of a case number. The researchers will keep all records of study, including data codes, the PI's office. The records shall be protected according to HIPAA regulations. A master key that links names and codes will remain a separate and safe place. The master key will be destroyed three (3) years after the end of the study.

Electronic files (REDCAP database, spreadsheets), containing all personally identifiable information will be protected with a password. Any computer that host files will also have protection by password to prevent access by unauthorized users. Only the researchers will have access to passwords. At the conclusion of this study, researchers will publish their findings. The PHI will be presented in summary and will be not identified in publications or presentations.

- b. Describe the plan to destroy the identifiers at the earliest opportunity that is appropriate for the research study. Identifiers may only be maintained following completion of a study if there is a legitimate reason for maintaining the data (e.g required by law, etc.).

The master key of the PHI will be destroyed three (3) years after the end of the study.

- c. Provide written assurances that the identifiable health information will not be re-used or disclosed to any other person or entity, except as required by law, for authorized oversight of the project or for other permitted research purposes.

Researchers, ASEM, UMASS Amherst, and UPR Medical Sciences Campus are required by law to protect identifiable health information. Personal health information will be confidential and will

not be re-used or disclosed to any other person or entity, except as required by law, for authorized oversight of the project or for other permitted research purposes.

2. Explain how the research could not be practicably conducted without waiver of authorization or an alteration to the authorization form.

3. Explain how the research could not be practicably conducted without access to and use of the individually identifiable health information.

The study requires medical record revision and could not be conducted without access to and use of the individually identifiable health information

The information listed in the waiver application is accurate and all research staff** will comply with the HIPAA regulations and the waiver criteria. All research staff have completed HIPAA training.

I assure that the information I obtain as part of this research (including protected health information) will not be reused or disclosed to any other person or entity other than those listed on this form, except as required by law. If at any time I want to reuse this information for other purposes or disclose the information to other individuals or entities, I will seek approval from the UPR-MSU IRB.

Principal Investigator Signature: C. A. Noyes

Name typed/printed: Carmen Mabel Arroyo Noyes

Date: Oct 2, 2015

*PHI: individually identifiable health information transmitted or maintained in any form (electronic means, on paper, or through oral communication) that relates to the past, present or future physical or mental health or conditions of an individual.
Note: Research staff is defined as **ALL study personnel (including PI) that is involved in the research.
***HIPAA Regulations allow IRBs to waive use of authorization form if all of the criteria listed above are met.

APPENDIX G
SOCIO-DEMOGRAPHIC INSTRUMENT

Instructions: Fill the blanks with an (X) and provide the number in the space provided.

1. Age: ___years
2. Weight: _____kgs
3. Race: ___Black ___Hispanic _____White
4. Education: Primary_____ Secondary_____ Post Secondary_____
- Bachelor degree___ Master degree___ Doctoral degree_____
5. Diagnoses: _____
6. Type of Surgery planned: _____
7. General Anesthesia proposed:_____
8. Pain presence: ___yes ___no. If yes, NRS score_____.

**APPENDIX H
DATA COLLECTION PLAN**

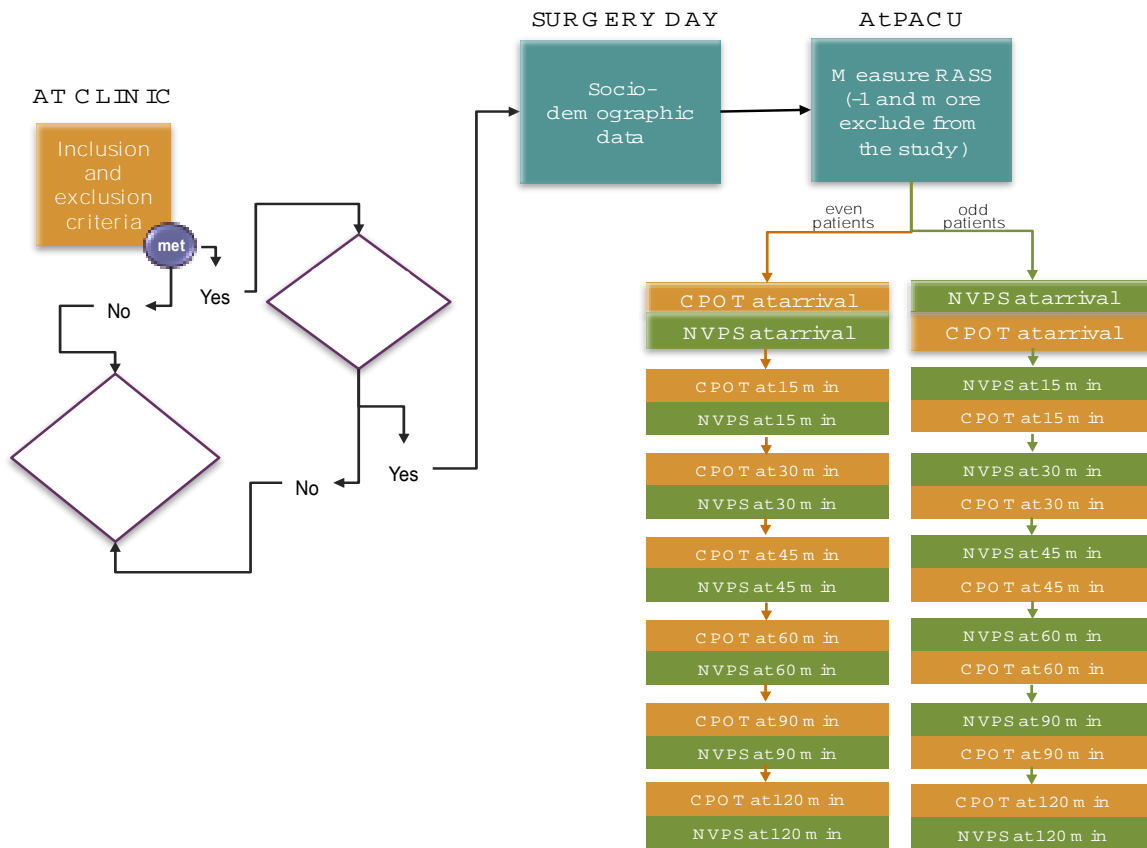
| Activity | Estimated Time |
|--|----------------|
| In advance Identify potential patients by consulting with gynecologist personnel, and review medical history and pre-anesthesia form for inclusion criteria | 10 minutes |
| Pre surgery visit 7-0 days before surgery | |
| Get patient verbal/written consent | 10 minutes |
| Day of surgery | |
| Obtain patient demographics and other data from chart | 5 minutes |
| Intervention Assess and rate acute pain during the early post-operative period using CPOT and NVPS-R, immediate arrival at 0 minute to 2 hours after arrival to PACU | 120 minutes |

APPENDIX I
PROJECTED TIMETABLE FOR DATA COLLECTION AND DATA ANALYSIS

| One month | Three months | Two months |
|--|---|---|
| Obtain Human Subjects Committee approval from UPR-MSC and UMASS IRB's. Develop data collection forms. Construct database. | Enroll sample patients. Collect data and enter into database. | Perform data analysis. Write dissertation. |

UPR, MSC, University of Puerto Rico, Medical Sciences Campus; UMASS, University of Massachusetts-Amherst

APPENDIX J PROCEDURES TO RECRUITMENT, ENROLLMENT, AND DATA MANAGEMENT



APPENDIX K
SCREENING AND ELIGIBILITY DETERMINATION

SCREENING AND ELIGIBILITY DETERMINATION
Acute Pain Symptom Assessment and Management in Nonverbal Puerto Rican Patients at Early Postoperative Period

Date: _____

Candidate #: _____

Inclusion Criteria:

Pre-operative

- Age \geq 21
- Able to give informed consent.
- Consenting abdominal, pelvic or gastrointestinal surgery

Screening at PACU:

- RASS = -4 to -2 (deep, moderate and light sedation) at PACU
 - Yes (enrolled patient)
 - No (exclude patient)

Exclusion Criteria:

- Patients with a previous diagnosis of chronic cognitive impairment (Dementia, Alzheimer) or neurologic impairment
- Non GETA

PACU

- Patient able to self-report acute pain, with an initial sedation scale (RASS) = -1, and 0 to 4.

Reason to reject to be part of the study: _____

Consent to participate: _____ Yes, _____ No

Patient ID Code: _____

APPENDIX L DATA COLLECTION FORM

DATA COLLECTION FORM

Acute Pain Symptom Assessment and Management in Nonverbal Puerto Rican Patients in the Early Postoperative Period

Name of rater: _____ Patient ID Code # _____ Date _____
 MR: _____ Patient: odd even _____ month/day/year

Socio demographics, Medical History, and Pre-anesthesia Baseline Measures

Age: _____ Weight: _____
 Gender: _____ Race: _____ Baseline
 Education: _____ Physiological measures
 ASA Physical status: _____
 Diagnoses: _____ BP _____ mmHg
 _____ HR _____ /min
 _____ RR _____ /min
 Type of Surgery: _____
 Previous analgesic tx before surgery: _____ SpO₂ _____ %

Pain Assessment
NRS

Surgery

| Baseline | Opioids | Other Meds | Anesthetics/Inhalational Agents |
|------------------------------|---------|------------|---------------------------------|
| Physiological measures | | | |
| BP _____ | _____ | _____ | _____ |
| HR _____ | _____ | _____ | _____ |
| RR _____ | _____ | _____ | _____ |
| SpO ₂ _____ | _____ | _____ | _____ |
| Length of the surgery: _____ | _____ | _____ | _____ |

Pain assessment at arrival to PACU

Time: _____

Physiological measures

BP _____

NVPS

CPOT

NRS

HR _____

RR _____

RASS

Pain Presence ____ Yes ____ NO
 Time _____
 Pain medications _____

SpO₂ _____

Pain assessment at 15 min

Time: _____

Physiological measures

BP _____

NVPS

CPOT

NRS

HR _____

RR _____

RASS

Patient awake
 Yes
 No
 Pain Presence ____ Yes ____ NO
 Time _____
 Pain medications _____

SpO₂ _____

Pain assessment at 30 min

Time: _____

Physiological measures

BP _____

NVPS

CPOT

NRS

HR _____

RR _____

RASS

Patient awake
 Yes
 No
 Pain Presence ____ Yes ____ NO
 Time _____
 Pain medications _____

SpO₂ _____

Pain assessment at 45 min

Time: _____

Physiological measures

BP _____

HR _____

RR _____

SpO₂ _____

Patient awake
 Yes
 No

NVPS

CPOT

RASS

Pain Presence ____ Yes ____ NO
 Time _____
 Pain medications _____

Pain assessment at 60 min

Time: _____

Physiological measures

BP _____

HR _____

RR _____

SpO₂ _____

Patient awake
 Yes
 No

NVPS

CPOT

RASS

Pain Presence ____ Yes ____ NO
 Time _____
 Pain medications _____

Pain assessment at 90 min

Time: _____

Physiological measures

BP _____

HR _____

RR _____

SpO₂ _____

Patient awake
 Yes
 No

NVPS

CPOT

RASS

Pain Presence ____ Yes ____ NO
 Time _____
 Pain medications _____

Pain assessment at 120 min

Time: _____

Physiological measures

BP _____

HR _____

RR _____

SpO₂ _____

Patient awake
 Yes
 No

NVPS

CPOT

RASS

Pain Presence ____ Yes ____ NO
 Time _____
 Pain medications _____

PACU Outcome (Discharge)

Total pain medication administered after PACU: _____

Time of discharge from PACU: _____

Transfer destination: _____

Patient awake
 Yes
 No

Final Pain Assessment

Side effects
 nausea
 vomiting
 hallucination
 dysphoria
 Unpleasant sensation

Legend: NRS-Numeric Rating Scale
 NVPS-Non Verbal Adult Pain Scale
 CPOT-Critical Care Pain Observation Tool
 RASS-Richmond Agitation Sedation Scale
 PACU-Post Anesthesia Care Unit

UPR-MCS IRB Protocol # A-5570115
 UMASS IRB Protocol # 2015-2603

APPENDIX M
TABLE OF ASSESSMENT OF ADEQUACY OF RANDOMIZATION

Assessment of Adequacy of Randomization

| Characteristics | CPOT n=20 <i>n (%)</i> <i>mean ± SD</i> | NVPS-R n=20 <i>n (%)</i> <i>mean ± SD</i> | P value |
|--|--|--|---------------------|
| Age in years | 51.2 ± 17.0 | 47.3 ± 17.4 | 0.5 ^d |
| Gender | | | |
| Female | 16 (55.2) | 13 (44.8) | |
| Male | 4 (36.4) | 7 (63.6) | 0.5 ^a |
| Weight in kg | 84.0 ± 22.8 | 75.6 ± 34.9 | 0.1 ^d |
| Primary diagnosis | | | |
| Uterine Myoma | | | |
| Yes | 3.0 (60.0) | 2.0 (40.0) | |
| No | 17.0 (48.6) | 18.0 (51.4) | 0.6 ^a |
| Hernia | | | |
| Yes | 1.0 (20.0) | 4.0 (80.0) | |
| No | 19.0 (54.3) | 16.0 (45.7) | 0.3 ^a |
| Gynecologic Carcinoma | | | |
| Yes | 9.0 (90.0) | 1.0 (10.0) | |
| No | 11.0 (36.7) | 19.0 (63.3) | 0.008 ^{a*} |
| Colon Carcinoma | | | |
| Yes | 1.0 (16.7) | 5.0 (83.3) | |
| No | 19.0 (55.9) | 15.0 (44.1) | 0.2 ^a |
| Ureter Carcinoma | | | |
| Yes | 0.0 (0.0) | 1.0 (100.0) | |
| No | 20.0 (51.2) | 19.0 (49.7) | 0.5 ^a |
| Others | | | |
| Yes | 7.0 (66.7) | 6.0 (33.3) | |
| No | 13.0 (48.1) | 14.0 (51.9) | |
| ASA Physical Status Classification System | | | |
| Healthy Patient | 3.0 (75.0) | 1.0 (25.0) | |
| Mild Systemic | 11.0 (40.7) | 16.0 (59.2) | |
| Severe Systemic | 5.0 (62.5) | 3.0 (37.5) | 0.4 ^a |

| | | | |
|--|---------------|---------------|--------------------|
| Incapacitating Systemic | 1.0 (100.0) | 0.0 (0.0) | |
| Total Anesthesia time (minutes) | 608.7 ± 155.4 | 575.5 ± 130.8 | 0.7 ^d |
| Opioids | | | |
| Fentanyl | | | |
| Yes | 20.0 (50.0) | 20.0 (50.0) | Cannot be assessed |
| Morphine | | | |
| Yes | 8.0 (38.1) | 13.0 (61.9) | |
| No | 12.0 (63.2) | 7.0 (36.8) | 0.1 ^b |
| Others | | | |
| No | 20.0 (50.0) | 20.0 (50.0) | Cannot be assessed |

^a Fisher Exact

^b Pearson's chi2

^c T-Test

^d Mann-Whitney

* p≤0.05

APPENDIX N
ASSOCIATION OF PAIN ASSESSMENT WITH RANDOMIZATION

Association of Pain Assessment with Randomization at Seven Occasions of follow-up (with MEANS and SD)

| Number, n | 1st | 2nd | P-Value |
|------------------------|-------------|-------------|---------|
| Means (SD) | | | |
| CPOT, minutes | | | |
| 0 | 2.55 (1.85) | 2.50 (2.31) | 0.70 |
| 15 | 2.30 (1.45) | 3.50 (1.85) | 0.05* |
| 30 | 2.60 (1.60) | 2.82 (1.88) | 0.78 |
| 45 | 2.22 (1.52) | 3.05 (1.90) | 0.11 |
| 60 | 2.12 (1.58) | 2.42 (2.04) | 0.58 |
| 90 | 2.2 (1.66) | 1.89 (1.41) | 0.62 |
| 120 | 1.93 (2.02) | 1.4 (1.43) | 0.63 |
| NVPS-R, minutes | | | |
| 0 | 2.50 (1.79) | 2.25 (2.02) | 0.51 |
| 15 | 2.30 (1.45) | 2.83 (1.65) | 0.32 |
| 30 | 2.50 (1.54) | 2.47 (1.50) | 0.89 |
| 45 | 2.17 (1.54) | 2.90 (1.74) | 0.18 |
| 60 | 1.82 (1.59) | 2.37 (1.67) | 0.24 |
| 90 | 2.07 (1.62) | 2.17 (1.62) | 0.87 |
| 120 | 1.86 (1.99) | 1.60 (1.35) | 0.98 |

* P-value<0.05

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