Prediction of Severe Postoperative Pain: Modification and Validation of a Clinical Prediction Tool

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PREDICTION OF SEVERE POSTOPERATIVE PAIN: MODIFICATION AND VALIDATION OF A CLINICAL RISK PREDICTION TOOL

By

Shayne Hauglum

A DISSERTATION

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PREDICTION OF SEVERE POSTOPERATIVE PAIN: MODIFICATION AND
VALIDATION OF A CLINICAL RISK PREDICTION TOOL

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Estimates show that up to 3 out of 4 patients have moderate to severe postoperative pain following surgery. As a result, patients suffering from postoperative pain not only face increased rates of morbidity and mortality but also report decreased satisfaction with care. Pre-operatively predicting patients at risk for severe postoperative pain may improve postoperative pain management, patient outcomes, and patient satisfaction.

A retrospective quantitative study design was conducted to examine the preoperative factors associated with the development of severe postoperative pain. The study sample was collected from the electronic health records (EHR) of all surgical patients at the University of Miami Hospital from October 2014 through April 2015. The first four months of data (N=1,794) was abstracted from the EHR to test the measurement and structural model using structural equation modeling (SEM), and to develop a prediction tool utilizing the regression coefficients. Validation utilized an independent sample (n = 1961) to confirm the prediction tools ability to predict severe postoperative pain.

Preoperative predictors were gender, age, ethnicity, preoperative pain intensity, type of surgery, and baseline hemodynamic heart rate and blood pressure. Structural equation modeling (SEM) examined the factors to determine the relationship between the predictive variables and severe postoperative pain, a numerical rating scale (NRS) of ≥ 6.
Results from the initial analysis supported independent links between baseline heart rate, preoperative pain intensity, expected surgical pain (low, moderate, high, highest), age, female gender, and Hispanic ethnicity to severe postoperative pain on postoperative day one (POD 1). The discrimination for the final model was fair, based on the receiver operator characteristic (ROC) curve 0.714.

The validity of the prediction equation was determined through use of an independent validation dataset (n=1,961). Using a data-derived cutoff point of 0.20, obtained from the ROC curve, the predicted scores were compared to the reported scores of severe postoperative pain showing a sensitivity of 73.33% and a specificity of 74.40%. An additional cutoff pint of 0.14 was analyzed, which showed an improved sensitivity of 74.19% and a specificity of 57.33%.

The study further demonstrates that severe postoperative pain can be predicted through the use of a simple modified validated prediction equation. Utilization of separate cutoff points allows for the development of intervention strategies based on the need for a higher specificity versus higher specificity. The developed prediction equation provides a tool for clinically anticipating patients at risk for the development of severe postoperative pain on postoperative day 1. Future research is needed to show if preoperative measures and interventions based on the prediction equation improve postoperative pain management, and therefore decrease the incidence of severe postoperative pain.
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Chapter 1

Introduction

Pain is a complex multidimensional symptom of sensory and emotional experience influenced by physiological, psychological, and situational factors. The pathways for its perception, interpretation, and responses form a network of well-established connections across the entire pain pathway. The bio-psycho-social experience of pain depends on a neurobiological network of pain experiences meshed together at the cognitive, affective, and sensory levels with its perceived intensity dependent on the extent of tissue damage, the perceiver's psychological state, and the adaptive experience of the occurrence (Vallath, Salins, & Kumar, 2013). While subjectively, pain remains multifaceted, individual experience of pain is affected by such factors as emotional and cultural aspects. Physiologically, pain results in many responses in an attempt to preserve the body’s homeostasis by helping to protect the individual. This complex multidimensional acute nociceptive system is fundamental for survival (Staehelin Jensen, 2008).

In addition to being a symptom, pain is a disease itself that is associated with a wide range of injuries and other diseases. In some of these conditions pain is an associated symptom and in others pain is the primary problem in which millions of Americans suffer from every year. This results in pain becoming a significant public health problem (Steglitz, Buscemi, & Ferguson, 2012). Even though pain is an experience that is expected in life, unmanaged pain is still a problem in healthcare and one of the most common phenomena encountered by medical practitioners, pain affects more Americans than diabetes and cancer combined. It is estimated 76.5 million Americans, or
26% of the population, had a problem with pain that persisted for more than 24 hours in
duration (National Center for Health Statistics, 2006). According to the Institute of
Medicine of the National Academics’ report, the number of Americans who suffer from
pain is even higher at 100 million Americans (Steglitz et al., 2012). This is compared to
29.1 million Americans suffering from diabetes (Centers for Disease Control and
the United States, 2014) and 13.7 million American with a history of cancer (Siegel et al.,
2012). The significance of pain and the suffering endured during pain has risen to the
point pain is now considered the fifth vital sign (Berry & Dahl, 2000; Phillips, 2000).

Further data representing the demographics of pain, from the 1999-2002 National
Health and Nutrition Examination Survey, reports that adults age 45-64 were the most
likely to report pain lasting greater than 24 hours (30%) with adults age 20-44 next at
25%, followed by adults age 65 years and over at 21% (Pleis, Ward, & Lucas, 2010). The
survey found women reporting pain more often than men. Additionally, the survey
reported on race and ethnicity and found non-Hispanic white adults reported pain more
often than other races or ethnicities. With this recognition of the incident of pain and its
widespread under treatment a number of guidelines have been developed in response,
such as the American Society of Anesthesiologists (ASA) guidelines (American Society
of Anesthesiologists Task Force on Acute Pain Management, 2012) for acute pain
management and the American Pain Society's quality improvement guidelines (American
Pain Society Quality of Care Committee, 1995). Despite these guidelines pain is still a
healthcare problem plaguing patients.
Following surgery, pain is a common and sometimes severe complication experienced by many patients. This is highlighted in a 2003 US survey reporting 80% of patients experienced acute pain after surgery, and of those 86% experienced moderate, severe, or extreme pain (Apfelbaum, Chen, Mehta, & Gan, 2003). In the same survey, experiencing postoperative pain was the most common concern (59%) of patients. This failure to adequately manage postoperative pain is problematic for the patient resulting in both physiological and psychological implications, which can have a significant effect on a patient’s postoperative outcomes and quality of life.

Failure to manage postoperative pain can lead to a number of adverse outcomes and include (but are not limited to) pulmonary and thromboembolic complications. In some surgical procedures this can have disastrous consequences. For instance, pulmonary complications remain the most frequent adverse outcome after esophagectomy and lung resection contributing to prolonged length of stay, higher surgical mortality, and increased costs (Agostini et al., 2010; Ferguson, Celauro, & Prachand, 2011). Ferguson et al. (2011) showed major pulmonary complications occurred in 38% of patients presenting for esophagectomy and were associated with a 10-fold increase in operative mortality (2.5% vs. 28%). As highlighted by the research, the clinical impact of unmanaged pain is lasting and has a significant effect. Moreover, severe postoperative pain is one of the major causes of patient dissatisfaction, a key indicator of patient outcomes, following surgery. Not only is pain problematic to the patient but failure to manage pain is reported by the Institute of Medicine Report (IOM): Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research to cost society at least $560-$635 billion annually (Steglitz et al., 2012).
Although acute pain is an important experience informing us of injury and motivating the individual to rest and recuperate to speed recovery, unmanaged, it has been estimated to lead to persistent chronic pain in 10-50% of individuals following common surgeries (Kehlet, Jensen, & Woolf, 2006). This is corroborated by a recent study in the United Kingdom that estimates the incidence of chronic pain after common procedures at 10-50% (Jones, & Bari, 2014). Using total surgical operations performed in the United Kingdom and the United States in 1994, Macrae (2008) estimated best-case incidence figures of chronic pain at more than 41,000 cases in the UK and 394,000 cases in the USA each year. Worst-case estimates were as many as 103,000 in the UK and 1.5 million in the USA. Although incidences may vary from report to report, what is clear is that individuals are at an alarming risk for the development of chronic pain after surgery. In fact, several risk determinates for chronic or persistent postoperative pain have been identified. Of importance to this study is the association noted between a high intensity of acute postoperative pain and the subsequent development of chronic pain. (Bisgaard et al., 2001; Bisgaard, Rosenberg, & Kehlet, 2005; Poleshuck et al., 2006).

As the research suggests, unmanaged pain immediately during the postoperative period may contribute to the development of persistent chronic pain. Of special interest to this study, known predictors of acute pain are also identified in the literature as predictors of chronic pain. Two examples of common predictors are age and gender (Singh & Lewallen, 2009). This linkage between predictors of acute pain and chronic persistent postoperative pain further stresses the importance of conducting pain predictor research.

In 2005, the American Pain Society (APS) recognized high quality pain management to include screening for the presence of pain, appropriate assessment, and
frequent reassessment of patient responses to treatment (Gordon, Dahl, Miaskowski, & et al., 2005). The APA task force concluded that a structured approach to assessment of current practice must move beyond assessment and communication of pain to improvements in pain treatment. The recommendations specify that approaches should ensure prompt recognition and treatment of pain. Unfortunately when looking at the current literature, the majority of research available on postoperative pain has focused primarily on the recommendations of assessment and postoperative management strategies. Despite these recommendations by the APA task force, screening for the "presence of" or "predictors of" postoperative pain is the area lacking empirical research, even with evidence supporting many preoperative factors being associated with the development of both acute and chronic postoperative pain. Predicting patients at risk before a surgical intervention occurs would ensure prompt recognition of pain before it develops thereby allowing for early pain management treatment plans to improve postoperative pain management.

Only a handful of studies have focused on risk stratifying these predictors to determine individuals at risk of developing severe acute postoperative pain (Janssen et al., 2008; Kalkman et al., 2003) before the surgical insult even occurs. This is important because not only is pain unmanaged and prevalent, but pain is debilitating and life threatening. Research expanding the current understanding of predictors of severe postoperative pain is therefore critical to develop health care treatment plans and policy decisions to provide timely, cost effective, quality, and safe evidence-based care. Improved identification and improved guidelines ultimately facilitate improvements in the quality of pain management.
If researchers and clinicians lack an understanding of those individuals at risk of developing severe postoperative pain then individual specific interventions cannot be designed to help reduce and/or prevent the occurrence of severe postoperative pain. Surprisingly, researchers have estimated that only one in four surgical patients in the United States receive adequate acute pain management (Phillips, 2000). Despite the emphasis on pain being the fifth vital sign, postoperative pain continues to be undermanaged and both harmful to patients and costly to society. Ultimately, the under treatment of acute postoperative pain is an important health care issue.

**Background**

The background for this study includes the incidence of moderate to severe postoperative pain; the impact of postoperative pain on outcomes; and the impact postoperative pain has on patient satisfaction. This will form the basis for understanding postoperative pain as it relates to this study.

Under management of postoperative pain continues to exist even after numerous studies have documented inadequate postoperative pain management. The incidence of moderate to severe postoperative pain is reported to be as high as 25%-76% (Apfelbaum, Chen, Mehta, & Gan, 2003; Huang, Cunningham, Laurito, & Chen, 2001; Pavlin, Chen, & Penaloza, 2002; Rocchi, Chung, & Forte, 2002; Svensson, Sjostrom, & Haljamae, 2001).

Since 1999, in the United States the under treatment of acute pain has led to the development and recognition of the acute assessment of pain as the fifth vital sign (Berry & Dahl, 2000; Phillips, 2000). In fact, the appropriate assessment and management of pain is an important component of daily patient care and a key focus of healthcare
providers’ the world over. Despite the recognition of pain and the introduction of efforts to create new guidelines and standards, pain continues to be undermanaged.

While the treatment of acute postoperative pain remains troubled and inefficient, the causes might be multifactorial. In a multicounty survey of 746 European hospitals, the researchers found 34% of respondents had no on-site staff training protocols and only 25% have written postoperative pain management protocols (Benhamou et al., 2008). Surprisingly 34% of respondents said pain was not even assessed. These multifactorial issues raise numerous issues beyond the scope of this study. Although the goal should be adequate pain relief for all patients, emphasis on this study is the early identification of predictive risk factors contributing to the development of postoperative pain, not the specific treatments and management strategies.

Another contributing element to these multifactorial issues is the fact healthcare provider frequently cannot see or define pain and must use a number of factors to assess and manage pain. Currently there is no objective measurement of pain and self-report pain is the most valid measure of the individual’s experience of pain. The assessment of pain therefore relies predominately on these patient self-reports. This reactive approach relies on the patient to experience pain and report it to the healthcare provider for help in modifying the pain intensity.

Other contributing elements, in addition to patient reported factors, require consideration and include age, gender, and presence of preoperative pain. By expanding our understanding of the direct relationship these preoperative factors play in the occurrence of postoperative pain and preoperatively identifying these patients at-risk, researchers and clinicians can develop management strategies to aggressively treat these
at-risk individuals. Mitigating or eliminating these preoperative risks when possible should improve patient pain postoperative and therefore improve patient satisfaction.

**Impact of Postoperative Pain on Patient Outcomes**

Acute postoperative pain is a significant problem undermanaged in both outpatient and inpatient clinical practice, and causes both physiological and pathophysiological responses. Tissue trauma, a consequence of surgery, results in depolarization of nociceptors generating impulses leading to activation of the afferent pain pathways causing transition of pain from the site of injury via the peripheral nervous system to the central nervous system where the subjective perceived experience of pain occurs. The increased input of unmanaged postoperative nociceptive pain from surgical injury can lead to the development of neuronal hyperexcitability and central sensitization. Although a more detailed discussion is beyond the scope of this paper, the consequences have serious ramifications for critically ill individuals, which may lead to an increase in morbidity and mortality postoperatively.

In 2002, Pavlin, Chen, Penaloza, Polissar, and Buckley demonstrated the relevance of pain as a factor complicating the recovery and discharge of patients after ambulatory surgery. The researchers found nineteen percent of patients reported severe pain after surgery. Pain was the most common cause of Phase 1 recovery delays, affecting twenty-four percent of overall patients. In fact, pain was found to be a significant independent predictor of total recovery duration. Patients who did require analgesics were discharged 54 minutes later than patients who did not require analgesic therapy. A number of researcher studies showed that sufficient pain management regimes following surgery reduces morbidity, improves patient outcomes, and even reduces
As depicted in Figure 1, common observed physiological responses to tissue damage from surgery include, but are not limited to, central processing/cognitive changes, neurohumoral alterations, neural plasticity, sympathoadrenal activation, and neuroendocrine responses (Sinatra, Leon-Cassasola, Viscusi, & McQuay, 2013). These physiological responses lead to a number of effects on key organs. Examples in the heart include catecholamine release leading to an increase in heart rate, enhanced contractility, and increased afterload, all factors increasing oxygen demand. Increasing oxygen demand may place individuals at risk of myocardial ischemia, especially if they suffer from poorly controlled and compensated coronary artery disease. In the lung, postoperative pulmonary dysfunction can be life threatening and delay recovery. By having adequate pain control postoperatively, expansion of chest wall is enhanced to allow for deep breathing, improved coughing, and cooperation with physical therapy. In 1998, Ballantyne and colleagues showed improved pain control significantly decreases the incidence of pulmonary morbidity. Adequate postoperative pain management has been shown to provide positive long-term effects resulting in less cognitive impairment following surgery (Perkins & Kehlet, 2000).
Figure 1. Physiological responses to tissue injury. (Sinatra, Leon-Cassasola, Viscusi, & McQuay, 2013).

Impact of Postoperative Pain on Chronic Persistent Postoperative Pain

Pain can become debilitating when it persists despite the lack of disease/injury or following appropriate tissue healing. As previously commented on, the existence of severe postoperative pain may lead to the development of chronic pain (Bisgaard et al., 2001; Bisgaard, Rosenberg, & Kehlet, 2005; Poleshuck et al., 2006). This development of chronic pain is not only disabling but has significant negative effects on quality of life with substantial ramifications to both the family and society. Chronic pain is estimated to cost society $150 billion annually (United States Bureau of the Census, 1996). This includes both direct costs related to healthcare utilization and indirect costs related to
disability, loss of productivity, lost tax revenue, and out of pocket expenses. As previously reported, the Institute of Medicine (IOM) reported the costs to be estimated to cost society $560 to $635 billion annually (Steglitz et al., 2012). The development of chronic postoperative pain has a significant negative impact on the cost of healthcare but more importantly result in poorer outcomes for those suffering from the development of chronic postoperative pain.

Adequate postoperative pain management has been shown to enhance quality of life and reduce risk of chronic postoperative pain following surgery (Kehlet, Jensen, & Woolf, 2006; Gottschalk & Raja, 2004). Chronic pain is associated with the poorest health-related quality of life and has double the risk of death by suicide compared with other chronic diseases (Tang & Crane, 2006). Consequently, inadequate acute pain management places individuals at risk for developing chronic pain. In fact, the prevalence of chronic pain resulting specifically from surgery has been found in 10-50% of individuals following commonly performed surgeries and in 2-10% of individuals this pain can be severe (Kehlet, Jensen, & Woolf, 2006). This prevalence of chronic postsurgical pain is an alarming finding as chronic pain often causes more suffering or disability than the surgery.

There is a growing body of literature interested in determining the factors responsible for the transition of acute pain from developing into chronic intractable pain. Identifying of such causal risk factors is the first step in developing effective treatment strategies. The focus of this study addresses those causal factors leading to the development of acute severe postoperative pain. This is critical because all chronic pain was once acute pain. Improved postoperative pain management should theoretically
lessen the occurrence and development of chronic pain after surgery. By identifying predictors of acute pain to develop strategies for improved identification and management we are preceding the transition of postoperative pain from acute to chronic pain. Addressing those factors preceding the whole cascade of acute and chronic pain addresses the ongoing issue of poorly managed postoperative pain and the development of chronic intractable pain from the earliest possible stage, before the nociception has occurred. The transition of acute pain to chronic pain may be prevented or modulated through preoperative identification of factors predicting those at risk of developing severe postoperative pain and allowing for improved management strategies to tackle this prevalent problem.

**Physiological, Psychological, and Situational Factors**

A number of predictors of pain have been found and fall into the following three physiological, psychological, and situational factors. As outlined in the literature review, recent research has shown predictors of pain play roles in the development of both acute and chronic postsurgical pain. In fact, a number of physiological factors have been associated with postoperative pain which include preoperative pain (Bisgaard, Klarskov, Rosenberg, & Kehlet, 2001; Caumo et al., 2002; Kalkman et al., 2003; Mamie et al., 2004; Rudin, Wolner-Hanssen, Hellbom, & Werner, 2008; Taenzer, Melzack, & Jeans, 1986), type of surgery (Kalkman et al., 2003; Janssen et al., 2008; Ip et al., 2009), American Society of Anesthesiologists (ASA) physical status (Caumo et al., 2002; Kinjo et al., 2012), and baseline hemodynamic parameters (Logan, Sheffield, Lutgendorf, & Lang, 2002).
Similarly, psychological factors studied include anxiety, psychological distress, and coping strategies (Ip et al., 2009; Mamie et al., 2004; Roth, Tripp, Harrison, Sullivan, and Carson (2007) but due to conflicting research, these psychological factors will not be included in the final analysis. Situational factors also contributing to the development of postoperative pain and include age (Bisgaard, Klarskov, Rosenberg, & Kehlet, 2001; Caumo et al, 2002; Chung, Richie, & Sun, 1997; Gagliese, Gauthier, Macpherson, Jovellanos, & Chan, 2008; Kalkman et al., 2003; Kinjo, Sands, Lim, Paul, & Leung, 2012; Lau & Patil, 2004; Thomas et al., 1998; Tsirline et al., 2013; Voulgari et al., 1991), gender (Cepeda & Carr, 2003; De Cosmo et al, 2008; Gagliese et al., 2008; Janssen, 2008; Kinjo et al., 2012; Lau & Patil, 2004; Thomas et al., 1998; Tsirline et al., 2013), and ethnicity (Dahmani et al., 2001; Faucett et al., 1994).

Although chronic pain is not the focus of this study it is worth mentioning the prevalence of preoperative risk factors play an important role in the development of chronic postoperative pain. Consequently, Katz and Seltzer (2009) found the following surgical factors to be associated with a greater risk of developing chronic postsurgical pain: increased duration of surgery, low volume surgical unit, open approach, pericostal stitches for thoracotomy, conventional hernia repair and intraoperative nerve damage. Furthermore, they found the presence, intensity, or duration of pain preoperatively is a risk factor for the development of chronic postsurgical pain along with severity of acute postoperative pain (Katz & Seltzer, 2009).

**Impact of Postoperative Pain on Patient Satisfaction**

Provision of the highest quality of care is the aim of all healthcare organizations and healthcare providers. Traditionally outcomes are looked at in terms of morbidity and
mortality rates and reflect the overall effect of care on a patient. With the consequences of both healthcare organizations and healthcare providers being critiqued and judged based on these outcome statistics. Morbidity and mortality rates don't solely account for the patients’ perspective on healthcare, which is becoming central to healthcare delivery. Because of this, patient perspectives have gained increasing attention and have been measured using patient reported outcomes with one main area of patient perspectives being satisfaction with care. This involves a complex relationship affected by the patient, the doctor, and the service factors (Chow et al., 2009).

Consequently, patient satisfaction with care and improvement in health status are becoming important criteria for quality of care. The IOM, a recognized leader on improving healthcare, stresses level of patient satisfaction when considering quality of care. In fact, the Centers for Medicare & Medicaid Services (CMS), insurance providers, and hospitals are all striving to better define and measure quality of healthcare. Patient satisfaction, as a major component of quality, is becoming an important component of pay-for-performance metrics. The Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey is a national standardized survey of patients' perspective of hospital care (CMS, 2013). The three goals outlined by the HCAHPS survey are to produce data about patients' perspectives of care, create new incentives for hospital to improve care, and enhance accountability by providing transparency of quality of hospital care provided.

In looking at research specific to patient satisfaction and postoperative pain, adequate pain management following invasive procedures is considered a critical factor when evaluating the value of interventions provided (Carlson, 2008). Recently,

Even going back to 1996, research by Beck and Larrabee reported a correlation between patients achievement of their pain management goals with patient opinion of quality of care, resulting in a perceived higher perception of quality of care when pain management goals are met. These research results support that patient satisfaction and perception has become an important means for healthcare to measure success. As far back as 1999, research has shown that patients’ level of satisfaction with their hospital care directly correlates with their level of satisfaction with pain management (Calvin, Becker, Biering, & Grobe, 1999). These two older research articles highlight the fact that patient satisfaction is not a new concern despite it being a new focus of healthcare. As recently as this year, the American Academy of Pain Medicine (2014) reported postsurgical pain control is linked to patient satisfaction with hospital experience. Overall, the evidence supports the association between pain management and patient satisfaction.

Despite increasing pain research, surgical patients continue to experience moderate to severe postoperative pain. Newer research has highlighted preoperative predictors of postoperative pain but lack clinical application. The presented research study highlights the need for research examining not just factors predicting postoperative pain, but the modification and validation of a tool to identify those clinically at risk to improve both patient outcomes and overall satisfaction.
Conceptual Framework

Guiding the structure of this study is the Theory of Unpleasant Symptoms (see Figure 2, a middle-range nursing theory developed by Lenz, Suppe, Gift, Pugh, & Milligan (1995) and later revised by Lenz, Pugh, Milligan, Gift, and Suppe (1997). The Theory of Unpleasant Symptoms provides utility in examining preoperative predictors of severe postoperative pain. Prior research utilizing the Theory of Unpleasant Symptoms supports and provides rational for utilization of this framework to examine the factors or predictors leading to the symptom of postoperative pain, a common occurrence following surgery and will be discussed further in chapter two.

The Theory of Unpleasant Symptoms was proposed to explain that there are sufficient commonalities among symptoms and consists of three main components: the symptoms that the individual is experiencing, the influencing factors, and the consequences of the symptoms experience (Lenz et al, 1997). Symptoms can occur alone but more often, multiple symptoms occur together with the three components of this model, interact with, and influence one another, resulting in similar multi-dimensional experiences including intensity, timing, distress, and quality.

The focus of this study is on the predictive factors and the single symptom of postoperative pain, but not the consequences (performance) of the symptom. Therefore, a complicating factor in eliciting descriptions of pain is the differences in individual ability to discern symptoms and therefore an assumption of this study. For the purposes of this dissertation the final stage of the Theory of Unpleasant Symptoms is performance, the outcome of the patient’s symptom experience. As the focus of this study is on the
influencing factors, this stage of performance and the reciprocal effects performance has on the physiological, psychological, and situational factors will not be explored further.

Examples of the use of this theory in the literature include studies relating fatigue to chronic obstructive pulmonary disease (Reishtein, 2005), post-partum depression (Corwin, Brownstead, Barton, Heckard, & Morin, 2005), cancer (Redeker, Lev, & Ruggiero, 2000), and end stage renal disease (Liu, 2006; McCann & Boore, 2000).

Influential Factors

Influential factors are events that must occur prior to the occurrence of the concept being analyzed (Walker & Avant, 1995). With severe postoperative pain being the concept of analysis, surgery must occur prior to the occurrence of postoperative pain. Surgery leads to tissue damage and/or visceral distention causing activation of nociceptors resulting in nerve signals traveling to the spinal cord and brain and the unpleasant sensory and emotional and physiological experience that occurs. Influential factors are the events, which influence the occurrence of the concept. In this study, the antecedents are the influential factors in the conceptual framework, Theory of Unpleasant Symptoms.

In the conceptual framework of this study, there are three influential factors, the physiological factors, the psychological factors, and the situational factors that influence the symptom experience of severe postoperative pain following surgery will be studied. Physiological and situational factors directly influence severe postoperative pain but the psychological factors have been shown to indirectly influence severe postoperative pain through the existence of preoperative pain (Kinjo et al., 2012).

In addition, predictor studies of postoperative pain are multifactorial and it is possible these predictors interact with each other to produce symptoms of postoperative pain. Figure 3 depicts the theoretical framework and illustrates the potential for physiological, psychological, and situational factors to influence the experience of pain and symptoms. Theoretical linkage between physiological, psychological, and situational factors is distinctly supported using the theory of unpleasant symptoms (Lenz, Pugh, Milligan, Gift, & Suppe, 1997). It is hypothesized that the preoperative predictor
variables gender, age, race/ethnicity, baseline blood pressure and heart rate, preoperative pain, and type of surgery will influence and potentially interact to produce pain postoperatively. The Theory of Unpleasant Symptoms allows for multiple variables to influence the experience of postoperative pain. The predictor factors may play a direct or indirect role in the development on the symptom of interest, postoperative pain.

Examination of the theoretical model conceptual definitions poses some ambiguous boundaries highlighted by Cobb (2007). Social support is listed in both psychological and situational factors; nutrition is listed in both physiological and situational factors, among others. These ambiguities have resulted in the proposed model (see Figure 3), which was developed from the literature review findings on preoperative predictors of postoperative pain.

Figure 3. Model of Preoperative Predictors of Postoperative Pain Utilizing the Theory of Unpleasant Symptoms.
Symptom Experience

Symptoms are a central focus of the Theory of Unpleasant Symptoms and can be considered alone or in combination. The revised model reflects more interaction among the three components of symptoms, influencing factors, and outcomes (Lenz, Pugh, Milligan, Gift, & Suppe, 1997). Each symptom is conceptualized to be a multidimensional experience to include intensity, timing, distress, and quality.

Even though the present study focuses on the single dimension of postoperative pain, pain is still a multi-dimensional experience that includes intensity, timing, distress, and quality. For the purpose of this study symptom experience will be defined as postoperative pain following tissue injury. Symptom experience will focus on the intensity of postoperative pain, a common mode of assessing and measuring the existence of postoperative pain.

Definitions

Nociception is defined as the detection of tissue damage by transducers in the skin and other tissues and the propagation of this sensory information to the central nervous system via A-delta and C fibers in the peripheral nerves.

Pain is the perception of nociceptors signals and is defined as an unpleasant sensory and emotional experience that is a personal, subjective experience that varies in intensity. It is both a physiological sensation and an emotional reaction to the nociceptor sensation. For the purpose of this thesis, severe postoperative pain will follow the ASA practice guidelines (American Society of Anesthesiologists Task Force on Acute Pain Management, 2012) definition and will be conceptualized as pain occurring following a surgical intervention. Measurement will consist of the numerical rating system (NRS), a
common clinically utilized tool for rating postoperative pain. The severity of pain will be studied as a continuous variable but categorized into mild (NRS = 0-3), moderate (NRS = 4-5), and severe pain (≥6) for describing both the preoperative and postoperative measurements of pain to remain consistent with the literature. Pain classification depends on the intensity, timing, distress level, and quality of the symptom.

**Chronic pain** is the persistence of pain 3-6 months beyond the expected period of healing.

**Difference between pain and suffering.** Pain is a sensation followed by a reaction while suffering is a more global encompassing concept or negative feeling that mars the individuals’ quality of life. Pain may be an expression of suffering but suffering is not an expression of pain.

**Intensity** refers to the dimension of pain rated by the individual in regards to strength, severity of pain, and amount of pain experienced based on the numerical rating system.

**Timing** refers to the frequency and duration in which pain occurs.

**Distress level** refers to the degree pain bothers or distresses the individual. This dimension that most influences the individual to seek amelioration of pain.

**Postoperative pain** is pain occurring following actual or potential tissue damage occurring from surgical intervention. Measurement and severity will be measured and categorized in the same format as that of pain.

**Analgesia** is the easing or absence of painful sensation despite the presence of normally painful stimulus.
**Physiological Factors** include normally functioning bodily systems, the existence of pathology, and the occurrence of tissue trauma from surgery. Physiological factors include preoperative pain, type of surgery, American Society of Anesthesiologists physical (ASA) status, and hemodynamic parameters.

**Psychological Factors** include the individuals’ mental state, mood and affective reaction. Despite the potential benefit of utilizing psychological factors, there is a great potential for a confounding association between psychological factors and preoperative factors to influence patient experiences of pain postoperatively. Research shows anxiety and depression are both indirect predictors of severe postoperative pain, not direct predictors of preoperative pain (Kinjo, Sands, Lim, Paul, & Leung, 2011). For the purposes of this study the psychological factors were not included as they are not direct predictors of severe postoperative pain.

**Situational Factors** include aspects of the social and physical environment that may affect the individuals experience and reporting of postoperative pain. Situational factors for this study include age, female gender, and race/ethnicity.

**Postoperative recovery period** refers to the immediate postoperative period of time following surgery required for the full recovery from anesthesia. For the purpose of this study, the postoperative recovery period will be considered the first hour after surgery.

**First 24 hours** refers to the period of time following discharge from the Post Anesthesia Care Unit (PACU) up to but not exceeding 24 hours following surgery.
Assumptions

The following will be considered assumptions in this research study:

1. There are commonalities across symptoms experienced by individuals and physiological, psychological, and situational factors influence the development of severe postoperative pain.

2. We can understand the meaning of experiences through communication, which may include facial expression, gestures and written or verbal expression (Gadamer, 1994; Polkinghorne, 1983).

3. Symptoms are individual subjective phenomenon and eliciting descriptions of pain is the differences in individual ability to discern symptoms.

Study Purpose

Although several risk factors have been determined, the interaction and independencies of these factors remain to be fully explained. As reported by Kalkman et al. (2003), it would be desirable to preoperatively determine those patients at risk for developing severe postoperative pain thereby improving pain management strategies.

The purpose of this study is to expand on earlier research in an attempt to further explain and identify those individuals at risk by examining the relationship of the predictor factors on the development of severe postoperative pain through the use of a tool to risk stratify the predictors. Previous studies have indicated the preoperative predictors gender, age, race/ethnicity, preoperative pain, type of surgery, and baseline hemodynamic parameters are correlated with severe postoperative pain. A thorough examination of these reported predictors is described and outlined thoroughly in the literature review.
This study will assess the modification and validation of a postoperative pain prediction tool (PPPT) first developed by Kalkman et al. (2003) to preoperatively predict the risk of severe pain in the first hour postoperatively. This prediction tool was later modified by Janssen et al. (2008) to enhance prediction in outpatients thereby identifying those individual at risk of developing severe postoperative pain. Both of these studies were carried out in Europe and contain predictors not commonly assessed in clinical practice in the United States.

Modifying these postoperative pain prediction tools with predictors that can be easily determined in the preoperative setting and applicable to existing clinical practice here in the United States will allow for improved assessment and management of patients suffering from poorly managed postoperative pain thereby leading to improved patient outcomes and patient satisfaction. The development of routine preoperative risk screening of all patients may help ensure that pain is recognized, documented, and promptly treated as outlined by the American Pain Society guidelines (Gordon, Dahl, Miaskowski, & et al., 2005).

Ultimately, identification of those individuals at risk preoperatively of developing severe postoperative pain allows for development and optimization of pain management strategies. In chapter 2, the major concepts of the theoretical model are introduced along with the key variables or predictor factors, each of which will be discussed in depth in the following chapter. The literature review is discussed sequentially by each physiological, psychological, and situational latent variable.
Primary Aims

1. Assess the relationship, as depicted by the modified model for the theory of unpleasant symptoms, between preoperative predictors and the development of severe postoperative pain.

2. Use results from AIM 1 to develop and modify a prediction tool for clinical practice.

Research Questions

1. Is there a significant relationship between preoperative predictors and the development of severe postoperative pain?
   a. What is the relationship between physiological factors and the development of severe postoperative pain?
   b. What is the relationship between situational factors and the development of severe postoperative pain?
   c. What is the relationship between both the physiological and situational factors on the development of severe postoperative pain?

2. To what extent do physiological and situational factors predict the severe postoperative pain?

Significance to Nursing

The current assessment of acute postoperative pain is through the use of self-reports of pain utilizing pain measurement tools. Although efforts have been made into refining self-report methodologies, there continues to be a number of biases and require an ability of the individual to communicate. Generally, most self-reporting measurement tools focus on intensity of postoperative pain over a brief period of time.
To improve postoperative pain outcomes one must first be able to assess for its occurrence.

The implementation of a prediction tool into the current clinical evaluation of pain has the potential to gain insight into factors of causation. It is helpful to consider mechanisms responsible for pain and how these mechanisms fit into the production of pain. Identification of mechanisms has been established in the literature but implementation of a tool for measuring and risk stratifying individuals at risk is lacking in clinical practice. A more comprehensive approach that identifies or categorizes individuals at risk has potential significance in aiding and improving the assessment and management of postoperative pain and be an invaluable diagnostic tool.

In light of the poor management of postoperative pain and abundance of research linking the impact of physiological, psychological, and situational factors on postoperative pain, there is a need for validating a tool to risk stratify these predictors for improved identification and management of those individuals at risk. Using the middle-range nursing theory of unpleasant symptoms (Lenz et al., 1997) provides a framework for exploring the preoperative factors in predicting postoperative pain and further tests the theoretical framework in the setting of postoperative pain.
Chapter 2

Review of The Literature

In this chapter the key physiological, psychological, and situational variables are discussed in depth as they relate to postoperative pain. In order to examine the literature surrounding the predictors of postoperative pain, three major areas of the literature will be examined. The first section focuses on a more detailed look at the Theory of Unpleasant Symptom literature. Section two will look at pain predictor studies, followed by section three addressing the specific predictors of postoperative pain. This is not intended as an exhaustive review; it provides a key to understanding the contribution of each of the variables related to the overall model of predictors in the occurrence of severe postoperative pain.

Theory of Unpleasant Symptoms

As mentioned in the previous chapter, the choice of using the Theory of Unpleasant Symptoms as a theoretical framework for this study emerged as consequence of seeking a reasonable and credible model to explain the results of this research study. According to Lenz et al. (1995, 1997), the theory of unpleasant symptoms potentially integrates existing information about a variety of symptoms (Lenz et al., 1995; Lenz et al., 1997). With symptoms as the central focus, the study of postoperative pain is ideally suited to utilization of this model. In order to focus on the influencing factors or predictors and the effect on postoperative pain, the model was revised for this research study.

A review of the literature revealed a number of studies utilizing the Theory of Unpleasant Symptoms as a theoretical framework. A majority of the studies focus on the
symptom and performance aspect as opposed to the influencing factors. For the purposes of this study the focus is exclusively on the symptom of postoperative pain and its influencing factors. Consideration will be given to studies focusing on influencing factors and symptoms with little consideration to studies focusing on the performance aspect of the model.

One key feature of the Theory of Unpleasant Symptoms is the antecedent physiological, psychological, and situational factors which all influence the symptom experience, in this case postoperative pain. No reported studies focusing on these antecedent factors specific to the Theory of Unpleasant Symptoms and their effects on postoperative pain was found in the literature. Despite this, one study found in the literature did focus on the contributions of situational, psychological, and physiological factors of sleep quality in women experiencing intimate partner violence (Woods, Kozachik, & Hall, 2010). Although the current study focuses on a different symptom, the study by Wood et al. (2010) highlights how the theory makes theoretical sense in studying predictors for the occurrence of severe postoperative pain. By adapting the Theory of Unpleasant Symptoms, the researchers were able to identify pivotal physiological, psychological, and situational factors regarding their effects on sleep quality. Undergoing a similar adaptation of the Theory of Unpleasant Symptoms will be used to help explain the findings of this study.

**Preliminary Studies**

The preliminary studies testing the Theory of Unpleasant Symptoms are discussed to explore the relationships between the variables and provide further theoretical explanation for this study. The research will be explored starting with general research
about research design, the influencing factors, research utilizing the specific symptom of pain, and lastly research specific to research testing the Theory of Unpleasant Symptoms via structural equation modeling.

**Retrospective study design.** Gift, Stommel, Jablonski, and Given (2003) utilized the Theory of Unpleasant Symptoms to guide the formation of research questions and to select variables for study in a retrospective study of lung cancer patients. The research is worth mentioning for its utilization of the Theory of Unpleasant Symptoms in a retrospective study. The research serves to help guide the current research as the current research intends to retrospectively look at predictors of postoperative pain, presently collected in clinical practice.

**Influencing/predicting factors.** Recently Eckhardt et al. (2014) used the Theory of Unpleasant Symptoms to study fatigue in patients with coronary heart disease. In the researchers’ application of the theory, co-morbid conditions, hypertension, diabetes, and medications were categorized as physiological factors; depressed mood was categorized as psychological factors; age, gender, income, and education were categorized as situational factors influencing the symptom of fatigue. The results further our understanding of the symptom of fatigue in patients with coronary heart disease and help establish precedence for utilization of age and gender as situational factors in the current study. This is an important factor in studying predictors of severe postoperative pain as age and gender have been shown to be predictive of severe postoperative pain.

Woods et al. (2010) study of subjective sleep quality in women experiencing intimate partner violence underscores the Theory of Unpleasant Symptoms ability in application as a theoretical model in studying the antecedents, predictors, or influencing
factors contributing to the development of symptoms experienced by individuals. In the study the researchers adapted the model from its full form to exclude the performance outcomes. Utilizing the adapted model, the researchers studied the situational factors, psychological, and physiological factors to show a relationship between the influencing factors and sleep quality. The study provides a foundation for the current research proposal, which theorizes to adapt the full Theory of Unpleasant Model to also exclude the performance outcomes. The study utilized a covariance structure analysis and tested alternate models that incorporated alternate variables and scales to derive the final model. The researchers study provides a similar format to guide the current research in formulating an adapted model from the Theory of Unpleasant Symptoms.

Symptom of pain. Starting with literature utilizing the theory in studying the symptom of pain, Wilson (2013) evaluated a Pain Target Program as compared to patient satisfaction in hospitalized post-surgical patients with acute pain. Although the researcher was unable to show a direct correlation between the Pain Target Program and patient satisfaction, the Theory of Unpleasant Symptoms was found to be an appropriate theoretical framework for the study of acute postoperative pain (Wilson, 2013). This finding adds credibility to the utilization of the Theory of Unpleasant Symptoms for studying predictors of severe postoperative pain. Addition research conducted by Huth and Broome (2007), described home outcomes of pain, medication use, fluid intake, and emesis twenty-four hours after tonsillectomy and adenoidectomy utilizing the Theory of Unpleasant Symptoms as the research framework. The symptoms were theorized to be affected by the type of surgery, the child’s anxiety level, and the pharmacological intervention administered by the caregiver. The study illustrates and provides preliminary
evidence on the development of moderate to severe postoperative pain levels at home. Although unrelated to the current proposed research, the study conducted by Huth and Broome (2007) does conceptualize similar indicators of the symptom of postoperative pain.

Using the Theory of Unpleasant Symptoms, Motl and McAuley (2009) examined the symptom cluster of fatigue, pain, and depression, and its direct and indirect association with physical activity behavior in a sample of patients with multiple sclerosis. Results indicated that the symptom cluster of fatigue, pain, and depression had a moderate and negative predictive relationship with physical activity behavior. The researchers findings are consistent with the Theory of Unpleasant Symptoms and extend previous research utilizing the model. The results have implications for follow up research addressing a cluster of symptoms focused approach to address the dimensions of symptoms following surgery in addition to postoperative pain. The present study focuses on the single dimension of postoperative pain, as opposed to a multidimensional cluster of symptoms, and the impact the influencing factors has on predicting its occurrence.

**Structural equation modeling.** In a study by So et al. (2013), the researchers adopted the theory of unpleasant symptoms to examine the relationship between the components of social support, prevalent symptoms, and health-related quality of life experienced by breast cancer patients. Social support was incorporated into the domain of the situational factor, prevalent symptoms into the domain of symptoms, and health-related quality of life into the domain of consequences of symptoms. The study illustrated the association of social support, a situational factor, has on relieving symptoms and its impact on consequences of symptoms. Specifically to influencing factors, the study
illustrates the utilization of the Theory of Unpleasant Symptoms in studying predictors and the direct and indirect impact they have on symptoms and consequences. Furthermore, the researchers’ adoption of the theory to develop a structural equation modeling (SEM) method of analysis provides further empirical evidence and theoretical plausibility to support the utilization of the Theory of Unpleasant Symptoms to determine multiple models predicting the development of severe postoperative pain to determine the direct impacts the indicator factors have on symptom of postoperative pain.

Ultimately the goal of the research proposal it the validation and implementation of a risk stratification tool for identifying preoperatively patients at risk for the development of severe postoperative pain. Tyler and Pugh’s (2009) case report represents empirical support for utilization of the Theory of Unpleasant symptoms into clinical practice. Application of the theory was utilized in a case report of a patient undergoing bariatric surgery (Tyler & Pugh, 2009) that examined all three domains of the model. Although not empirically tested, the case report does provide an example of the theory utilization to provide a clearer understanding of the patient’s symptoms, how the symptoms interact with one another, and how they are affected by physiological, psychological, and situational factors. Of importance to this research study, the patients’ situational factors were described as contributing a great deal to the patients’ unpleasant symptoms. The application of the theoretical model in clinical practice adds explanation of the practical utilization of the developed risk stratification tool, developed in this research study, into clinical practice.

It should be noted the current research study is not intended to test the Theory of Unpleasant Symptoms but utilizes the propositions to conceptualize the symptom of
postoperative pain and examine those influencing factors, which predict the development of severe postoperative pain for validation of a predictive tool for clinical practice.

**Studies of Pain Predictors**

Pain is a serious consequence of injury. It is a complex phenomenon influenced by physiological, psychological, and situational factors not simply a sensory experience arising from stimulation of pain receptors. The following literature highlights empirical findings specific to predictor research looking at the development of pain. This section of the literature review is an attempt to explore the pain predictor factors to help outline the current study, which looks at a specific type of pain, postoperative pain. The risk factors in this review include studies looking at physiological, psychological, and situational factors as they pertain to pain. Literature predicting pain in general may identify predictors and predictor characteristics that are also relevant to postoperative pain.

**Physiological Factors**

Pain research has begun to pinpoint many mechanisms that underlie many clinical pain states. Studies have shown a cascade of neurobiological events that provide as a warning role in acute pain states. Physiological factors related to pain in general will be outlined to search for evidence of factors contributing to pain. Type of surgery and ASA physical status classification system will not be covered in this section, as this is specific to surgery and will be covered under the next section reviewing predictors of postoperative pain.

First, pain is influenced by a combined set of brain regions: thalamus; mid/rostral anterior cingulate cortex; primary and secondary somatosensory cortex; anterior, mid, and posterior divisions of the insular cortex; dorsal, mid, and ventral prefrontal cortices;
and brainstem nuclei and parts of the basal ganglia and is referred to as a "pain matrix" (Tracy, 2011). Other areas such as the amygdala, hippocampus, and cerebellum can also be activated, dependent on the mood, cognitive state, and context to produce altered experiences (Tracey & Dickenson, 2012). Under normal conditions there is a delicate balance between these excitatory and inhibitory systems. In neuropathic or inflammatory conditions this balance may be shifted towards a reduced or increased facilitation from the brainstem (Staehelin Jensen, 2008).

Adding further complexity to the equation is the role cortisol plays, the primary hormone produced by the adrenal cortex, as a central role of the stress response. Adrenocortical activity and sympathetic activity are primary effectors of the stress response and may be involved in modulating pain. In patients with hypertension, an association between higher blood pressure and a reduced pain sensitivity has been established (Al’ Absi, Petersen, & Wittmers, 2000; Falcone, Auguadro, Sconocchia, & Angoli, 1997; Ghione, 1996). Evidence points to a role of the baroreflex system in modulating nociception. In 2002, Al’ Absi, Petersen, and Wittmers studied pain perception in men and women using cold pressure testing to study adrenocortical and hemodynamic predictors. Findings show a significant relationship between cortisol levels in men but not in women on the average pain rating measured during cold pressure testing. Results show further evidence of cortisol changes to painful stimuli. Furthermore, a relationship between blood pressure (BP) and heart rate and pain perception has been established which shows a negative association between cortisol levels and pain perception in men and a positive association between BP and pain in women. These differences demonstrate different physiological predictors of pain by gender.
**Psychological Factors**

The interaction of psychological variables and pain is relatively complex. Numerous studies have shown a strong association between pain and psychological factors (Dersh, Polatin, & Gatchel, 2002). Patients suffering from psychological factors of depression and anxiety tend to have more complaints of pain and greater impaired functioning, while numerous episodes of pain, diffuse pain, increased pain are all associated with severity of depression and anxiety (Bair, Wu, Damush, Sutherland, & Kroenke, 2008). Patients with coexisting pain, depression, and anxiety experienced more severe pain and greater pain interference from activities compared to patients with pain alone. Additional empirical evidence has established persistent pain is significantly association with depression and anxiety (Huyser, 1999; McWilliams, Cox, & Enns, 2003; Wilson, Mikail, D’Eon, & Minns, 2001). Furthermore, Von Korff, Dworkin, Le Resche, and Kruger (1988) established that depression and pain concurrently have a greater effect than either variable alone. This evidence outlines the very complex nature of the interaction psychological variables play in pain.

**Negative Affective States.** A well-documented reciprocal relationship exists between negative affective states and pain that is mediated through the amygdala. In fact, the amygdala can enhance and inhibit pain processing. Pain also enhances amygdala activity. Persistent pain states causes electrophysiological, pharmacological, and biochemical neuroplastic changes (Neugebauer, Li, Bird, & Han, 2004). The researchers identified the following areas requiring further analysis: the effects of a heightened level of amygdala activity regarding both the pain-enhancing and pain-inhibiting systems and the negative affective-states effect on pain processing. This is illustrated in Figure 4.
below showing a hypothetical model of interaction between increased amygdala activity with negative affective states, pain, and pain responses.

Figure 4. The Amygdala and Persistent Pain. (Neugebauer, Li, Bird, & Han, 2004).

Adding further complexity, the psychological variables of anxiety and depression commonly co-exist (Bair et al., 2008). This is corroborated by research conducted by Mergl et al. (2007), who postulated that the nature of depression and anxiety may be a common pathology and not independent of one another. The results of the Mergl et al. (2007) study show depression alone without comorbidity (anxiety/somatoform disorder) occurred significantly less often and the comorbidity of depression with anxiety or somatoform disorder was associated with a high odds ratio (6.25). Not only is there evidence supporting the interaction between psychological factors and pain but common psychological factors may not be independent factors at all.

**Commonalities of depression and pain.** Research is also shedding light on the commonalities of depression and pain. Depression is a result of a neurochemical imbalance or deficiency of key neurotransmitters. With depletion of neurochemicals the
transmission system for nociceptive messages may lose its modulation effect so that minor signals are amplified (Bair, Robinson, Katon, and Kroenke, 2003). A common theory holds that depression and pain follow the same descending pathway in the central nervous system. Brain regions involved in emotions send many projections to brainstem structures involved in the descending pain modulation system, a system that regulates nociceptive processing (Tracey & Dickenson, 2012). Some researchers label the interaction as the depression-pain syndrome (Lindsay, 1982), implying the conditions coexist and share commonalities.

Research by Lindsay (1982) with 300 patients who suffered from chronic pain, found 87% met the criteria for depression. In a literature review conducted by Bair et al. (2003), the authors found several studies addressing how the risk of depression increases as a function of worsening pain, therefore showing an association between depression and pain (Kroenke & Price, 1993; Magni, Marchetti, Moreschi, Merskey, & Luchini, 1993; Von Korff et al., 1988).

In a study of patients with major depressive disorder, Maneeton, Maneeton, and Srisurapanont (2013) found pain and depression to be highly correlated. Individuals with major depressive disorder were found to have more prevalence of pain, severity of pain, and number of locations when compared to general patients. Furthermore, somatic symptoms of depression are common among people with pain, and their occurrence is often attributed directly to the experience of pain. In 2001, Wilson et al. found if these symptoms are excluded from the diagnosis of major depressive disorder, it results in a marked reduction in the number of patients diagnosed. This is important because pain itself is associated with a number of somatic symptoms, some of which may overlap with
somatic symptoms of depression. In a review of 83 studies this was shown to create difficulties in accuracy for the definitive diagnosis of depression (Fishbain, Cutler, Rosomoff, & Rosomoff, 1997).

**Pain catastrophizing.** Pain catastrophizing was introduced by Ellis in 1962 and since then has been associated with a number of pain related outcomes. Pain related catastrophizing in a broad sense is conceptualized as a negative mental set or cognitive-affective response towards anticipated or actual pain. It is conceived as a set of exaggerated and negative cognitive and emotional schema characterized by the tendency to magnify the threat of the pain stimulus and feel helpless with a relative inability to inhibit pain related thoughts (Quartana, Campbell, & Edwards, 2009). Pain catastrophizing is most typically used to conceptualize and assess trait-like variables.

In 2011, Forsythe at al. studied sex differences in 155 college students to look at gender and ethnic differences and experimental pain outcomes. The researchers found threat/harm and challenge appraisals both play a unique and important role in the pain experience. Threat/harm appraisal was found to be inversely related to pain tolerance and challenge appraisal was found to be positively related to pain tolerance. Furthermore, pain catastrophizing, a negative mental set towards pain (Sullivan et al., 2001), was positively related to both pain intensity and pain unpleasantness. Interestingly, pain catastrophizing partially mediated race differences in pain tolerance and mediated gender differences in pain intensity. Of note, pain related cognition was found by the researchers to be more important than gender and ethnicity in predicting experimental pain variables. These results suggest cognitive factors are associated with coping.
Experimental and clinical research has shown catastrophizing to be significantly correlated to state and trait anxiety, depression, fear of pain, and coping effectiveness raising questions of confounded measurement and construct redundancy. Sullivan et al. (2001) raised concerns on the magnitude of correlations among measures of state and trait anxiety, depression, fear of pain, and coping effectiveness to question their conceptual and operational distinctiveness. Despite the researchers concern, research has consistently shown catastrophizing to be associated with a heightened pain in both experimental and clinical studies in both adults and children (Sullivan et al., 2001).

The problem of assessing psychological factors in relation to predicting pain is the concern that they share a common vulnerability. This is shown in a path analysis performed by Kinjo et al. (2012) where the researchers found the psychological factors studied directly correlated with preoperative pain not the intended outcome of this study, postoperative pain. Furthermore, assessing catastrophizing may be a more appropriate predictor of pain than depression or anxiety. In fact, catastrophizing may activate "pain schema" guiding influences on cognition leading to increased pain experiences. A study by Ploghaus et al. (1999), using magnetic resonance imaging of the brain, found evidence of experience-based changes in neural signal patterns. This is further evidence showing catastrophizing to be a marker of increased pain experiences.

The psychological factors inter-relationship and interplay with the physiological process that underlies pain continues to create controversy on the association with heightened pain experiences. A study by Bandura et al. (1987) provided evidence of an association between psychological factors and endogenous opioids. The researchers found administering naloxone interfered with enhancing effects of cognitive strategies.
The findings add further evidence to suggest catastrophizing may be linked to actions of endogenous opioids. Adding further confusion are the results found by Frew and Drummond (2007) implying that Hyperalgesia response to psychological distress was tempered by opioid release.

Somatic symptoms of depression are common among people with chronic pain, and their occurrence is often attributed directly to the experience of pain-related discomfort. Interestingly, if these symptoms are excluded from the diagnosis of major depressive disorder, it results in a marked reduction in the number of major depressive disorder diagnoses.

Unfortunately, the above evidence questions the conceptualized idea that catastrophizing is a negative mental set or cognitive-affective response towards anticipated or actual pain, further raising the concern of utilizing pain catastrophizing as an independent direct predictor of postoperative pain separate and distinct from preoperative pain.

**Situational Factors**

Situational factors explored, which predict pain, include age, gender, and race/ethnicity. This section reviews general research related to these mentioned situational factors and pain in general with postoperative specific situational factors explored in more depth later on. Specific to age, all research reviewed pertains to adults only.

**Age.** There appears to be an age factor when it comes to pain perception in adults. Early research by Woodrow et al. (1975) found on average pain tolerance decreased with age. Results reported by Walsh, Schoenfeld, Ramamurthy, and Hoffman (1989) are
consistent with the Woodrow et al. (1975) report. In the study, the researchers applied a cold pressure test by immersion of a limb in cold water to elicit a pain experience and found an increase in pain sensitivity and a decrease in pain tolerance with increased age. Interestingly when looking at gender, the research showed a consistent decrease in tolerance time as males’ age increased but minimum change in tolerance time was noted as female age increased. This is contrary to research presented below specific to gender differences but may reflect age related gender differences. Unfortunately, a lack of research was found addressing this specific phenomenon.

Using questionnaires, Soares, Sundin, and Grossi (2003) analyzed associations between different pain variables in individuals between the ages of twenty to sixty five plus. Although older individuals had longer duration of pain, younger individuals had more severe pain. More recently, older age was one of seven factors predicting pain severity at 3 months following serious injury (Holmes et al., 2010).

Although research specific to the mechanisms causing a decreased sensitivity to pain in older individuals is lacking, research looking at neurochemical changes in adults have been associated with natural aging. For instance, neurochemical changes in the various proteins within the central auditory system have been shown to be associated with aging (Gray, Engle, & Recanzone, 2014). This seems a plausible explanation for age related changes but like most aspects of pain, a more multifactorial explanation is probably closer to the truth. Overall, there appears older and younger individuals experience pain differently with a tendency for younger individuals to experience more intense pain or an increased sensitive to pain.
Gender. Considerable evidence indicates gender related differences have been consistently described in the literature in response to painful stimuli, pain experiences, and pain responses. Specifically, women are more prone to being sensitive to both experimental pain and experiencing clinical pain (Valeberg, 2008) and report significantly higher pain intensity than men (Forsythe, Thorn, Day, & Shelby, 2011; Sheffield, Biles, Orom, Maixner, & Sheps, 2000; Unruh, Ritchie, & Merskey, 1999). Although there were no significant gender differences in location or type of pain, women tended to report more physical symptoms associated with pain (Sheffield et al., 2000). In most studies reviewed by Unruh (1996), women report more severe levels of pain intensity, more frequent pain and pain of longer duration than do men.

A review conducted by Fillingim, and Ness (2000) focused on gender-related influences on pain and analgesic responses and found prevailing support the presence of gender-related hormones influence nociceptive processing. Earlier meta-analyses conducted by Riley III, Robinson, Wise, Myers, and Fillingim (1998) indicate a moderate to large effect sizes for sex differences in pain responses to experimental induced pain and only a small to moderate effect sizes when studies focused on menstrual cycle effects (Riley III, Robinson, Wise, & Price, 1999).

Interestingly, when looking at the Mu-opioid receptors, variations in Mu-opioid receptors levels appear to differ between men and women. Smith et al. (2006) found an association between high-estrogen state and an increase in regional and baseline Mu-opioid receptor availability with greater endogenous opioid neurotransmission activation during pain. Although also similar in males, during low-estrogen states found in women, significant reduction in endogenous opioid tone was associated with a hyperalgesia
response (Smith et al., 2006). These findings establish the significant role estrogen plays in modulating opioid neurotransmission and the associated psychophysical responses to a pain experience. This is corroborated by earlier work by Zubieta et al. (2002).

Review of literature measuring pain perception and intensity found the following differences in gender. Forsythe et al. (2011) found males demonstrated lower pain intensity, longer pain tolerance, and higher challenge appraisal. Challenge appraisal, a 16-item measure designed to assess threat/harm and challenge, was positively related to pain tolerance (Forsythe et al., 2011). Sheffield et al. (2000) measured pain perception using an evaluation of pain intensity and pain unpleasantness to a series of thermal stimuli and found women showed a tendency to rate the stimulus as more unpleasant and more intense than men. The researchers concluded differences in gender pain perceptions might be related to differences in opioid activity and baroreceptor-regulated pain receptors. This follows along results by Cepeda and Carr (2003) concluding that women have more intense pain and require 30% more morphine to achieve a similar degree of analgesia compared with men.

In general, the research suggests that there are important gender differences in pain susceptibility and perception. Interestingly, a difference in neurochemical physiology appears to be present. This may contribute to differences in not only the presence of pain but also the management strategies employed to deal with pain.

**Race/Ethnicity.** Several studies have shown race and/or ethnicity differences in pain perception. In 1972, Woodrow et al. reported significantly lower pressure pain tolerances among African-Americans compared to non-Hispanic Caucasians, in a sample of over 40,000 subjects. Walsh et al. (1989) reported findings of higher cold pressure
pain tolerance among non-Hispanic Caucasians compared to a group of African-Americans and Hispanics. Findings from these two older studies are consistent with each other and suggest greater experimental pain sensitivity among African-Americans than non-Hispanic Caucasians.

In more recent years, additional findings further suggesting ethnic differences in pain perception has been reported. Sheffield et al. (2000) reported marginally higher ratings of pain intensity and significantly higher ratings of thermal pain unpleasantness among African-Americans compared to non-Hispanic Caucasians. Edwards, Doleys, Fillingim, and Lowery (2001) reported African-Americans had higher levels of clinical pain as well as greater pain related disabilities than white research participants. Most recently, in the 2011 Forsythe et al. study of college students, the researchers also looked at race differences and found African-Americans demonstrated lower pain tolerance compared to white Americans.

Collectively these research findings support the association of ethnic differences in reported clinical pain. The results suggest African-Americans may be associated with enhanced sensitivity to noxious stimuli as shown by higher pain intensity and lower pain tolerance compared to non-Hispanic Caucasians.

Summary of Pain Predictors

The studies of pain predictors found the important situational factors age, gender, and race/ethnicity differences exist in relation to different pain experiences. Along with these factors, the physiological factors of blood pressure and heart rate seem to be associated with pain and more importantly predicting pain. Psychological factors encountered in the literature include anxiety, depression, and pain catastrophizing.
Although pain control using psychological interventions is well established, the mechanism by which psychological factors enhance pain is less well understood. Bandura et al. (1987) provided evidence of an association between psychological factors and endogenous opioids. Moreover, work by Tracy (2011) highlighted how baseline fluctuations in neural activity determine whether pain experiences arise from noxious stimulation. Although, psychological factors could influence the perception of pain, psychological factors could likewise arise from ineffective regulation of nociception.

The clinical implications of the relationship between psychological factors and pain is noteworthy, unfortunately it is still not readily apparent why psychological factors contribute to pain experiences. Interestingly, catastrophizing may mediate the relationship between psychological factors and pain and may be a potential tool for future interventional strategies geared at managing predictive factors preoperatively before the nociceptive stimuli.

**Studies of Postoperative Pain Predictors**

A review of the literature was conducted to identify the physiological, psychological, and situational factors leading to the development of postoperative pain. The purpose of this review is to identify preoperative predictors for postoperative pain for inclusion in the current research study. The focus of the literature review was those studies looking at postoperative pain intensity, the method of assessing preoperative and postoperative pain widely used in clinical practice. Currently, the etiology and treatment of pain produced by surgery is different than other clinical pain conditions (Brennan, 2011). To advance our ability to predict postoperative pain the following literature will be explored in more specificity in relation to surgery.
This section of the literature will follow the same format as the previous section addressing predictors of pain with the empirical findings will be discussed separately under each influencing factor to provide a systematic review of the current relevant literature. In a qualitative systematic review conducted Ip, Abrishami, Peng, Wong, and Chung (2009), preoperative pain, age, gender, type of surgery, and anxiety were found to be significant predictors for postoperative pain. An additional source of predictor studies for this review was a systematic review performed by Ip et al. (2009), covering a period from 1806 to 2008, and found 48 eligible articles looking at demographic factors, psychological factors, preoperative pain, and surgical factors. Articles pertaining to analgesic consumption are not explored in this review, as the focus is pain intensity not analgesic consumption.

More recently, in 2010, Werner, Mjöbo, Nielsen, and Rubin found 11 of the 14 articles studied reported significant predictors for acute postoperative pain between the periods of 1966 and 2009 (Bisgaard, Klarskov, Rosenberg, & Kehlet, 2001; Granot, Lowenstein, Yarnitsky, Tamir, & Zimmer, 2003; Hsu, Somma, Hung, Tsai, Yang, & Chen, 2005; Martinez, Fletcher, Bouhassira, Sessler, & Chauvin, 2007; Nielsen, Norgaard, Rasmussen, & Kehlet, 2007; Pan et al, 2006; Rudin, Wolner-Hanssen, Hellbom, & Werner, 2008; Strulov et al., 2006; Weissman-Fogel et al, 2009; Werner, Duun, & Kehlet, 2004; Wilder-Smith, Hill, Dyer, Torr, & Coetzee, 2003). The smaller number of articles discovered is most likely the result of the researcher’s focus on studies investigating the correlation between responses to preoperative applied experimental pain stimulus and clinical postoperative pain. Despite this narrower focus the findings further the understanding on predictors related to the development of postoperative pain. Only
those 11 articles found by the researchers to predict postoperative pain intensity were reviewed and include the following. In five of the studies, predictors were classified by the American Society of Anesthesia (ASA) classification status (Bisgaard, Klarskov, Rosenberg, & Kehlet, 2001; Hsu, Somma, Hung, Tsai, Yang, & Chen, 2005; Nielsen, Norgaard, Rasmussen, & Kehlet, 2007; Pan et al, 2006; Wilder-Smith, Hill, Dyer, Torr, & Coetzee, 2003). Five studies reported the presence of preoperative pain (Bisgaard, Klarskov, Rosenberg, & Kehlet, 2001; Martinez, Fletcher, Bouhassira, Sessler, & Chauvin, 2007; Pan et al, 2006; Rudin, Wolner-Hanssen, Hellbom, & Werner, 2008; Werner, Duun, & Kehlet, 2004). Six studies assessed psychological variables of psychological vulnerability, anxiety, depression, and/or pain catastrophe sizing (Bisgaard, Klarskov, Rosenberg, & Kehlet, 2001; Hsu, Somma, Hung, Tsai, Yang, & Chen, 2005; Pan et al, 2006; Rudin, Wolner-Hanssen, Hellbom, & Werner, 2008; Strulov et al., 2006; Weissman-Fogel et al, 2009). Type of surgery was reported in all 11 studies. In addition type of anesthesia was reported in all 11 studies.

The above empirical findings will be discussed separately under each physiological, psychological, and situational influencing factor in addition to other studies found in the literature.

**Physiological Factors**

Physiological factors are conceptualized as preoperative pain, type of surgery, ASA status, and hemodynamic parameters, all factors related to the patients physiological responses and pathology.

**Preoperative pain.** Humans respond to painful events with neuroplasticity, both peripherally and centrally, which are mediated by a number of biochemical factors. The
presence of pain triggers strong affective responses. Whether pain is a sensation or an emotional response has long been debated and for the purposes of this study the presence of preoperative pain, irrelevant of the cause, will be studied. Importantly, the literature supports preoperative pain as being positively correlated with the development of postoperative pain.

Ip et al. (2009) review found a positive correlation in 6 studies showing preoperative pain experience was a common predictor of postoperative pain intensity (Bisgaard, Klarskov, Rosenberg, & Kehlet, 2001; Caumo et al., 2002; Kalkman et al., 2003; Mamie et al., 2004; Rudin, Wolner-Hanssen, Hellbom, & Werner, 2008; Taenzer, Melzack, & Jeans, 1986). In a 1998 study, Thomas, Robinson, Champion, McKell, & Pell found high preoperative pain severity to correlate with relative severity of pain postoperatively, reinforcing the importance preoperative pain has on postoperative pain severity. This has been studied by Rudin et al. (2008) who found preoperative pain and heat pain perception were significant predictive factors for the presence of high postoperative pain. Most recently, Tsirline et al. (2013) found the presence of preoperative pain was the most significant preoperative predictor of postoperative pain.

In 2002, Caumo et al. demonstrated higher levels of pain and chronic pain immediately before surgery were independent predictors for the development of moderate to intense postoperative pain. The researcher’s possible explanation was that the presence of preoperative pain could change neuroplasticity. To expand on this concept, a study conducted by Wilder-Smith, Tassonyi, and Arendt-Nielsen (2002), demonstrated preoperative pain could induce neuroplastic changes, placing individuals at risk for increased vulnerability for increased postoperative pain. This research sheds light on the
fact neuroplasticity may play an important role in the development of postoperative pain. Further support of these findings was described by Bisgaard et al. (2001) whereby the researchers used a preoperative cold pressure test and found patients who were grouped as pain-sensitive had significantly more postoperative pain compared to the pain-tolerance group.

It is important to touch on the complex sensory and affective aspects of pain. Kalso (1997) described the direction of the memory of pain is determined by factors such as emotion, expectation of pain, peak intensity of previous pain, and current pain intensity. The complex interaction between the sensory and affective mechanisms in the development of both preoperative and postoperative pain must be taken into account; unfortunately most research to date does not address this.

Further research needs to help add clarity to the chain of factors involved preoperatively before determining effects on postoperative pain. This is shown in Kinjo et al. (2012) path analysis where the researchers looked at variables predicting postoperative pain and found the presence of preoperative pain to have the strongest direct effects on postoperative pain. In fact, the researchers found the preoperative Telephone Interview for Cognitive Status (TICS) and geriatric depression scale (GDS) to directly correlate with preoperative pain not postoperative pain.

Possible explanations for these research finding of greater preoperative pain being directly associated with use of preoperative opioids, female gender, and greater number of preoperative depressive symptoms is that (a) administration of opioids may blunt affective component of pain without dulling the sensation (Gustein & Akil, 2001); (b) females experience more severe postoperative pain and require more analgesics than men.
(Cepeda & Carr, 2003); (c) effects of mu-opioid receptor blockage on pain and emotional distress may be different between genders (Zubieta et al., 2002; Smith, 2006); (d) high cognitive function is directly associated with less preoperative pain (Zubieta et al., 2002; Smith, 2006). The path analysis shows use of preoperative opioids, female gender, and greater number of preoperative depressive symptoms reduces some or all of the explanatory power of the more distant variables on the outcome of postoperative pain (Kinjo et al., 2012). For example, part of the effect of gender on preoperative pain and not postoperative pain may be a function of the fact women has more preoperative pain. Likewise the psychological factors studies were shown to be directly related to preoperative pain. Therefore the overall effect of cognitive status and depression should be examined in a model that excludes psychological factors; otherwise the effect of preoperative pain will be underestimated. Moreover, the preoperative pain factor was the only factor that was directly linked to both postoperative pain on day 1 and day 2.

In 1998, Thomas et al. found high preoperative pain severity was the only factor found which was associated with all four negative outcomes, which assessed relative severe postoperative pain, worse than expected pain experience, inadequate pain control, and low satisfaction with analgesia/pain management. Specifically looking at potential predictors of relatively severe postoperative pain, the researchers found the presence of preoperative pain to be related to the highest odds of developing severe postoperative pain. The order of significant predictors found from highest to lowest probability was: the presence of high preoperative pain severity (3.09), high expected pain severity (2.41), gender (female/male, 1.73), pain duration > 3 months (1.70), and age (extra year, 0.98),
= .01 (Thomas et al., 1998). These findings are consistent with other discoveries in the literature showing the significance of preoperative pain in predicting postoperative pain.

A number of prediction models have consistently found preoperative pain to be a significant independent predictor of moderate to severe postoperative pain (Caumo et al., 2003; Janssen et al., 2008; Kalkman et al., 2003). These findings further support and indicate a linkage between past and present pain.

In light of the empirical findings the presence of preoperative pain has on the development of postoperative pain, further research needs to address the psychological factors affecting preoperative pain. This provides further justification to modify the prediction tool to exclude psychological factors in this research. Regardless of where the antecedents begin, the presence of preoperative pain has been shown to significantly affect postoperative pain and will be included in the prediction model.

**Type of surgery.** Type of surgery was found to be an important predictor in a prediction rule developed by Kalkman et al. (2003) and later modified by Janssen et al. (2008). Ip et al. (2009) systematic review found 6 studies that established surgical factors as an important predictor of postoperative pain. Specifically, abdominal surgery (Chia et al., 2002; Chung, Ritchie, & Su, 1997; Kalkman et al, 2003), orthopedic surgery (Chung, Ritchie, & Su, 1997; Kalkman et al, 2003), and thoracic surgery (Chia et al., 2002) were the surgeries associated with postoperative pain. In the large study of 10,080 conducted by Chung et al. (1997), urology, general surgery, and orthopedic surgery were 17 times more likely to produce pain than ophthalmic surgery. Gynecological, neurological, and plastic surgery were found to produce at least 9 times as likely to produce pain compared to ophthalmic surgery. Furthermore, Ip et al. (2009) found 2 studies were patients
undergoing abdominal and emergency surgeries required more analgesia (Dahmani, Dupont, Mantz, Desmonts, & Keita, 2001; Voulgari et al., 1991). Early research by Voulgari et al. (1991) found postoperative pain levels significantly increased with abdominal surgery.

The more recent 2001 study by Dahmani et al. found a significant influence of surgical factors on postoperative analgesic requirements. In fact, the context of surgery (emergency) was the most predictive factor found by the researchers. Although not the intended outcome for the study, an increased reported pain levels is associated with an increased postoperative opioid requirement (Voulgari et al., 1991), therefore adding further evidence to support the use of type of surgery in the final model.

**ASA physical status.** ASA physical status classification system (ASA) status is an assessment used for assessing the overall physical health of an individual preoperatively with the goal of attempting to stratify risk. In looking at the literature pertaining to predictors of postoperative pain, only a few studies evaluated the association has on postoperative pain. A review conducted by Ip et al. (2009) only found one study (Caumo et al., 2002) correlated ASA status as being a predictive factor for postoperative pain. The study contained a sample size of 346 and finding showed only an ASA status of III was significantly correlated with postoperative pain in patients undergoing abdominal surgery. A further review of the literature found ASA status to be associated with postoperative pain in only one additional study (Kinjo et al., 2012). Higher ASA status was found by Kinjo et al. (2012) to directly correlate with higher postoperative pain. The researches postulate a possible explanation is that patients with higher ASA scores are more likely to be chronically ill and therefore have coexisting
chronic pain. A point worth noting, the study by Kinjo et al. (2012) studied only patients who were over 65 years of age or older.

**Hemodynamic parameters.** Results of a correlational analyses by France (1999) indicated that higher preoperative resting systolic blood pressure was associated with significantly lower pain ratings at 24 hours post surgery and significantly lower ratings on all pain measures at 48 hours post surgery. This corroborates non-surgical research in the fact elevated presurgical blood pressure effects pain perception. Baseline pain, anxiety, and heart rate were found to significantly correlate to maximum pain report (Logan, Sheffield, Lutgendorf, & Lang, 2002). The researchers did not enter baseline heart rate into the final model as baseline was not a significant independent predictors but heart rate response was. Proposed mechanisms between heart rate response and pain reported are the baroreceptor reflex arcs and sympathetic activation.

In the Kalkman et al. (2003) study of predictors of postoperative pain, the researchers failed to show both heart rate and blood pressure as significant predictors of severe postoperative pain. Kinjo et al. (2012), for reasons of their own, chose not to include hemodynamic parameters in the path analysis predicting postoperative pain. Interestingly, research conducted by Rudin et al. (2008) additionally did not include hemodynamic variables in their research model. In fact, the review conducted by Ip et al. (2009) failed to show hemodynamic parameters as a predictive factor for postoperative pain despite the evidence in non-surgical pain studies showing baseline blood pressure and heart rate parameters influence pain.
Psychological Factors

Psychological factors are conceptualized to include anxiety, psychological distress, and coping strategies. Ip et al.’s (2009) systematic review found anxiety to be a consistent predictor of postoperative pain intensity in 15 studies. Psychological distress, other than anxiety, was found to be correlated to postoperative pain in 7 studies and coping strategies were found to predict postoperative pain in 4 studies. Conversely, 3 studies failed to show any relationship between psychological distress and postoperative pain. Interestingly, Mamie et al. (2004) found chronic sleeping difficulties, self-rated by the patient, was the sole predictor of severe postoperative pain at rest. The findings by Mamie et al. (2004) may reflect a particular psychological factor, such as an anxious and depressive personality, or a preexisting preoperative pain condition causing chronic sleep disturbances and needs further investigation to determine the association these factors play on predicting postoperative pain.

Despite empirical evidence supporting psychological factors as predictors of severe postoperative pain other previous studies of men and women have found conflicting results regarding the effects psychological factors have on the development of postoperative pain. Furthermore postoperative pain research assessing catastrophizing as a preoperative predictor is limited. It has not been fully revealed how pain catastrophizing affects the intensity of postoperative pain.

The Ip et al. (2009) review found only one article addressing catastrophizing, which found no association with postoperative pain. Regression analyses performed by Roth, Tripp, Harrison, Sullivan, and Carson (2007) showed that catastrophizing was found to be a significant predicted of preoperative pain and postoperative day two pain.
but not postoperative day one. In fact, preoperative variables were not found to predict postoperative pain. The high association found by the researchers between catastrophizing and negative mood supports suggestion that catastrophizing may be better classified among the category of mood and anxiety disorders. This contrasts to previous research conducted by Pavlin, Chen, Penaloza, Polissar, and Buckley (2002) who found that the Pain Catastrophizing Scale was a significant predictor of acute postsurgical pain in the post anesthetic care unit. The researchers unfortunately did not assess pain prior to surgery; therefore it was not possible to rule out the possibility that variations in postoperative pain could be accounted for by preoperative pain levels. This distinction is important because in a large number of studies preoperative pain levels have been found to be significant predictors of postoperative pain.

Thomas, Robinson, Champion, McKell, & Pell (1998) found assessment of anxiety preoperatively as a potential predictor of relative severity of pain postoperatively but failed to show any observed associations between anxiety about pain, anxiety about risks and problems, and depression as potential predictors of relatively severe postoperative pain. Further findings by Cohen, Fouladi, and Katz (2005) originally found an association between preoperative distress and postoperative pain and analgesic consumption. Interestingly, after controlling for age, concurrent postoperative factors, and preoperative coping, the association between preoperative distress and postoperative pain and analgesic consumption was no longer significant. As suggested by the researchers, coping strategies may be more predictive of postoperative pain and analgesic consumption than preoperative distress. In fact, postoperative days 0-4 found postoperative pain at rest to not be significant factor.
More recently, Rudin et al. (2008) looked at predictors of postoperative pain after laparoscopic tubal ligation surgery and concluded presurgical clinical pain and preoperative heat pain sensitivity were important predictors of postoperative pain in both the univariate analyses and the multiple regression model for both rest and active states. The researchers found psychometric estimates of vulnerability, anxiety, and depression contributed to the model but to a lesser degree. In the multiple regression model, the researchers found the addition of State-Trait Anxiety Inventory-Trait (STAI-T) to presurgical clinical pain and preoperative heat pain sensitivity increased the predictive power for maximum visual analog scale (VAS) during walking or staircase climbing. The addition of psychological factors increased the predictive power only for maximal VAS during changes from supine to standing position. Psychological factors were a significant predictive variable only for movement-related maximal pain.

A recent study conducted by Kinjo et al. (2012) on 350 patients looked at variables predicting postoperative pain using path analysis in older patients. Psychological variables were measured using the 15-item Geriatric Depression Scale (GDS) and the 11-item Telephone Interview for Cognitive Status (TICS) to reflect depression and mental state. The researchers found preoperative psychological factors were not directly associated with postoperative pain but indirectly affected postoperative pain through preoperative pain. In fact, the use of preoperative opioids was more than two times the association than either depression or cognitive status alone.

Although the researchers found the presence of preoperative pain had the strongest effects on postoperative pain, consistent with previous reported research, the strongest indicator of preoperative pain appears to be the use of preoperative opioids not
psychological factors. Research conducted by Bisgaard et al. (2001) measured neuroticism (psychic vulnerability) and found a significant association with postoperative pain. The neuroticism test included questions addressing preoperative pain, depression, sleep disturbance, and anxiety among other questions. These findings raise questions regarding the true independent nature of psychological factors in determining postoperative pain. Furthermore, patients reporting high levels of pain show higher accounts of a variety of disturbing emotions, especially anxiety and frustration (Wade et al., 1990). These findings suggest that patients suffering from increased levels of preoperative pain have higher anxiety levels placing patients at an increased risk for poor postoperative state (de Groot et al., 1997). These findings by Groot et al. (1997) are further corroborated by Caumo et al. (2001), who revealed a significant association is present between degree of preoperative state-anxiety and preoperative pain. Moderate to intense preoperative pain was associated with high preoperative anxiety.

Even though researchers have found that psychological factors contributed to the development of postoperative pain, upon investigating the literature, no research was found addressing the nature of psychological factors in the development of preoperative pain. These findings by Kinjo et al. (2012) raise questions on the validity in assessing psychological factors as direct predictors of postoperative pain independent of preoperative pain.

Part of the difficulty in accurately determining the nature psychological factors play in the development of postoperative pain arises because of the failure to address other important factors in the preoperative environment that effect postoperative pain. For example, the presence of psychological factors may lead to an increased preoperative
pain intensity, which has been found by a number of researchers as being the strongest predictor of postoperative pain. Furthermore, in most anxiety studies, coping strategies have not been studied independent of level of anxiety in predicting postoperative pain.

In light of the conflicting research, the lack of research focused on psychological factors, and the lack of clinical assessment of psychological factors in current practice, psychological factors were not included in the research study. The aim of this study is to look at easily administered direct predictor of severe postoperative pain. Given the diverse nature of anxiety disorders, structured interviews or specialized self-report measures designed to assess anxiety specific to a particular disorders are likely needed to adequately detect anxiety disorders (McWilliams et al., 2003). Additionally, specialized objective score to measure an anxiety or depressive state are extremely cumbersome and impractical for application in the routine preoperative visit. Future research needs to address the nature psychological factors play in the development of preoperative pain to determine their predictive nature.

**Situational Factors**

Situational factors are conceptualized to include aspects of the patients’ environment that may affect the patients’ experiences and reporting of the symptom of postoperative pain. In studying postoperative pain, age and gender were identified as situational factors.

**Age.** For the purposes of this study, age is specific to adults and research reviewed in the literature is limited to adults. As previously discussed age is a situational factor which is commonly found factor that correlates negatively with pain and specifically postoperative pain (Bisgaard, Klarskov, Rosenberg, & Kehlet, 2001; Caumo
et al, 2002; Chung, Richie, & Sun, 1997; Gagliese, Gauthier, Macpherson, Jovellanos, & Chan, 2008; Kalkman et al., 2003; Kinjo, Sands, Lim, Paul, & Leung, 2012; Lau & Patil, 2004; Thomas et al., 1998; Tsirline et al., 2013; Voulgari et al., 1991). Postoperative pain age related research are consistent with general pain research and the negative correlational findings suggest that the older the patient, the lower the postoperative pain and analgesic requirements. The systematic review conducted by Ip et al. (2009) found six studies further showing a correlation between age and postoperative pain intensity (Bisgaard, Klarskov, Rosenberg, & Kehlet, 2001; Caumo et al, 2002; Chung, Richie, & Sun, 1997; Gagliese, Gauthier, Macpherson, Jovellanos, & Chan, 2008; Kalkman et al., 2003; Lau & Patil, 2004).

Gagliese et al. (2008) findings suggest age related factors might affect pain intensity postoperatively. Furthermore, Kalkman et al. (2003) found age an independent predictor of severe postoperative pain with younger age having a higher probability. In 2002, Caumo et al. study found younger patients presented higher risk for reporting moderate to intense postoperative pain. In the prior year, Bisgaard et al. (2001) study showed a significant inverse association between age and the postoperative total visual analogue scale (VAS) and the maximal VAS ratings during the first week postoperatively. These newer research finding enhance Thomas et al. (1998) research showing for each extra year of life, there was a 0.98 probability of reporting a high pain score when compared to the previous year ($p = .01$), in other words a decreased likelihood.

**Gender.** Postoperative pain intensity related to gender has been found in a number of studies. Being female has been shown to be associated with more
postoperative pain (Cepeda & Carr, 2003; De Cosmo et al, 2008; Gagliese et al., 2008; Janssen, 2008; Kinjo et al., 2012; Lau & Patil, 2004; Thomas et al., 1998; Tsirline et al., 2013). Recently Kinjo et al. (2012) found female gender to be a significant direct predictor of postoperative pain. Interestingly, female gender was also found to be a significant predictor of preoperative pain making female a direct and indirect predictor of postoperative pain. This could be related to a number of gender differences, which include but not limited to hormonal responses, genetic factors, and psychosocial components involved in pain perception.

In 2002, Caumo et al. found gender an important correlate of pain intensity, with females being associated with higher pain intensity. Lower pain was found to be associated with being male in a study conducted by Gagliese et al. (2008). This is further corroborated by research conducted by Thomas et al. (1998) who found female gender correlated with worse than expected pain severity postoperatively, in fact females had a 1.73 probability of severe postoperative pain compared to males ($p = .01$). Despite these findings supporting gender as a risk factor, Ip et al. (2009) review found one study showing less pain postoperative for female patients (Chia et al., 2002).

**Race/Ethnicity.** Although there is ample evidence associating race and ethnic differences in relation to pain in general, few studies have found any linkage between race and ethnicity for the development of postoperative pain. The systematic review conducted by Ip et al. (2009) only found one study addressing ethnicity from a search covering a period from 1806 to 2008 (Dahmani et al., 2001). After a thorough review of the literature, only as far back as 1994, Faucett et al. reported greater postoperative pain among Latino and African American patients compared to Caucasian patients. The
researchers reported on acute postoperative dental pain in a sample of 543 patients. More recently, ethnicity was suggested by Dahmani et al. (2001) to be a predictive factor of postoperative morphine requirements. The Caucasians group was found to require more morphine than the African Americans and Asian ethnic groups.

A discrepancy seems to occur between these two research-finding showing Latino and African American experience more pain and Caucasians require more morphine. Possible explanations in the research is (a) the expression of pain and analgesic requirement differs between various ethnic groups; (b) racial and ethnic disparities in pain management leads to inaccurate reporting of pain intensity levels (Mossey, 2011). Staton et al. (2007) observed physicians underestimated the pain scores of African-American patients by greater than 2 points on the 11-point numerical rating system (NRS) 47% of the time, versus 33.5% of the time for non-African Americans. This was in contrast to non-African American being overestimated twice as likely. Not only will disparities in pain management lead to under and over reporting but it also potentially leads to the under and over intraoperative management of perceived pain by the anesthesia provider. This could feasibly explain differences in the literature.

Despite the lack of empirical linkage and discrepancies in the literature between both race and ethnicity specifically for the development of postoperative pain, the overwhelming association of pain differences in the more general literature on pain warrants inclusion of race/ethnicity in the current study. It would be shortsighted to not appreciate the importance race/ethnicity plays in postoperative pain.
Summary of Postoperative Pain Predictors

The results of the literature suggest that the presence of preoperative pain, type of surgery, and hemodynamic parameters are the most common physiological factors affecting postoperative pain. Overwhelming evidence supports the role preoperative pain plays in predicting postoperative pain (Bisgaard et al., 2001; Caumo et al., 2002; Janssen et al., 2008; Kalkman et al., 2003; Kinjo et al., 2012; Mamie et al., 2004; Rudin, Wolner-Hanssen, Hellbom, & Werner, 2008; Taenzer, Melzack, & Jeans, 1986; Thomas et al., 1998; Tsirline et al., 2013; Wilder-Smith et al., 2002). In addition, type of surgery, another physiological factor, was found to be an important predictor in a number research studies and prediction rules (Chia et al., 2002; Chung et al., 1997; Dahmani et al., 2001; Kalkman et al, 2003; Janssen et al., 2008; Voulgari et al., 1991). In regards to ASA status, the literature failed to show evidence beyond two studies, which suggested the predictive qualities of postoperative pain (Caumo et al., 2002; Kinjo et al., 2012).

Despite evidence supporting hemodynamic parameters predicting pain in the general literature (Al’Absi et al., 2000; Falcone et al., 1997; Ghione, 1996; Logan et al., 2002), there seems to be a under representation in the literature specific to postoperative pain (France, 1999). Therefore, hemodynamic factors, baseline blood pressure and heart rate, will be included along with preoperative pain, and type of surgery in an attempt to add clarity and answer the aim of this study. Due to the tentative nature of ASA status in predicting postoperative pain, it will not be utilized as a factor in predicting severe postoperative pain.

Situational factors found in the literature to affect postoperative pain are age, female gender, and race/ethnicity. Age seems to be inversely related to postoperative pain
Bisgaard, Klarskov, Rosenberg, & Kehlet, 2001; Caumo et al, 2002; Chung, Richie, & Sun, 1997; Gagliese, Gauthier, Macpherson, Jovellanos, & Chan, 2008; Kalkman et al., 2003; Lau & Patil, 2004) and gender is associated with females having a higher pain intensity and frequency of postoperative pain (Cepeda & Carr, 2003; De Cosmo et al, 2008; Gagliese et al., 2008; Janssen, 2008; Kinjo et al., 2012; Lau & Patil, 2004; Thomas et al., 1998; Tsirline et al., 2013). Ethnicity, another situational factor, has been linked to predicting both morphine consumption and pain intensity levels postoperatively (Dahmani et al., 2001; Faucett et al., 1994). All these situational factors will be included in the model modification to determine the best model fit for analysis and validation.

The available literature is conflicting regarding the complex nature psychological factors play as direct predictor of postoperative pain. As outlines in the systematic review conducted by Ip et al. (2009), a number of psychological factors were found to be correlated with postoperative pain along with a number of articles failing to show such a correlation. Research performed by Roth, Tripp, Harrison, Sullivan, and Carson (2007) showed that catastrophizing, a negative mental set or cognitive-affective response towards anticipated or actual pain, was not found to be a significant predictor of postoperative day one pain. In fact, the researchers showed catastrophizing was a significant predictor of preoperative pain and postoperative day two pain. Adding further conflict to the complex nature is the research study conducted by Thomas et al. (1998). In their study the researchers found assessment of anxiety preoperatively failed to show any observed associations between anxiety about pain, anxiety about risks and problems, and depression as potential predictors of relatively severe postoperative pain. Furthermore,
Rudin et al. (2008) look at predictors of postoperative pain and found psychological factors were a significant predictive variable only for movement-related maximal pain.

Questions raised from the literature points to the true independent nature of psychological factors in determining postoperative pain as reported by a number of research findings (Caumo et al., 2001; De Groot et al., 1997; Wade et al., 1990). As mentioned in the literature review specific to pain, an overwhelming body of knowledge is shows commonalities in psychological factors and the factor of preoperative pain (Bair et al., 2003; Kroenke & Price, 1993; Lindsay, 1982; Magni et al., 1993; Maneeton et al., 2013; Tracey & Dickenson, 2012; Von Korff et al., 1988; Wilson et al., 2001). Therefore, are psychological factors independent of preoperative pain or in fact a common and not independent physiological pathway? It may be determined in future studies psychological variables are predictive of preoperative pain and not postoperative pain as suggested by some authors. To expand on this point, in the study by Kinjo et al. (2012), psychological factors were found to not directly be associated with postoperative pain but instead associated with preoperative pain.

There is no question if there is an association between psychological variables and pain, the problem is determining if there is a difference between them. Despite the potential benefit of utilizing psychological factors, there is a great potential for a confounding association between psychological factors and preoperative factors to influence patient experiences of pain postoperatively. This leads to an oversimplification of a complex systemic interaction. Nevertheless it is important to acknowledge the potential impact psychological variables play on postoperative pain. In order to provide more effective and comprehensive strategies of postoperative pain management and to
enhance health related quality of life, it is important to identify the predictors of severe postoperative pain. Based on these findings and other findings in the literature providing evidence of an association between psychological factors and endogenous opioids, psychological factors will be excluded from this study but require follow up research to determine their effects on the direct relationship with preoperative pain.

However little is known about how these influencing factors predict postoperative pain. The aim of this study is to assess the relationship between preoperative predictors and the development of severe postoperative pain and risk stratify the relationship depicted. This will be accomplished through modification of a prediction tool developed in 2003 by Kalkman et al. to preoperatively predict the risk of severe pain in the first hour postoperatively. This prediction tool was later modified by Janssen et al. (2008) to enhance prediction in outpatients. Both prediction models showed good calibration. In fact the modified prediction tool by Janssen et al. (2008) showed a simple adjustment was all that was needed to recalibrate the prediction rules for a new population. For this reason, the same prediction rule and outcome definitions will be used with the following modifications: inclusion of (a) race/ethnicity, (b) the hemodynamic baseline parameters of heart rate and blood pressure; and exclusion of (c) the Amsterdam Preoperative Anxiety and Information Scale (APAIS), and (d) exclusion of incision size.

Despite the empirical evidence of the predictive nature of race, ethnicity, and baseline hemodynamic parameters, all will be included in the model testing. Race and/or ethnicity were not measured in by Kalkman et al. (2003) study, but an abundance of the literature supports its inclusion in this research study.
The researchers reliance on anxiety as the sole psychological factor in predicting severe postoperative pain is further clouded by the lack of empirical evidence supporting one psychiatric disorder as being significantly associated with pain-related disability (McWilliams et al., 2003). Considering the fact that trait-anxiety has been associated with higher preoperative pain (Caumo et al., 2001) and found to be a direct predictor of preoperative pain (Kinjo et al., 2012) not postoperative pain, this study will focus on only those factors directly related to the development of postoperative pain. Because the psychological factors remain a subject of debate, modification of the prediction rule will exclude the Amsterdam Preoperative Anxiety and Information Scale (APAIS) questionnaire used in the original prediction tool. The APAIS consists of six questions, each scored on a 5-point Likert scale from 1 (not at all) to 5 (extremely) and is specifically designed to assess the patient’s preoperative anxiety score and an information-seeking behavior score assessing the patient’s need for information regarding the scheduled surgery and anesthesia. Of importance, the routine testing of psychological factors is not currently common in clinical anesthesia practice, making inclusion of psychological factors not feasible for the purpose of establishing a clinically applicable tool for preoperatively predicting postoperative pain. Psychological testing is more difficult than one may appreciate raising question of the appropriateness of its utilization in a prediction model.

Another potential area of concern regarding the prediction tool developed by Kalkman et al. (2003) is the inclusion of incision size as a predictor of severe postoperative pain. Although it was found to be a significant factor in predicting severe postoperative pain, theoretically incision size and expected pain by surgical classification
type are not separate constructs but a measurement of the same construct and bring into question the discrimination of the two items. Extreme collinearity can occur when separate variables actually measure the same thing (Kline, 2011). Two ways to deal with extreme collinearity are to eliminate variables or combine redundant ones into a composite variable (Kline, 2011).

In reviewing the literature, the only studies addressing incision size and postoperative pain in a multi-surgical sample, were those conducted by Kalkman et al. (2003) and Janssen et al. (2008). Only research comparing a single surgical procedure to look at the effect of different incision sizes or techniques on postoperative pain was found (Prasad, Mukherjee, Kaul, & Kaur, 2011). Furthermore, a study by Ogonda et al. (2005) found no significant difference being detected between the mini-incision and standard-incision groups regarding postoperative pain scores or morphine consumption. As discussed by Waltz et al. (2010), unless the item measures or assesses the objective, any scores obtained will be questionable.

Since incision size is predicted preoperatively and not directly measured, it is difficult to conceptualize how this is a separate measure or predictor of severe postoperative pain from type of surgery. Numerous research uncovered in the literature review reflects the type of surgery as an important predictor of severe postoperative pain not surgical incision size. When reviewing the surgical classification system by Janssen et al. (2008), those surgical procedures with the high and the highest expected pain seem to already account for larger surgical incisions.

Unfortunately, unanticipated larger than expected incision size cannot be predicted but if incision size were directly measured intraoperatively or postoperative
would make theoretical sense to include in a model of severe postoperative pain. After looking at the conceptual framework and the empirical evidence with the goal of preoperatively predicting the risk of postoperative pain, incision size will be removed from this prediction model analysis due to questions of its objective to predict severe postoperative pain. If there is sufficient evidence that an item is not functioning as it should and is not content valid then it is recommended that it be removed from the measure (Waltz et al., 2010).
Chapter 3: Research Methods

Overview

This chapter describes the research design, participant selection, sample, setting, procedures for protection of human subjects, data collection procedures, study variables and measures, along with the data collection and analysis plan. A detailed discussion will be included outlining the instruments selected to measure the variables.

Research Design

The purpose of this study was to first explore the predictor factors of postoperative pain. Following a determination of the predictors, the second purpose was to develop a prediction rule and validate the tool to risk stratify individuals with respect to severe postoperative pain. Modifying and validating a clear and concise prediction measurement tool is critical in predicting those individuals at risk of developing severe postoperative pain, thus allowing for intervention strategies to be developed and tested to treat patients with severe pain. Researchers at the University Medical Center in the Netherlands developed a model for prediction. Utilizing a simple model adaptation, this study modified and validated a prediction tool for the occurrence of severe postoperative pain (Kalkman et al., 2003).

The central guiding questions, (a) is there a significant relationship between preoperative predictors and the development of severe postoperative pain and (b) to what extent do physiological and situational factors predict the severe postoperative pain was answered utilizing a retrospective, quantitative approach. Specifically, structural equation modeling (SEM) was utilized to determine the best prediction model along with
regression coefficients analysis to modify a regression equation prediction rule. This explicit methodology guided the method of data collection and data analysis.

A retrospective quantitative study design was appropriate because the purpose of this study was to identify currently collected and reported predictors of severe postoperative pain. A prospective design was considered but not feasible due to the duration of time needed to capture a significant sample size of already reported data. This made a retrospective design more feasible to undertake to first describe the relationships between the preoperative predictors and severe postoperative pain and secondly to modifying and validating a current prediction tool.

The primary focus of this study was postoperative pain, specifically pain intensity. The eight preoperative predictors of severe postoperative pain include gender, age, race/ethnicity, baseline blood pressure and heart rate, preoperative pain, and type of surgery were all be measured as follows. Gender, age, and race/ethnicity were collected as part of the demographic information of each participant. The hemodynamic parameters blood pressure and heart rate was recorded from the preoperative baseline data obtained on the day of surgery. Presence and severity of preoperative pain was rated on the same NRS scale utilized to measure the severity of pain postoperatively. The preoperative severity was categorized into mild (NRS = 0-3), moderate (NRS = 4-5), and severe pain (≥6). Type of surgery was categorized by the surgical classification system developed by Janssen et al. (2008). The only restrictions to type of surgery was the exclusion of cardiac surgery and emergency surgeries due to the challenges assessing the presence of severe postoperative pain in this population within the first hour after surgery.
The outcome, presence of severe postoperative pain, was measured using the numerical rating system (NRS), a common clinically utilized tool for rating postoperative pain. The NRS consists of an 11-point severity scoring system, where 0 indicates no pain and a 10 indicates the most severe pain imaginable. The outcome of severe pain was determined as a NRS rating score of \( \geq 6 \).

**Methods**

**Participant Selection Strategies**

Patients’ receiving surgical intervention was the targeted sample. Utilizing a retrospective chart review of the electronic medical records (EMR), all electronic medical records were utilized to target subjects to seek the total population of individuals receiving surgery at one large medical center in southeastern Florida.

**Retrospective Chart Review**

Utilizing a retrospective chart review is an important methodology that has the potential to provide predictive severe postoperative pain research with valuable data. Despite the limitations of incomplete documentation, difficulty in interpretation information found, problematic verification of information, and variances in the quality of the recorded information, a major advantage of conducting a chart review for this study is the ability to access a rich amount of existing data with relatively few resources (Gearing, Mian, Barber, & Ickowicz, 2006). As outlined by Worster & Haines (2004), the quality of data obtained from chart reviews is not necessarily inferior to prospectively collected information. Use of the retrospective chart review was ideally suited to this study as the variables of interest were currently recorded and therefore already existed and therefore readily available.
Extracting the data required a number of steps. First, an exhaustive examination of the literature was conducted. This was followed by a careful conceptualization to develop the research questions. Additional clinical expertise in the symptom of postoperative pain and clinical research methods was sought in an effort to uncover any unanticipated problems or benefits while preventing any methodological barriers. As outlined by Gearing et al. (2006), operationalization of the study variables requires the variables to be defined and a review of how other researchers have operationalized variables. An exhaustive review has been discussed in the previous sections and the current chapter along with a thorough effort to measure the variables of interest to be consistent with the uncovered evidence. Management, storage, and analysis of the data are discussed later in this chapter. This study was undertaken with the consideration for future prospective studies addressing both future preoperative predictor studies of severe postoperative pain but also interventional strategies for its management.

**Inclusion and Exclusion Criteria**

Individuals who meet the following inclusion and exclusion criteria were extracted from the EMR for participation in this study over a period of six months. The first four months of data were collected to test the model followed by a two-month period of data collection to validate the data.

The inclusion/exclusion criteria for this study include:

1. Patients 18-85 years of age who are receiving a surgical intervention at the medical center. This age range was chosen as a target to stay consistent with the developed (Kalkman et al., 2003) and the modified study (Janssen et al., 2008) prediction tools modified for this study.
2. All psychological factors were excluded from this study due to issues with commonalities between negative affective states and preoperative pain.

3. Individuals undergoing emergency and cardiac procedures were excluded due to the fact the surgical procedures may compromise the patients’ ability to accurately report postoperative pain, leading to issues in the validity of the data obtained.

4. Women who were pregnant were also excluded from this study due to issues in hormonal alteration and variations in Mu-opioid receptors levels. As outlined in the literature, an association between high-estrogen states, as occurs during pregnancy, may increase Mu-opioid receptor availability and therefore lead to greater endogenous opioid neurotransmission activation during pain. In an attempt to remove this confounding effect, pregnancy was also excluded from this study.

Sample Selection

The original prediction tool developed by Kalkman et al. (2003) utilized a sample size of 1,416 surgical inpatients. Follow up research conducted by Janssen et al. (2007) was conducted with a sample size of 549 outpatients retrospectively from patient who underwent surgery during the period of time between 1997 and 1999. To modify and validate the prediction rule, data was collected over a period of 6 months from October (2014) to April (2015) at the University of Miami Hospital, Miami Florida. The data obtained from October, 2014 to January, 2015 was used to modify the rule, with the subsequent data from February, 2015 to April, 2015 utilized to assess the predictive performance of the rule.
The proposed structural model consists of the two exogenous latent factors, physiological and situational factors. The physiological factor was theorized to explain variation in these observed variables: baseline blood pressure, baseline heart rate, severity of preoperative pain, and type of surgical procedure. The situational factor was theorized to explain variation in these observed variables: age, gender, and race/ethnicity. The two exogenous latent factors of physiological and situational factors were tested to determine the relationship with the endogenous observed factor, postoperative pain.

Power Analysis. Using G*Power 3.1 a minimal sample size of 138 was needed to achieve a power of .95 with an anticipated effect size of 0.3 (Faul, Erdfelder, Lang, & Buchner, 2007). The actual sample size for the initial four months of data abstraction utilized for the initial model testing was 1,794 individual charts. The validation set resulted in an additional 1,961 individual charts for the validation testing of the prediction rule. This is consistent with the original study by Kalkman et al. (2003) and the modification by Janssen et al. (2008).

**Recruitment Setting**

Following human subjects approval by the Institutional Review Board of the University of Miami, de-identified data was extracted for analysis. Due to the nature of this study (retrospective chart review), participants were not recruited but all charts reviewed were conducted at one setting, the University of Miami Hospital, Miami Florida.

**Protection Of Human Subjects**

Approval for the study was obtained from the Institutional Review Board of the University of Miami prior to initiation of the study. No data was excluded based upon
gender, race, ethnicity, or religion. This study posed no major risks for participants of this study, due to the retrospective nature of the analysis of clinically collected data from the electronic medical record. Furthermore, data was de-identified and therefore no individuals received any monetary reward for participating in this study. Also, the retrospective design prevented any perceived coercion to participate. Only researchers, mentors, and advisors had access to the data. Furthermore, the data remained in an encrypted computer and will be destroyed 5 years after the data analysis.

**Study Variables and Measures**

The main variables for this research study are age, gender, race/ethnicity, baseline blood pressure and heart rate, severity of preoperative pain, and type of surgical procedure. The main variables are described below according to study aim one and the corresponding research question one. Aim two utilizes all the same variables as aim one but assesses and risk stratifies the relationship depicted by the modified model to develop a prediction tool for clinical practice and therefore will not be addressed separately in this section. The outcome variable, postoperative pain was used to address both aims of the study. An outline of the associated variables measured and the instruments used to measure the variable is depicted in Table 1.

**Measurement of Physiological Factors**

Physiological factors of baseline blood pressure and heart rate, severity of preoperative pain, and type of surgical procedure were measured using baseline standardized measures and categorical determinations.

**Measurement and measures of baseline blood pressure and heart rate** were measured using electronic sphygmomanometers are predominantly utilized in clinical
practice for blood pressure measurements since the disappearance of the mercury sphygmomanometer. The newer automated non-invasive blood pressure measurement devices obtain sufficient data with little human intervention and do not depend on an observer's hearing ability to detect Korotkoff sounds. A study by Chio, Urbina, Lapointe, Tsai, and Berenson (2011) using a DynaPulse and standard Hg BP measurements found consistency of measurements. Briton et al. (1997) demonstrated the DynaPulse mean measurements differed less than 3 mmHg from measures of intra-arterial blood pressure. Although the DynaPulse is only one non-invasive blood pressure monitoring device on the market, the research findings support the use of automated non-invasive blood pressure monitoring findings for collection of clinical data of baseline blood pressure for the purposes of this study.

As the literature review outlines, despite empirical evidence little research has included baseline heart rate as a variable of study but was included to determine if it adds predictive value. The baseline heart rate included only the preoperative reported heart rate and not the heart rate response.

**Measurement and measures of preoperative pain rating** was measured using the same 11-point severity scoring numerical rating system (NRS) utilized to measure postoperative pain, which is thoroughly described under the measurement of postoperative pain rating below. The parameter of preoperative pain used for analysis consisted of a single baseline pain score collected preoperatively.

**Measures of type of surgical procedure** was measured by the Surgical Classification System developed by Janssen et al. (2008) and attached in Appendix A. Type of surgery (Ip et al., 2009) and risk of surgery (Kinjo et al., 2012) was shown to be
positively correlated with postoperative pain and risk of surgery. Kinjo et al. (2012) determined risk of surgery and divided the risk into three levels (low, intermediate, and high) based on data about the type of surgery, length of surgery, and intraoperative blood loss. Finding only found high surgical risk to positively predict pain of postoperative day two. Unfortunately, the researchers choice of risk of surgery does not address specifically surgical pain risk. Earlier research by Kalkman et al. (2003) used the classification of type of surgery including Ophthalmic, Laparoscopic, Ear/nose/throat, Abdominal, Orthopedic, and Other. This surgical classification was based on predictions of postoperative nausea and vomiting and not acute postoperative pain. This simplistic classification was expanded by Janssen et al. (2008) to include a more thorough representation of surgical procedures ranging from lowest expected pain to highest expected pain. The type of surgery classification was developed from current clinical practice, clinical experience, and interviews with practitioners in an attempt to create a more sensitive prediction of postoperative pain. The specificity of the Janssen et al. (2008) surgical classification system, as opposed to some researcher’s use of the risk of surgery, was ideally suited for this research study and was used to categorize type of surgery in this study. Despite the limited empirical evidence specifically utilizing this surgical classification system, utilizing for this study helped add further validation. A thorough outline of the surgical classification system is detailed in Appendix A.

**Measures of Situational Factors**

The measure of the situational factors age and gender was collected as reported by patients in the EMR, by years for age and categorically as either male or female for gender. Race/ethnicity was categorized consistent with research findings found in the
literature search to one of the following categories: African-American, Asian, Hispanic, and Caucasian.

**Measure of Outcome Variable, Postoperative Pain**

Measures of postoperative pain rating, the outcome variable, relies on subjective patient reports of pain intensity through assignment of values to qualify the pain experience. Measurement occurred at two separate time points: (a) the initial pain score upon admission to the PACU and subsequent assessments over the first hour, which corresponds to the initial recovery from anesthesia; and (b) the initial postoperative pain score following discharge from the PACU and admission to the surgical floor, which corresponds to the period of time between discharge from PACU and not exceeding 24 hours following surgery. Hospital staff, utilizing routine institutional practice, obtained the pain scores postoperatively.

Several well-known measures have been developed to measure the patients’ pain intensity, the four-point verbal categorical rating scale (VRS), the numeric rating scale (NRS), and visual analogue scales (VAS). The VRS consists of an individual choosing a provided verbal description most closely associated with his or her pain intensity, "no pain", "moderate pain, and "severe pain". Although similar to the VRS, the VAS consists of a single straight non-numerical line representing the patients’ pain experiences with one end signifying "no pain" and the other end signifying "the worst pain imaginable". The patient is instructed to mark an X on the area corresponding most accurately to their present pain intensity. The NRS consists of an 11-point severity scoring system indicating pain intensity, where 0 indicates "no pain" and a 10 indicates "the most severe pain imaginable".
The numeric rating scale (NRS) and visual analogue scales (VAS) assess pain intensity. Empirical evidence supports the similarities in sensitivities between the NRS and VAS in acute postoperative pain, with both being superior to the VRS in assessing the patient’s subjective feeling of present pain intensity after surgery (Breivik, Björnsson, & Skovlund, 2000; Breivik, 2008). The VRS was found to underestimate the most intense pain (Breivik et al., 2000). The NRS is described by the authors as being more practical than the VAS and for the majority of individuals it is easier to understand. Furthermore, the NRS 11-point severity scoring is versatile and can be utilized in a number of clinical settings such as during preoperative telephone interviews. The scale can be used to rapidly assess not only pain intensity but also worsening or improving levels as utilized to ascertain therapeutic effectiveness of current pain management strategies. Importantly, the NRS is routinely utilized in clinical practice to assess patients’ pain intensity both preoperatively and following surgery in the PACU.

Presence of severe postoperative pain, the outcome measure, was measured using the NRS for rating postoperative pain. The outcome of severe pain utilized by Kalkman et al. (2003) was a NRS rating score of ≥ 8. Ferreira et al. (2011) analyzed, through multivariate analysis, optimal cut points for mild, moderate, and severe pain and determined a cut point score of 4 for moderate pain and 8 for severe pain, which is consistent with the study by Kalkman et al. (2003). In Janssen et al. (2008) updating and testing of the original prediction model, the researchers chose to use a more widely accepted definition of severe postoperative pain, ≥6 instead of the ≥8 cut off originally established by Kalkman et al. (2003). The ≥6 definition was also utilized in the
modification rule study conducted in 2008. The authors chose the more liberal definition in both studies in an effort to adhere to current pain treatment protocols.

A ≥7 cutoff point was outlined in Breivik et al. research on the assessment of pain (Breivik, Björnsson, & Skovlund, 2000; Breivik, 2008). This is consistent with older research conducted by Serlin, Mendoza, Nakamura, Edwards, and Cleeland (1995) delineating different levels of cancer pain severity, 1-4 correspondent to mild pain, 5-6 moderate pain, and ≥7-10 severe pain.

Despite the different thresholds for severe postoperative pain, the definition of severe postoperative pain utilized for this scale modification followed the classification consistent with the prediction studies reported by Janssen et al. (2008) and consist of any NRS rating of ≥ 6 occurring in the first hour after surgery.

Table 1

*Variables and instruments used to measure the data*

<table>
<thead>
<tr>
<th>Variable</th>
<th>Instrument</th>
</tr>
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<tbody>
<tr>
<td>Age</td>
<td>Years for age</td>
</tr>
<tr>
<td>Gender</td>
<td>Categorically as either male or female</td>
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<tr>
<td>Race/Ethnicity</td>
<td>African-American</td>
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<td></td>
<td>Asian</td>
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<tr>
<td></td>
<td>Hispanic</td>
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<tr>
<td></td>
<td>Caucasian</td>
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<tr>
<td>Baseline Blood Pressure</td>
<td>Recorded non-invasive blood pressure measurement</td>
</tr>
<tr>
<td>Baseline Heart Rate</td>
<td>Recorded preoperative heart rate measurement</td>
</tr>
<tr>
<td>Preoperative Pain Rating</td>
<td>NRS 11-point severity scoring</td>
</tr>
<tr>
<td>Type of Surgical Procedure</td>
<td>Modified type of surgery classification system</td>
</tr>
<tr>
<td>Postoperative Pain Rating</td>
<td>NRS 11-point severity scoring</td>
</tr>
</tbody>
</table>
Data Management Strategies

The data management strategies include the modes of data collection and data analysis.

Modes of Data Collection

Following IRB approval, patients were recruited retrospectively from the medical records at the University of Miami Hospital. The data for the study was abstracted via the database administrator (DBA) and copied to the PI's data collection tool. As outlined by Worster and Haines (2004), the following data abstraction strategies was employed in an effort to avoid bias and increase interobserver and intraobserver reliability: (a) the abstractors were blind to the study aims to reduce subjectivity; (b) establishment of unambiguous variable definitions were defined along with unambiguous inclusion and exclusion criteria; (c) rules about missing or conflicting data was established and outlined separately; (d) the abstractors were advised at the beginning that their work would be checked for accuracy; and (e) the reliability of the abstracted data was performed in random samples.

Data Abstraction

The data was collected from one source, the patients' electronic medical record; therefore a single data abstraction form was used. After all the information was copied and stored in the data collection tool, a data quality check consisted of randomized entry verification checking and rechecking data entry for entry errors. Descriptive statistics was run for all the variables to look for missing responses and out of range data.

The date abstraction range consisted of a period of six months. The initial four months of data was utilized in the model testing and the initial modification of the
prediction rule. The last two months, validation set, of data abstracted remained separate and independent from the initial population for the sole purpose of providing external validation of the prediction rule.

**Missing Data and Conflicting Data**

Missing data may lead to nonresponse bias in the results as subjects with missing data may differ from the other subjects but as described by Kline (2011), a few missing values, less than 5% of a single variable, is of little concern. The design of the study attempted to capture currently acquired practice data therefore minimizing missing data.

Conflicting data was examined to identify values outside the permissible range of each measurement tool. Individual records with conflicting data were examined for data entry accuracy. The process of checking the frequency distributions of all the study variables were also took place until no values outside the range of values is identified. In a case of a univariate outlier, the score was transformed. If the case identified had a multivariate outlier, and had an extreme score on two or more variable, then the case was removed from the analysis.

**Modes of Data Analysis**

For the purpose of this study, individual charts reviewed found meeting the established inclusion and exclusion criteria but missing predictor factor data and outcome data was not included in the analysis except were expressly stated. Analysis was conducted using the preoperative physiological and situational factors to determine association with the occurrence of severe postoperative pain. Data abstracted over the first four months of the data was utilized to test the models, addressing the aims of this
study. Following model testing, the last two months of abstracted data from the electronic medical record was used to validate the developed prediction rule.

Descriptive statistics were utilized to describe the sample characteristics including the age of participants, number of men and women selected, and the race/ethnicity of participants. Age and race/ethnicity of participants were analyzed to determine possible age or race/ethnicity related differences for the development of severe postoperative pain. Likewise, male and female participants were analyzed to detect possible gender differences. Statistical Package for the Social Sciences (SPSS) was used to execute the descriptive statistical analysis in this study.

In order to analyze which of the predictors is most suited to predict severe postoperative pain, a multivariate approached was required. For the purpose of this study structural equation modeling (SEM) was employed. In order to use SEM, latent constructs of the observed data were constructed. These theoretical variables, which are not observed but are conceptualized to exist, are known as latent variables. The latent construct, physiological factors is indicated by the following observed data of preoperative pain, baseline blood pressure, baseline heart rate, and type of surgery. The latent construct, situational factors is indicated by the observed data age, gender, and race/ethnicity. The postoperative pain scores measured the construct symptom in this study, severe postoperative pain. The theoretical model and corresponding latent constructs are consistent with the Theory of Unpleasant Symptoms (Lenz et al., 1995).

The analytic strategy followed the steps outlined by Kline (2011) for SEM as depicted in Figure 5. SEM was utilized in two parts, the measurement model and the structural model, to describe the relationship between the dependent postoperative severe
pain variable and the independent predictors (age, gender, race/ethnicity, preoperative pain, baseline blood pressure and heart rate, and type of surgery). All analysis was performed utilizing Mplus Version 7 (Muthén & Muthén, 1998-2012).

![Flowchart of the basic steps of SEM](image)

Figure 5. Flowchart of the basic steps of SEM (adapted from Kline, 2011, p.92).

Specification is the representation of the hypothesis, the basic steps outlined by Kline (2011) were adapted to include the process of specification by drawing a model diagram, a common process using a set of standardized graphical symbols, outlined in Figure 5.

Confirmatory factor analysis (CFA) was undertaken to determine the multivariate measurement model. The observed dependent variable of severe postoperative pain was the outcome variable and the independent predictors was the factors, as represented in Figure 3. Identification was conducted to identify any values outside the range
permissible to the measured responses. If any outliers were identified, the entire individual data entry was examined and errors corrected if correctable or the data entry was removed from the data analysis. This is described more thoroughly in the missing data and conflicting data section under modes of data collection. An acceptable fitting measurement model was assessed for each latent variable that represents the data, as determined by the following cutoffs: non-significance $\chi^2 (p > .05)$, root mean square error of approximation (RMSEA) value less than 0.05, and a comparative fit index (CFI) value of 0.90 or better (Kline, 2011). Once an acceptably fitting measurement model was determined, the full structural model or path analysis was utilized to describe the model and the effects of the independent variables to portray the relations through two types of relationships: the relationships among the factors and the relationship between the factors and severe postoperative pain. The path coefficients indicate the direct effect of the variables theorized to be the cause of severe postoperative pain. The measurement models and the structural model are described below based on the research aims and research questions for this study.

**Preliminary Analysis**

Assessment of the underlying assumptions was conducted to ensure accurate inferences of the data through SPSS prior to importing the data and utilizing Mplus Version 7 (Muthén & Muthén, 1998-2012). This analysis was conducted to test the assumptions of univariate and multivariate normality, linearity and homoscedasticity. If issues are discovered with the assumption, transformation was made and described prior to conducting the SEM analysis. Once the assumptions were tested, a two-step approach
was conducted to test the proposed theoretical model; the measurement model and the structural model.

Testing of Specific Aims

Aim One

Assess the relationship, as depicted by the modified model for the theory of unpleasant symptoms, between preoperative predictors and the development of severe postoperative pain.

Research Questions

1. Is there a significant relationship between preoperative predictors and the development of severe postoperative pain?
   a. What is the relationship between physiological factors and the development of severe postoperative pain?
   b. What is the relationship between situational factors and the development of severe postoperative pain?
   c. What is the relationship between both the physiological and situational factors on the development of severe postoperative pain?

The measurement and structural models were developed, tested, and analyzed to assess the relationship between the preoperative predictors and the development of severe postoperative pain answering the above research questions.

Measurement Models

The measurement models developed in this study consists of the physiological factor measurement model, depicted in Figure 6, and the situational factor measurement model, depicted in Figure 7.
In the physiological factor measurement model, preoperative pain, baseline blood pressure, baseline heart rate, and type of surgery were analyzed to determine the latent exogenous variable, physiological factors. Likewise, the situational factor measurement model was assessed to determine if age, gender, and race/ethnicity adequately determined the latent exogenous variable, situational factors.

As is in line with the recommendations by Kline (2011), several fit indices were used to assess model fit, as there is no single statistical "gold standard". In the present study, model fit was assessed using the following goodness-of-fit indices: non-significance $\chi^2$ testing, root mean square error of approximation (RMSEA), and comparative fit index (CFI). Based on the assessment of each measurement model's fit to the data, approximate re-specification was conducted to improve the model fit if the model fails to meet the exact test fit. If re-specification was performed, it was explicitly noted and reported and acknowledged the magnitude and possible sources of the misfit. The data analysis plan for each study aim and related research questions is summarized below.

![Figure 6. Physiological factor measurement model.](image-url)
Figure 7. Situational factors measurement model.

**Structural Model**

In order to analyze which predictors is best suited to predict severe postoperative pain, a structural models was tested utilizing the model of preoperative predictors of postoperative pain, which utilizes the Theory of Unpleasant Symptoms. The physiological and situational factors were selected following the theoretical constructs and each measurement model will be tested. Following testing of each measurement model, the structural model was tested to address the relationships between the latent variable to address the specific aims and research questions of the study, depicted in Figure 8. As depicted in Figure 8, there are two latent exogenous variables and one observed endogenous variable. The structural model has 11 parameters, which specifies the hypothesized relationships. Assessment of the structural model involved determining where the theoretical relationship specified in the model, as depicted in Figure 8, is supported by the data. This involved the following steps: assessment of the fit of the structural model, using comparative fit indices; model modification, if necessary, providing theoretical and statistical evidence justifies modification.
Figure 8. Structural Model. Path diagram depicting the structural relations for the preoperative predictors of severe postoperative pain.
**Aim Two**

Use results from AIM 1 to develop and modify a prediction tool for clinical practice.

**Research Question**

To what extent do physiological and situational factors predict severe postoperative pain?

To investigate the unique value of each measure in predicting severe postoperative pain, the predictors were analyzed using the regression coefficients using a modified factor list originally created by Kalkman et al. (2003) to reflect the final model predictors and answer the research question. The prediction equation developed from the regression coefficients will reflect the probability of severe postoperative pain.

In 2008, instead of developing a new prediction rule Janssen et al. showed simple adjustments of the original prediction rule, established by Kalkman et al. (2003), could be made for a new group of patients. The simple recalibration method improved the calibration of the original prediction rule and was sufficient for modification. Steyerberg, Borsboom, van Houwelingen, Eijkemans, and Habbema (2004) provided further evidence in the literature on validation and updating of a previously published model. Instead of redeveloping a prediction model, this study will be based on the original prediction model (Kalkman et al., 2003) and modified model (Janssen et al., 2008) to independently validate a modified prediction equation.

In this present study the goal was to follow along this notion and adjust the model based on the predictors of this study by applying the rule with an alternative model more closely aligned with currently collected clinical indicators in North America, as theorized
and outlined in this study. The updated prediction model was adjusted to reflect this new cohort of patients. The coefficients from the final model were used to estimate probabilities of severe postoperative pain. The relative size of the regression coefficients for each independent predictor or risk factor was used to create the prediction equation, for the purpose of linking individual predictor scores to predict risk of developing severe postoperative pain.

The usefulness of the prediction rule is its ability to detect an individual at risk of developing severe postoperative pain. Using the cut-off scores of $\geq 6$, as previously described, the continuous NRS measurement will be converted into a categorical classification to describe two groups, those not at risk and those at risk for the development of severe postoperative pain as well as the likelihood that an individual will have severe postoperative pain. The composite score along with the individual indicator scores will be analyzed using the cut-off scores to determine those who will develop severe postoperative pain was created to determine those who develop “severe postoperative pain” and those who have “no severe postoperative pain”. The threshold for predicting those who will develop severe postoperative pain was determined by giving equal weight to sensitivity and specificity with no imposed ethical, cost, or prevalence constraints. The cutoff value was chosen using the more commonly used Youden index, the point on the receiver operating characteristic curve (ROC) curve, which maximizes the vertical distance from the specificity and sensitivity equity line (Kumar & Indrayan, 2011).

The sensitivity and specificity was analyzed to determine the predictive rules ability to correctly discriminate between those with and without severe postoperative
pain. Sensitivity is the prediction rules ability to accurately identify individuals in a group who have an illness or complaint (Stewart & Conner, 2005). Likewise, specificity is the prediction rules ability to accurately identify individuals who do not have an illness or complaint (Stewart & Conner, 2005).

In determining the likelihood and quantify the utility of the predictive rule to determine that an individual will develop severe postoperative pain or not develop it, the predictive values was analyzed. The positive and negative predictive values will quantify the probability of a particular outcome given an individuals prediction score (Dodd & Korn, 2008). The sensitivity, specificity, positive and negative predictive values are important measures to assess to determine the predictive accuracy of the prediction tool, which is important for identifying those individuals requiring clinical intervention.

The validity of a given predictor-criterion relationship is simply the correlation between the predictor and the criterion in the specific population (Waltz, et al., 2010). To obtain a realistic representation of the relationship, cross validation was employed. This process is described by Waltz et al. (2010) as requiring two separate and independent samples from the population. The original sample, the derivation set, utilized to test the model was utilized to create the prediction equation and second validation set was used to test the external validation of the prediction model.

Findings reported by Held, Bové, Steurer, and Held (2012) highlight the amount of optimization is large when regression models are fit to a data set without validation. In order to assess the predictive performance of the prediction rule and improve performance, external validation of the model was accomplished with the second validation set, which is an independent data set of abstracted information collected from
the electronic medical record. In an attempt to test generalization over time, a data set was collected over a period of two months at the University of Miami Hospital. The data from the last two months of the six-month period of abstracted data was set aside solely for the purpose of external validation of the predictive rule. This process ensured a higher level of validity from testing of before application in clinical practice.

**Summary**

A retrospective, descriptive and correlational research design was used in this study. Descriptive statistics were utilized to describe the sample characteristics of participants. In order to analyze which of the predictors is most suited to predict severe postoperative pain, multivariate approached utilizing structural equation modeling (SEM) were employed. All data was analyzed using both SPSS along with Mplus.
Chapter 4: Results

Overview of Analytic Strategy

This chapter presents the results of the research, starting with the participant characteristics, the subsequent preliminary analysis, and the hypothesis testing of each specific aim.

All analyses were conducted at an alpha level of .05. The main purpose of the analysis was to explain the relationship between the observed factors of baseline blood pressure, baseline heart rate, preoperative pain rating, type of surgical procedure, age, gender, and ethnicity and the outcome of severe postoperative pain. Before proceeding with the structural equation modeling (SEM), an extensive examination of the variables was examined utilizing SPSS to analyze the descriptive statistics and compare the mean scores, standard deviations and correlations. The empirical model was analyzed using Mplus, a computer program used for structural equation models. Using SEM, the data was examined for both the measurement model and the structural model to determine the relationship between a number of physiological (baseline blood pressure, baseline heart rate, preoperative pain rating, and type of surgical procedure) and situational factors (age, gender, and ethnicity) has on the observed variable, severe postoperative pain captured at three separate time points (PACU, admission to nursing floor after leaving the PACU, and discharge).

A multivariate model of factors influencing the outcome of severe postoperative pain was conceptualized and derived from the literature and clinical experience (see Figure 8). The theoretical or latent variables were drawn as circles in the model. These are physiological and situational factors. Boxes are used to describe the observed
measures (factors) of each latent construct. Each factor variable has an error (residual) variable represented by a circle with an arrow leading to the factor. Single-headed arrows are used to represent unidirectional causal relationships and double-headed arrows represent bidirectional causal relationships. This model examines the relationship between and among the empirically and theoretically derived variables and constructs to explain or predict severe postoperative pain.

**Participant Characteristics**

Data used in this analysis, was obtained retrospectively from the electronic medical record in two separate files following the outlined methods described in chapter three. The first sample (Sample 1) was captured from the period of October 1, 2014 through January 31, 2015. The 4-month period of time was used to test the models and create the prediction tool. The second set of data (Sample 2), from the time period February 1, 2015 through April 15, 2015, was utilized strictly to validate the prediction tool.

**Sample 1**

In terms of demographic characteristics, sample 1 consisted of 1794 participants, 941 men and 853 women receiving inpatient surgery at the University of Miami Hospital. The demographics and characteristics of the sample are shown in Table 2 and 3. The mean age of the participants was 55.59 (SD = 16.08; range 18 to 85). Of the 1794 individual charts identified in this study, 31.7% ($n = 569$) were African-Americans, 0.6% ($n = 10$) were Asians, 33.1% ($n = 593$) were Hispanics, and 34.7% ($n = 622$) were Non-Hispanic Caucasian.
Table 2
Demographic Date for continuous Measured Variables of Sample 1

<table>
<thead>
<tr>
<th>Variable</th>
<th>N</th>
<th>Mean</th>
<th>Standard Deviation</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Syst. BP</td>
<td>1,794</td>
<td>127.89</td>
<td>17.14</td>
<td>87</td>
<td>203</td>
</tr>
<tr>
<td>Diast. BP</td>
<td>1,794</td>
<td>69.57</td>
<td>11.29</td>
<td>23</td>
<td>117</td>
</tr>
<tr>
<td>Heart Rate</td>
<td>1,794</td>
<td>76.01</td>
<td>13.96</td>
<td>38</td>
<td>133</td>
</tr>
<tr>
<td>Preop Pain</td>
<td>1,771</td>
<td>1.278</td>
<td>1.56</td>
<td>0</td>
<td>10</td>
</tr>
<tr>
<td>Age</td>
<td>1,794</td>
<td>55.59</td>
<td>16.08</td>
<td>18</td>
<td>85</td>
</tr>
</tbody>
</table>

Table 3
Demographic Date for Categorical Measured Variables of Sample 1

<table>
<thead>
<tr>
<th>Variable</th>
<th>Categories</th>
<th>Frequency</th>
<th>Percent (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of Surgery</td>
<td>Lowest Expected Surgical Pain</td>
<td>311</td>
<td>17.3</td>
</tr>
<tr>
<td></td>
<td>Low Expected Surgical Pain</td>
<td>423</td>
<td>23.6</td>
</tr>
<tr>
<td></td>
<td>Moderate Expected Surgical Pain</td>
<td>218</td>
<td>12.2</td>
</tr>
<tr>
<td></td>
<td>High Expected Surgical Pain</td>
<td>445</td>
<td>24.8</td>
</tr>
<tr>
<td></td>
<td>Highest Expected</td>
<td>397</td>
<td>22.1</td>
</tr>
<tr>
<td>Ethnicity</td>
<td>Caucasian</td>
<td>622</td>
<td>34.7</td>
</tr>
<tr>
<td></td>
<td>African American</td>
<td>569</td>
<td>31.7</td>
</tr>
<tr>
<td></td>
<td>Asian</td>
<td>10</td>
<td>0.6</td>
</tr>
<tr>
<td></td>
<td>Hispanic</td>
<td>593</td>
<td>33.1</td>
</tr>
<tr>
<td>Gender</td>
<td>Male</td>
<td>941</td>
<td>52.5</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>853</td>
<td>47.5</td>
</tr>
</tbody>
</table>

Total Sample
(N=1,794)
Sample 2

The demographic characteristics of sample 2 consisted of 1,961 participants, 1,014 (51.7%) men and 947 (48.3%) women receiving inpatient surgery at the University of Miami Hospital. The demographics and characteristics of the sample are shown in Table 4 and 5. The mean age of the participants was 53.60 (SD = 16.71; range 18 to 85). Of the 1,961 individual charts identified in this study, 35.3% ($n = 692$) were African-Americans, 0.8% ($n = 15$) were Asians, 31.0% ($n = 608$) were Hispanics, and 32.9% ($n = 646$) were Non-Hispanic Caucasian.

Table 4
Demographic Data for Continuous Measured Variables of Sample 2

<table>
<thead>
<tr>
<th>Variable</th>
<th>N</th>
<th>Mean</th>
<th>Standard Deviation</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Syst. BP</td>
<td>1,961</td>
<td>128.11</td>
<td>16.31</td>
<td>88</td>
<td>186</td>
</tr>
<tr>
<td>Diast. BP</td>
<td>1,961</td>
<td>70.42</td>
<td>10.68</td>
<td>40</td>
<td>109</td>
</tr>
<tr>
<td>Heart Rate</td>
<td>1,961</td>
<td>75.50</td>
<td>13.71</td>
<td>41</td>
<td>132</td>
</tr>
<tr>
<td>Preop Pain</td>
<td>1,940</td>
<td>1.44</td>
<td>1.60</td>
<td>0</td>
<td>10</td>
</tr>
<tr>
<td>Age</td>
<td>1,961</td>
<td>53.60</td>
<td>16.71</td>
<td>18</td>
<td>85</td>
</tr>
</tbody>
</table>
Table 5
Demographic Data for Categorical Measured Variables of Sample 2

<table>
<thead>
<tr>
<th>Variable</th>
<th>Categories</th>
<th>Frequency</th>
<th>Percent (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of Surgery</td>
<td>Lowest Expected Surgical Pain</td>
<td>396</td>
<td>20.2</td>
</tr>
<tr>
<td></td>
<td>Low Expected Surgical Pain</td>
<td>412</td>
<td>21.0</td>
</tr>
<tr>
<td></td>
<td>Moderate Expected Surgical Pain</td>
<td>219</td>
<td>11.2</td>
</tr>
<tr>
<td></td>
<td>High Expected Surgical Pain</td>
<td>431</td>
<td>22.0</td>
</tr>
<tr>
<td></td>
<td>Highest Expected</td>
<td>503</td>
<td>25.7</td>
</tr>
<tr>
<td>Ethnicity</td>
<td>Caucasian</td>
<td>646</td>
<td>32.9</td>
</tr>
<tr>
<td></td>
<td>African American</td>
<td>692</td>
<td>35.3</td>
</tr>
<tr>
<td></td>
<td>Asian</td>
<td>15</td>
<td>0.8</td>
</tr>
<tr>
<td></td>
<td>Hispanic</td>
<td>608</td>
<td>31.0</td>
</tr>
<tr>
<td>Gender</td>
<td>Male</td>
<td>1014</td>
<td>51.7</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>947</td>
<td>48.3</td>
</tr>
</tbody>
</table>

Total Sample (N=1,961)

Preliminary Analysis

Data Quality

The preliminary data analysis was accomplished before proceeding with the structural equation modeling analysis for the purpose of comprehending the data distribution, the differences between the two samples, and the correlations among the variables within the two samples.

Sample 1. Sample 1 stated with 6,749 cases queried from the electronic medical record. The initial data collected from the EHR included all scheduled procedures; therefore 2,604 non-surgical cases were deleted from the analysis. After removing he cases unrelated to the study aim, 4,145 cases were further assessed for inclusion. Following this, an extensive comparison of the cases resulted in a number of cases being excluded due to systemic missing data issues leaving 2,407 cases. Following the
exclusion of non-surgical cases unrelated to the intended focus of the study as well as cases with systemic missing data, the sample was narrowed to 2,407 individual patient charts. Despite a number of excluded cases the resulting large sample of cases makes it more likely to reject the null hypothesis reducing the likelihood of a Type II error.

A further 565 (23.47%) were deleted from the analysis due to further missing data issues related to the outcome variable, severe postoperative pain. Finally, the variables were assessed for any values outside the range of permissible responses with listwise deletion of any outliers. Total cases retained and included in both the preliminary analysis and the SEM analysis was 1,794. The listwise deletion of cases is represented in Figure 10.

**Sample 2.** Sample 2 started with 4,818 cases and undergoing the same comparisons as conducted with sample 1; cases were removed due to data issues as outlined in Figure 9. The resulting final sample for sample 2 was 1,961 cases.

![Figure 9. Figure depicting listwise removal of cases and final sample size](image-url)
Between Sample Comparison

Comparisons between the independent variables were made to detect significant differences between the means of sample 1 and sample 2. Independent sample t-tests were computed to determine the differences between the continuous variables baseline systolic and diastolic blood pressure, baseline heart rate, preoperative pain, and age. Chi square test of independence was conducted on the categorical variables type of surgery, ethnicity, and gender.

Independent sample t-tests. Results of the independent sample t-tests indicate the following. There was no significant differences in the scores for baseline systolic blood pressure from sample 1 ($M = 127.86$, $SD = 17.12$) and sample 2 ($M = 128.11$, $SD = 16.31$); $t(3,801) = -0.47$, $p = .641$; there is a significant difference between baseline diastolic blood pressure from sample 1 ($M = 69.42$, $SD = 11.33$) and sample 2 ($M = 70.42$, $SD = 10.68$); $t(3,801) = -2.79$, $p = .005$; there is no significant difference between baseline heart rate from sample 1 ($M = 75.90$, $SD = 13.98$) and sample 2 ($M = 75.50$, $SD = 13.71$); $t(3,801) = 0.91$, $p = .362$; there is a significant difference between preoperative pain from sample 1 ($M = 1.28$, $SD = 1.56$) and sample 2 ($M = 1.44$, $SD = 1.60$); $t(3,757) = -3.11$, $p = .002$; and lastly there is a significant difference with age between sample 1 ($M = 56.14$, $SD = 16.81$) and sample 2 ($M = 53.60$, $SD = 16.71$); $t(3,801) = 4.68$, $p < .001$.

Chi square test of independence. Prior to analyzing the data with the chi-square test, the data met the assumptions of being categorical with two or more independent groups. The variables type of surgery (lowest, low, moderate, high, and highest expected pain), ethnicity (Caucasian, African American, Asian, and Hispanic), and gender (male
and female) were tested to compare sample 1 and sample 2 to determine associations in
the two populations.

Type of surgery and expected pain was observed to have a significant association
between sample 1 and sample 2; lowest \( (n=713) \), low \( (n=854) \), moderate \( n=445 \), high
\( (n=889) \), highest \( (n=902) \), \( \chi^2(4) = 19.02, p = .001 \). When looking at ethnicity, no
observed significant association was found between the two samples, Caucasian
\( (n=1,292) \), African American \( (n=1,271) \), Asian \( (n=25) \), and Hispanic \( (n=1,215) \), \( \chi^2(3) = 7.33, p = .062 \). Lastly, gender was also not observed to have any significant association
between both male groups \( (n=1,983) \) and female groups \( (n=1,820) \), \( \chi^2(1, n=1,820) = 0.09, p = .580 \)

**Summary.** Overall comparisons between sample 1 and sample 2 show some
significant and non-significant relationships between the variables. It makes theoretical
sense to find both associations and non-associations between both separate samples
despite the independent nature of the samples. The two samples reflect both a difference
in time points of the collection periods, but also similarities in the patient population
presenting to the hospital and surgical procedures performed.

When looking at the physiological factors, baseline hemodynamic parameters
show no difference between baseline systolic blood pressure and heart rate and a
difference with diastolic blood pressure. It is not apparent the reason for the different
findings between systolic and diastolic blood pressure between both samples but findings
may be due to new evidence of interarm differences in blood pressure readings (Clark,
Taylor, Shore, & Campbell, 2012). In addition differences were found in preoperative
pain and type of surgery as expected. Furthermore, when looking at the frequencies,
distributions, and the descriptive of preoperative pain intensity, it reflects the majority of individuals present to surgery with “no” or “little pain”. Therefore, it is not surprising the significantly relationship between sample 1 and sample 2 in regards to preoperative pain intensity.

When assessing the situational factors (demographics), findings suggest no association in the two samples. It is not known if the difference in physiological and situational data will affect the final validation of the prediction tool but should be considered in interpreting the results.

**Re-Specification And Recoding Of Data**

After dealing with any outliers and missing data issues the data for both sample 1 and sample 2 was respecified. The surgical procedures were recoded into numerical categories following the surgical classification expected pain developed by Janssen et al. (2008) outlined in Appendix A. Gender and ethnicity was also recoded as outlined in chapter 3. Preoperative pain was captured at two separate time points; preoperative pain from the nursing floor prior to transfer to the preoperative holding area presurgery; and the preoperative pain scores from the preholding area immediately preceding surgery. The maximum pain scores using an 11-point-numerical rating score (NRS) from the two time points were used to indicate the preoperative pain score utilized for analysis.

In addition to preoperative pain, postoperative pain was respecified into one variable at the three separate time points, PACU, nursing floor admission postoperatively, and discharge. The postoperative pain specification followed the outcome of severe postoperative pain definition as a NRS ≥ 6.
Pain occurring in the PACU was measured at four separate time points corresponding to the first hour in the post anesthesia care unit (PACU). The raw data captured the postoperative pain intensity scores at admission to the PACU and the 15 minute, 30 minutes, and 45 minute pain assessments. In addition, postoperative pain scores were captured at two separate time points at the nursing assessment occurring at the admission from the patient postoperatively to the general surgical nursing floor as well as at the nursing assessment upon discharge home.

First the four separate postoperative pain scores were recoded categorically into “No Severe Postoperative Pain” indicated by a NRS of 0 to 5 and “Severe Postoperative Pain” indicated by a NRS of 6-10. Following the recoding, the four separate time points were respecified into one combined postoperative pain variable. This follows the same outline described in the study conducted by Kalkman et al. (2003). Likewise the nursing assessment upon admission to the general surgical floor following surgery and the nursing assessment at the time of discharge home was respecified into “No Severe Postoperative Pain” indicated by a NRS of 0 to 5 and “Severe Postoperative Pain” indicated by a NRS of 6-10.

**Defining independent categorical variables.** Prior to path analysis, the categorical variables of type of surgery, gender and ethnicity were coded using the define term in Mplus to create an analysis against a comparison group for interpretation. Type of surgery comparisons consists of 5 different groups: (1) surgeries with the lowest expected pain (reference group) (2) surgeries with low expected pain, (3) surgeries with moderate expected pain, (4) surgeries with high expected pain, and surgeries with the highest expected pain. Gender consisted of male and female groups, with male being the
reference group. Initially the Ethnicity comparisons consisted of 4 groups: (1) Caucasian (reference group), (2) African American, (3) Asian, and (4) Hispanic. Unfortunately, the inclusion of the Asian ethnic as a separate ethnic minority turned out to be problematic due to insufficient cases (n=10), leading to questions about the appropriateness of the analysis for the Asian ethnic group. The small sample size would lack precision and results statistically unreliable. The Asian ethnic group was therefore included into the Caucasian comparison group, leaving 3 groups: (1) Caucasian, (2) African American, and (3) Hispanic. The combined Caucasian/Asian group remained the comparison group.

Assumptions

The assumptions of logistic regression are more relaxed but still need to be considered to avoid any biased parameter estimates. Before analyzing the data in SEM, assessments were conducted to test the assumptions of univariate and multivariate normality, linearity, independence, and homoscedasticity in sample 1. The data from sample 1 was used to analyze the models and create the prediction rule. Sample 2 was not assessed for strict adherence as it is strictly being used as a validation of the developed prediction rule created from sample 1. As mentioned previously, a between sample comparison of the two samples was performed.

Multivariate Normality. Logistic regressions do not need to be multivariate normal. Despite this the assessment of the normality of the data was assessed as it yields a more stable solution. Using SPSS, preliminary results indicated the data was normally distributed for all the variables with the exception of preoperative pain scores. Further assessment of the skewness of the factors, showed a skewness within the acceptable range of 1 to -1 with the exception of preoperative pain, skewness = -8.419. The
substantial skewness of preoperative pain represents a negative skew of the data in both samples. Theoretically this negative skewness is not unexpected as the majority of patients in both samples presenting for surgery have no preoperative pain resulting in a large distribution of the data to the left with a NRS = 0. When assessing the kurtosis, the same findings resonate with all the factors with an excess kurtosis finding with preoperative pain $> 3$, kurtosis $= 70.435$. Despite these violations the logistic regression analysis does not need multivariate normality and therefore of little concern for the analysis.

**Linearity and Multicollinearity.** Although a logistic regression does not need a linear relationship, as the measurement scale of the outcome is dichotomous, those with “no severe postoperative pain” and those with “severe postoperative pain”, linearity of data prevent biased parameter estimation. The difference between the observed variables and the outcome variable is the non-linear log transformation to the odds ratio.

To prevent bias the linearity was assessed for sample 1 for each variable in relation to each of the three dependent variables through SPSS using the data curve estimation. The data curve estimations for the data highlighted the following linearity assumption findings. The baseline heart rate, preoperative pain intensity scores, type of surgical procedure, ethnicity, age, and sex variables and the postoperative pain intensity scores relationship were all sufficiently linear. Both the systolic and diastolic baseline blood pressures and postoperative pain intensity scores relationships were insufficiently linear.

The baseline diastolic blood pressure, heart rate, preoperative pain intensity scores, type of surgical procedure, ethnicity, and age variables and the postoperative pain
intensity scores occurring on the surgical floor postoperative show a sufficiently linear relationship. The baseline systolic blood pressure and sex and postoperative pain intensity scores on the surgical floor postoperatively show an insufficiently linear relationship.

The baseline heart rate, preoperative pain intensity scores, and type of surgical procedure variables and the postoperative pain intensity scores at the time of discharge showed a sufficiently linear relationship. The systolic, diastolic baseline blood pressures, ethnicity, age, and sex and postoperative pain intensity scores showed an insufficiently linear relationship.

The nonlinear relationships uncovered in the curve estimation highlight a limitation of the analysis. A consistent finding throughout the postoperative pain intensity time points was the nonlinearity of the baseline blood pressure measurements.

Again using SPSS, the multiple linear model was tested for sample 1 using all the factors with sex as the dependent variable, results show the Durbin-Watson d = 1.826, which is between the two critical values of 1.5 < d < 2 (Kline, 2011). The F-test is highly significant, thus it is assumed there is a linear relationship between the variables, $R^2 = .056$, $F (7, 1786) = 15.11, p < .001$. The multicollinearity was assessed in the linear regression model showing tolerance > 0.1 and a VIF < 3 for all the variables (Kline, 2011). This process was repeated with preoperative pain intensity as the dependent variable and the results show the Durbin-Watson d = 1.946 with a highly significant F-test, $R^2 = .017$, $F (7, 1786) = 4.32, p < .001$, thus it further assumes there is a linear relationship between the variables. Again the multicollinearity was assessed in the linear regression model showing tolerance > 0.1 and a VIF < 3 for all the variables.
This process was repeated one last time with baseline blood pressure as the dependent variable and the results show the Durbin-Watson $d = 1.772$ with a highly significant F-test, $R^2 = .328, F(7, 1,786) = 124.48, p < .001$. Again the multicollinearity was assessed in the linear regression model showing tolerance $> 0.1$ and a VIF $< 3$ for all the variables. Overall, the linear regression analyses found no issues with multicollinearity.

In addition, unidimensionality of the factors was assessed through the use of Cronbach’s alpha and showed no factors to be greater than .7.

**Independence.** Although independence of the cases cannot be assessed statistically or graphically, the collection of data was independent. Despite the limitations in assessing independence, in an attempt to insure independence of the cases, the scatter plots of the residuals were analyzed and the random appearance of the plots suggests independence.

**Homoscedasticity.** Homoscedasticity was not assessed because the outcome variables are all bimodal, “no severe postoperative pain” and “severe postoperative pain”, resulting in heteroscedastic relationship between the residuals and the values of each variable.

**Assessment of Measurement Model**

Using the multivariate model, the physiological factor and situational factor measurement model analysis were conducted to measure the latent construct of both the physiological and situational factors. Using sample 1, the sample size for all tests of the measurement model was $n = 1,794$. Before assessing the model fit of the measurement models, missing data were handled using the full information maximum likelihood
(FIML) imputation method. Estimation was initially conducted in maximum likelihood (ML) imputation but converted to the mean and variance-adjusted weighted least squares (WLSMV) estimator due to categorical variables for the model fit statistics. The WLSMV does not assume a normal distribution of variables and provides the best possibility for model analysis for categorical data (Kline, 2011).

Based on the assessment of each measurement model fit, indicated modifications were conducted in an attempt to improve the measurement model fit. There were two latent variables and 8 factors of those latent constructs for a total of 17 parameters to be estimated.

**Original Assessment of Measurement Model**

In the present study, the two separate measurement model goodness-of-fit indices were assessed using the chi-squared non-significance χ² testing, root mean square error of approximation (RMSEA), and comparative fit index (CFI).

**Situational factor model.** Theory suggested that a single latent factor explained the scores of the measures ethnicity, age, and gender. A confirmatory factor analysis (CFA) was used to test this model and the original measurement model passed the goodness-of-fit indices. The chi-squared statistic was accepted (χ² = 3.633, df = 3, p = .304) but when assessing the other fit indices, the model was saturated making the model fit indices not informative (see Table 5). Additional analysis of the results indicates ethnicity (B = -0.021, S.E. = 0.232, p = .928), age (B = 11.202, S.E. = 122.942, p = .927), and gender (B = -0.021, S.E. = 0.232, p = .928), failed to significantly load on the latent situational factor. Because of the differences in measurement scales it is difficult to compare the validity of the different predictors. Therefore, the standardized loadings
were examined and reflected the same nonsignificant findings for all three factors. Overall, the latent variable failed to explain variance in the indicators.

**Physiological factor model.** Theory suggested that a single latent factor explained the scores of the measures baseline blood pressure, baseline heart rate, preoperative pain rating, and type of surgical procedure. Using CFA to test this model, the original measurement model failed to pass the goodness-of-fit indices. The chi-squared statistic was rejected ($\chi^2 = 399.960, df = 10, p < .001$). The other fit indices suggested inadequate fit of the measurement model to the data (RMSEA = .059, CFI = .919), see Table 5.

Based on the assessment of each measurement model's fit to the data, approximate re-specification was conducted to improve the model fit as the models failed to meet the exact test fit. The following covariance between errors for baseline heart rate and baseline diastolic blood pressure, as well as between type of surgical procedure and baseline diastolic blood pressure, were added to the re-estimated model. Model fit of the re-specified model was acceptable. The chi-squared statistic was rejected, ($\chi^2 = 399.960, df = 10, p < .001$) but the other fit indices were acceptable (RMSEA = .045, CFI = .972), see Table 6. Factor loading for the observed variable show two of the items load significantly on the latent variable: baseline systolic blood pressure ($B = 11.776, S.E. = 5.910, p = .046, 95\% CI [0.193, 23.359]$), baseline diastolic blood pressure ($B = 7.968, S.E. = 3.987, p = .046, 95\% CI [0.154, 15.782]$). Three items were nonsignificant: baseline heart rate ($B = 0.799, S.E. = 0.605, p = .187, 95\% CI [-0.386, 2.357]$), preoperative pain ($B = -0.052, S.E. = 0.048, p = .278, 95\% CI [-0.145, 0.042]$), and type of surgical procedure ($B = 0.031, S.E. = 0.039, p = .433, 95\% CI [-0.046, 0.108]$). The errors in baseline heart rate
and baseline diastolic blood pressure were not significantly correlated \((B = 13.201, \text{S.E.} = 7.385, p = .074, 95\% \text{CI } [-1.274, 27.676])\). The errors in type of surgical procedure and baseline diastolic blood pressure were significantly correlated \((B = -1.211, \text{S.E.} = 0.374, p = .001, 95\% \text{CI } [-1.945, -0.477])\). Again, because of the differences in measurement scales, the standardized loadings were examined and reflected the same nonsignificant findings for all five factors.

The latent physiological factor explained 47.3\% of the variation in baseline systolic blood pressure, 49.9\% of the variation in baseline diastolic blood pressure, 0.3\% of the variation in baseline heart rate, 0.1\% in the variation in preoperative pain, and 0.1\% in the variation in type of surgical procedure.

Table 6

Summary of Goodness of Fit Indices for Original and Modified Measurement Models

<table>
<thead>
<tr>
<th>Model</th>
<th>(X^2)</th>
<th>(df)</th>
<th>RMSEA</th>
<th>CFI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Situational Factor</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Original</td>
<td>3.633</td>
<td>3</td>
<td>.000</td>
<td>1.0</td>
</tr>
<tr>
<td>Physiological Factor</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Original</td>
<td>399.960**</td>
<td>10</td>
<td>.059</td>
<td>.919</td>
</tr>
<tr>
<td>Modified</td>
<td>399.960**</td>
<td>10</td>
<td>.045</td>
<td>.972</td>
</tr>
</tbody>
</table>

\*p < .05  
\**p < .001

**Full measurement model.** The parameters for the full measurement model, the combined situational and physiological models was not assessed due to the inability of the situational factor latent model to pass the criteria for analysis. An attempt to measure a structural model with ethnicity, age, and gender regressed directly on postoperative pain with the physiological model could not be computed due to the latent physiological factor
being not positive definite. The number of iterations was increased to 50,000 with a continued inability to compute. Due to the difficulty in estimating, the model is ill defined and not to be trusted. Creating over-complexity of the model for the sole purpose of model fit will not test a particular hypothesis. Outside this analysis, the model has no intrinsic value and since the aim of the research is to determine the predictability of the observed factors for the development of severe postoperative pain and not test the theory of unpleasant symptoms, the measurement models were removed and a path analysis was conducted to look at the individual factors. Furthermore, failure to identify the full measurement model resulted in the data not being trusted for further analysis using the theoretical construct.

The resulting theoretical construct was reviewed resulting in the elimination of the latent variables to analyze the individual factors ability to predict severe postoperative pain and not testing of the theoretical model. The resulting changes in the theoretical model did require a change in aim 1 of the research study. The initial aim to assess the relationship, as depicted by the modified model for the theory of unpleasant symptoms, between preoperative predictors and the development of severe postoperative pain was changed to assess the relationship of the individual predictors and the development of severe postoperative pain. Consequently, the analysis was altered to remove the measurement component and perform three separate structural path analyses to determine the individual variable relationships on postoperative pain at the three separate time points (PACU, nursing shift assessment on admission postoperatively, and discharge).
Assessment of Path Analysis/Structural Model

After an inability to establishing an acceptable measurement model, data path analysis model was used to analyze the relationship between the observed variables (baseline blood pressure, baseline heart rate, preoperative pain rating, type of surgical procedure, age, gender, and ethnicity) and the outcome variable “Severe Postoperative Pain.” Three separate path analysis models, one for each of the three separate time points, was used as depicted in Figure 10, 11, and 12. For the path models the analysis was conducted in maximum likelihood (ML) imputation. The outcome variable, severe postoperative pain, is a dichotomous variable with outcome of “no severe postoperative pain” and “severe postoperative pain” as the responses. Due to the binary nature, SEM transforms the binary outcome into a logit variable creating an odds ratio of the outcome for each regressed predictor (Kline, 2011).

Sample Correlations

Sample correlations between the measured variables were analyzed and are presented in Table 7. No large associations were discovered; the highest association was that between systolic blood pressure and diastolic blood pressure. The variables originally were measured together as blood pressure and separated into systolic and diastolic readings for the analysis. When placed in the path analysis as being correlated with one another, no improvement was found in the path model when utilizing the log likelihood.
<table>
<thead>
<tr>
<th></th>
<th>Syst BP</th>
<th>Diast BP</th>
<th>Heart Rate</th>
<th>Preop Pain</th>
<th>Age</th>
<th>Low</th>
<th>Moderate</th>
<th>High</th>
<th>Highest</th>
<th>African American</th>
<th>Hispanic</th>
<th>Female</th>
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<tr>
<td>Syst BP</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Diast BP</td>
<td>.483</td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>Heart Rate</td>
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<td>.125</td>
<td>1</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preop Pain</td>
<td>.043</td>
<td>-.004</td>
<td>.007</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>.263</td>
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<td>.123</td>
<td>.006</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>.009</td>
<td>.002</td>
<td>.060</td>
<td>.065</td>
<td>.055</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>.038</td>
<td>-.027</td>
<td>.029</td>
<td>.078</td>
<td>.029</td>
<td>.207</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>High</td>
<td>-.017</td>
<td>-.057</td>
<td>.010</td>
<td>.125</td>
<td>.030</td>
<td>.322</td>
<td>-.215</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Highest</td>
<td>.005</td>
<td>-.013</td>
<td>.102</td>
<td>.018</td>
<td>.040</td>
<td>.299</td>
<td>-.200</td>
<td>.310</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>African American</td>
<td>.007</td>
<td>.001</td>
<td>.108</td>
<td>.041</td>
<td>.097</td>
<td>.104</td>
<td>.010</td>
<td>.025</td>
<td>-.082</td>
<td>1</td>
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<td>Hispanic</td>
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<td>.016</td>
<td>.062</td>
<td>.044</td>
<td>.036</td>
<td>.026</td>
<td>.040</td>
<td>.039</td>
<td>.030</td>
<td>-.477</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>.178</td>
<td>-.181</td>
<td>.013</td>
<td>.006</td>
<td>.044</td>
<td>.038</td>
<td>-.024</td>
<td>.019</td>
<td>.104</td>
<td>-.026</td>
<td>.005</td>
<td>1</td>
</tr>
</tbody>
</table>

Note. Syst BP = Baseline systolic blood pressure  
Diast BP = Baseline diastolic blood pressure
Figure 10. Path Model 1. Path diagram depicting the structural relations for the preoperative predictors of severe postoperative pain during the first hour in PACU.
Figure 11. Path Model 2. Path diagram depicting the structural relations for the preoperative predictors of severe postoperative pain upon admission to the nursing floor postoperatively.
Figure 12. Path Model 3. Path diagram depicting the structural relations for the preoperative predictors of severe postoperative pain at discharge.
Findings Related to Study Aims and Research Questions' Results

The central aim of this research was the relationship between the measured predictor factors on the observed factor of severe postoperative pain. Findings are addressed by estimating separate regressions for each dependent variable relationship as outlined in each specific aim and subsequent research questions.

**Modified Aim 1**

Aim 1 assesses the relationship between preoperative predictors and the development of severe postoperative pain. The following three questions focus on the observed outcome variable at three separate time points and the relationship between each measured variable on the outcome of severe postoperative pain.

The parameter estimates represent the unstandardized parameter estimates; the reported $p$-values represent the unstandardized parameters significance. The exponentiated coefficient, odds ratio, for each variable is also included in the corresponding Tables. The reference categories for categorical predictors are lowest expected pain, male, and Caucasian. Unstandardized and standardized regression coefficients are depicted in Tables along with the odds ratios and significance for each variable.

**Modified Research Question for Aim 1**

**Question 1: postoperative pain in PACU.**

a. Is there a significant relationship between the preoperative predictors and the development of severe postoperative pain in the PACU?

In path 1, the observed variables of preoperative pain, baseline blood pressure, baseline heart rate, type of surgery, age, gender, and ethnicity were positioned to test the
relationship on the outcome of severe postoperative pain occurring during the first hour in the PACU. Table 8 presents the parameter estimates (regression coefficients) for the direct effects predicting severe postoperative pain in the PACU using a logistic regression. The correlations between all the variables are positive, with the exception of age, which shows an inverse relationship between age and postoperative pain.
Table 8

Model 1. To preoperatively predict the occurrence of severe postoperative pain (NRS≥6) within the first hour of PACU

<table>
<thead>
<tr>
<th>Variable</th>
<th>Unstandardized Estimate (b)</th>
<th>Standardized Estimate (B)</th>
<th>OR*</th>
<th>p-value&lt;sup&gt;c&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Syst. BP</td>
<td>0.005</td>
<td>0.043</td>
<td>1.005</td>
<td>.211</td>
</tr>
<tr>
<td>Diast. BP</td>
<td>0.006</td>
<td>0.034</td>
<td>1.006</td>
<td>.321</td>
</tr>
<tr>
<td><strong>Heart rate</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.008</td>
<td>0.059</td>
<td>1.008</td>
<td>.035</td>
</tr>
<tr>
<td>Preoperative pain&lt;sup&gt;b&lt;/sup&gt;</td>
<td>0.060</td>
<td>0.047</td>
<td>1.061</td>
<td>.086</td>
</tr>
<tr>
<td><strong>Type of surgery</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lowest Pain</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low Pain</td>
<td>0.504</td>
<td>0.108</td>
<td>1.655</td>
<td>.030</td>
</tr>
<tr>
<td>Moderate Pain</td>
<td>-0.325</td>
<td>0.156</td>
<td>2.564</td>
<td>&lt; .001</td>
</tr>
<tr>
<td>High Pain</td>
<td>-0.089</td>
<td>0.337</td>
<td>4.680</td>
<td>&lt; .001</td>
</tr>
<tr>
<td>Highest Pain</td>
<td>1.904</td>
<td>0.400</td>
<td>6.710</td>
<td>&lt; .001</td>
</tr>
<tr>
<td>Age (years)</td>
<td>-0.010</td>
<td>-0.080</td>
<td>0.990</td>
<td>.008</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>0.251</td>
<td>0.062</td>
<td>1.279</td>
<td>.032</td>
</tr>
<tr>
<td><strong>Ethnicity</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caucasian/Asian</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>African American</td>
<td>0.275</td>
<td>0.059</td>
<td>1.283</td>
<td>.080</td>
</tr>
<tr>
<td><strong>Hispanic</strong></td>
<td>0.358</td>
<td>0.079</td>
<td>1.394</td>
<td>.015</td>
</tr>
</tbody>
</table>

<sup>a</sup> Reference group  
<sup>b</sup> NRS (0-10)  
<sup>c</sup> Unstandardized  
*Odds ratio greater than 1 indicates higher odds of severe postoperative pain
**Significant effects.** The following significant relationships were found in the continuous variables. For every 1 unit increase in heart rate, the log odds increased by 0.008 for severe postoperative pain resulted in a 1.008 times greater odds of developing severe postoperative pain versus not developing severe postoperative pain ($b=0.008$, S.E. $=0.004$, $p<.035$, OR $=1.008$). For every 1 unit increase in age, the log odds decreased by 0.010 resulting in a 0.990 times lesser odds of developing severe postoperative pain ($b=-0.010$, S.E. $=0.004$, $p=.004$, OR $=0.982$).

For the categorical predictors, the following results were found. Type of surgery resulted in a significant difference between the reference group, low expected pain, and the low expected, moderate expected, high expected, and highest expected pain groups. For the low group, a 1 unit increase in low expected pain resulted in the log odds increased by 0.008 for severe postoperative pain resulting in a 1.008 times greater odds of developing severe postoperative pain versus not developing severe postoperative pain compared to the lowest expected pain group ($b=0.504$, S.E. $=0.231$, $p=.030$, OR $=1.655$). For the moderate group, a 1 unit increase resulted in the log odds increased by 0.942 for severe postoperative pain resulting in a 2.564 times greater odds of developing severe postoperative pain versus not developing severe postoperative pain compared to the lowest expected pain group ($b=0.942$, S.E. $=0.250$, $p<.001$, OR $=2.564$). For the high expected pain group, a 1 unit increase resulted in the log odds increased by 1.543 for severe postoperative pain resulting in a 4.680 times greater odds of developing severe postoperative pain versus not developing severe postoperative pain compared to the lowest expected pain group ($b=1.543$, S.E. $=0.215$, $p<.001$, OR $=4.680$). For the highest expected pain group, a 1 unit increase in expected pain resulted in the log odds
increased by 1.904 for severe postoperative pain resulting in a 6.710 times greater odds of developing severe postoperative pain versus not developing severe postoperative pain ($b = 1.904, \text{S.E.} = 0.216, p < .001, \text{OR} = 6.710$).

Gender resulted in a significant difference in severe postoperative pain depending on if the individual was male or female. Being female resulted in a 0.246 increase in the log odds of severe pain compared to being male with a 1.279 times greater odds of developing severe postoperative pain ($b = 0.246, \text{S.E.} = 0.114, p = .032, \text{OR} = 1.279$).

Ethnicity only showed a significant difference in the Hispanic ethnic group, which resulted in a 0.332 increase in the log odds of severe pain compared to Caucasians with a 1.394 times greater odds of developing severe postoperative pain ($b = 0.332, \text{S.E.} = 0.136, p = .015, \text{OR} = 1.394$).

When looking at the coefficient of determination, R-squared, path model 1 explained 16.1% of the variance for severe pain in the first hour of the PACU (0.161, S.E. = 0.022, $p < .001$).

**Question 2: postoperative pain upon admission to the nursing floor postoperatively.**

b. Is there a significant relationship between the preoperative predictors and the development of severe postoperative pain upon admission to the nursing floor postoperatively?

The observed variables of preoperative pain, baseline blood pressure, baseline heart rate, type of surgery, age, gender, and ethnicity were positioned to test the relationship on the outcome of severe postoperative pain occurring during the initial assessment of the patient upon admission to the nursing floor postoperative. Table 9 presents the parameter estimates (regression coefficients) for the direct effects predicting
severe postoperative pain in the PACU using a logistic regression. Consistent with Model 1 results, the correlations between all the variables are positive, with the exception of age, which shows an inverse relationship between age and postoperative pain.

**Significant Effects.** Only significant relationships found were, baseline heart rate, preoperative pain, age, and high expected surgical pain. All the significant findings in Model 2 were found in Model 1 with the addition of preoperative pain now being significant. For every 1 unit increase in heart rate, the log odds increased by 0.012 for severe postoperative pain resulted in a 1.012 times greater odds of developing severe postoperative pain versus not developing severe postoperative pain ($b = 0.012$, S.E. = 0.006, $p < .043$, OR = 1.012). For every 1 unit increase in preoperative pain a 0.186 increase in the log odds of severe postoperative pain resulted in a 1.204 times greater odds of developing severe postoperative pain ($b = 0.186$, S.E. = 0.049, $p < .001$, OR = 1.204). For every 1 unit increase in age a 0.019 decrease in in the log odds of severe postoperative pain resulted in a 0.981 times odds of developing severe postoperative pain ($b = -0.019$, S.E. = 0.006, $p = .001$, OR = 0.981). Lastly, for the high expected pain group, a 1 unit increase resulted in the log odds increased by 0.340 for severe postoperative pain resulting in a 1.405 times greater odds of developing severe postoperative pain versus not developing severe postoperative pain compared to the lowest expected pain group ($b = 0.340$, S.E. = 0.100, $p = .001$, OR = 1.405).

The path model 2 explained 15.6% of the variance for severe pain upon admission to the nursing floor postoperatively ($0.156$, S.E. = 0.030, $p < .001$).
Table 9

Model 2. To preoperatively predict the occurrence of severe postoperative pain upon admission to the nursing floor postoperative

<table>
<thead>
<tr>
<th>Variable</th>
<th>Unstandardized Estimate (b)</th>
<th>Standardized Estimate (B)</th>
<th>OR*</th>
<th>p-value&lt;sup&gt;c&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Syst. BP</td>
<td>0.000</td>
<td>-0.001</td>
<td>1.000</td>
<td>.985</td>
</tr>
<tr>
<td>Diast. BP</td>
<td>0.001</td>
<td>0.005</td>
<td>1.001</td>
<td>.925</td>
</tr>
<tr>
<td>Heart rate</td>
<td>0.012</td>
<td>0.089</td>
<td>1.012</td>
<td>.043</td>
</tr>
<tr>
<td><strong>Preoperative pain</strong>&lt;sup&gt;b&lt;/sup&gt;</td>
<td><strong>0.186</strong></td>
<td><strong>0.150</strong></td>
<td><strong>1.204</strong></td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

**Type of surgery**

<table>
<thead>
<tr>
<th>Lowest Pain</th>
<th>a</th>
<th>a</th>
<th>a</th>
<th>a</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low Pain</td>
<td>0.089</td>
<td>0.036</td>
<td>1.093</td>
<td>.689</td>
</tr>
<tr>
<td>Moderate Pain</td>
<td>0.254</td>
<td>0.129</td>
<td>1.289</td>
<td>.084</td>
</tr>
<tr>
<td><strong>High Pain</strong></td>
<td><strong>0.340</strong></td>
<td><strong>0.309</strong></td>
<td><strong>1.405</strong></td>
<td><strong>.001</strong></td>
</tr>
<tr>
<td>Highest Pain</td>
<td>0.019</td>
<td>0.023</td>
<td>1.020</td>
<td>.817</td>
</tr>
</tbody>
</table>

| Age (years)                | **-0.019**                   | **-0.051**                  | **0.981** | **.001**          |

<table>
<thead>
<tr>
<th>Gender</th>
<th>a</th>
<th>a</th>
<th>a</th>
<th>a</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>0.049</td>
<td>0.012</td>
<td>1.050</td>
<td>.784</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ethnicity</th>
<th>a</th>
<th>a</th>
<th>a</th>
<th>a</th>
</tr>
</thead>
<tbody>
<tr>
<td>Caucasian/Asian</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>African</td>
<td>0.227</td>
<td>0.051</td>
<td>1.255</td>
<td>.322</td>
</tr>
<tr>
<td>American</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hispanic</td>
<td>0.187</td>
<td>0.046</td>
<td>1.206</td>
<td>.374</td>
</tr>
</tbody>
</table>

<sup>a</sup> Reference group  
<sup>b</sup> NRS (0-10)  
<sup>c</sup> Unstandardized  
*Odds ratio greater than 1 indicates higher odds of severe postoperative pain
**Question 3: postoperative pain at discharge.**

c. Is there a significant relationship between the preoperative predictors and the development of severe postoperative pain at the time of discharge from the hospital?

Lastly, the observed variables of preoperative pain, baseline blood pressure, baseline heart rate, type of surgery, age, gender, and ethnicity were positioned to test the relationship on the outcome of severe postoperative pain occurring during the discharge assessment. Table 10 outlines the unstandardized, standardized coefficients, odds ratio, and significance for each variable.

The significant effects of the predicting variables to the dependent outcome variable were baseline diastolic blood pressure, heart rate, and low to highest expected surgical pain. The correlations are all positive with postoperative pain at the time of discharge.

**Significant Effects.** The significant relationship of baseline diastolic blood pressure shows, for every 1 unit increase in diastolic blood pressure, the log odds increased by 0.058 for severe postoperative pain resulted in a 1.060 times greater odds of developing severe postoperative pain versus not developing severe postoperative pain ($b = 0.058$, S.E. = 0.026, $p < .026$, OR = 1.060). The significant relationship of baseline heart rate shows, for every 1 unit increase in heart rate, the log odds increased by 0.036 for severe postoperative pain resulted in a 1.036 times greater odds of developing severe postoperative pain versus not developing severe postoperative pain ($b = 0.036$, S.E. = 0.016, $p < .022$, OR = 1.036). Regarding expected surgical pain; for every 1 unit increase in low expected pain, the log odds increases by 11.161 ($b = 11.161$, S.E. = 2.613, $p <$
for every 1 unit increase in moderate expected pain, the log odds increases by 11.687 ($b = 11.687$, S.E. = 2.603, $p < .001$); for every 1 unit increase in high expected pain, the log odds increases by 12.460 ($b = 12.460$, S.E. = 2.521, $p < .001$); for every 1 unit increase in highest expected pain, the log odds increases by 11.768 ($b = 11.768$, S.E. = 2.538, $p < .001$).

The path model 3 explained 85.7% of the variance for severe pain at the time of discharge ($0.857$, S.E. = 0.047, $p < .001$).
Table 10

Model 3. To preoperatively predict the occurrence of severe postoperative pain (NRS≥6) occurring during the discharge assessment

<table>
<thead>
<tr>
<th>Variable</th>
<th>Unstandardized Estimate (b)</th>
<th>Standardized Estimate (B)</th>
<th>OR*</th>
<th>p-value&lt;sup&gt;c&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Syst. BP</td>
<td>-0.019</td>
<td>-0.065</td>
<td>0.981</td>
<td>.288</td>
</tr>
<tr>
<td>Diast. BP</td>
<td>0.058</td>
<td>0.135</td>
<td>1.060</td>
<td>.026</td>
</tr>
<tr>
<td>Heart rate</td>
<td>0.036</td>
<td>0.110</td>
<td>1.036</td>
<td>.022</td>
</tr>
<tr>
<td>Preoperative pain&lt;sup&gt;b&lt;/sup&gt;</td>
<td>0.195</td>
<td>0.065</td>
<td>1.216</td>
<td>.078</td>
</tr>
<tr>
<td><strong>Type of surgery</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lowest Pain</td>
<td>a</td>
<td>a</td>
<td>a</td>
<td>a</td>
</tr>
<tr>
<td>Low Pain</td>
<td>11.161</td>
<td>0.974</td>
<td>70360</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Moderate Pain</td>
<td>11.687</td>
<td>0.786</td>
<td>***</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>High Pain</td>
<td>12.460</td>
<td>1.072</td>
<td>***</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Highest Pain</td>
<td>11.768</td>
<td>1.110</td>
<td>***</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Age (years)</td>
<td>-0.009</td>
<td>-0.031</td>
<td>0.991</td>
<td>.544</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>a</td>
<td>a</td>
<td>a</td>
<td>a</td>
</tr>
<tr>
<td>Female</td>
<td>0.741</td>
<td>0.077</td>
<td>2.098</td>
<td>.121</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caucasian/Asian</td>
<td>a</td>
<td>a</td>
<td>a</td>
<td>a</td>
</tr>
<tr>
<td>African American</td>
<td>0.710</td>
<td>0.064</td>
<td>2.034</td>
<td>.210</td>
</tr>
<tr>
<td>Hispanic</td>
<td>-0.299</td>
<td>-0.030</td>
<td>0.741</td>
<td>.607</td>
</tr>
</tbody>
</table>

<sup>a</sup> Reference group  
<sup>b</sup> NRS (0-10)  
<sup>c</sup> Unstandardized  
*Odds ratio greater than 1 indicates higher odds of severe postoperative pain  
*** Not reported in Mplus analysis
Follow-up Analysis: Postoperative Day One Path

The three path models uncovered some similarities and some differences between the three separate time points for the assessment of severe postoperative pain. Due to the findings, a fourth Model was analyzed to look at severe pain on postoperative day one (POD 1), a common assessment interval in postoperative pain. Looking at pain on POD 1 is consistent with research conducted by Kinjo et al. (2012). The researchers looked at predictors for postoperative pain on POD 1 using a path analysis to determine any associations between the predictors and postoperative pain. In light of the multiple time points within the POD 1 period, the creation of a POD1 model was accomplished by combining the outcome of severe postoperative pain in the PACU with severe pain upon admission to the nursing floor. The max scores of both created the new outcome variable postoperative day 1 pain (POD1Pain). Analysis was carried out in Mplus following the same format as for the other model path analyses. The observed variables of preoperative pain, baseline blood pressure, baseline heart rate, type of surgery, age, gender, and ethnicity were positioned to test the relationship on the outcome of severe postoperative pain on POD 1.

An overview of the standardized obtained is shown in Figure 13. Table 11 presents the parameter estimates (regression coefficients) for the direct effects predicting severe postoperative pain on POD 1 using a logistic regression. Consistent with Model 1 results, the correlations between all the variables are positive; with the exception of age continuing to shows an inverse relationship between age and postoperative pain. The significant effects of the predicting variables to the dependent outcome variable of severe pain on POD 1 were baseline heart rate, preoperative pain, age, low to highest expected
surgical pain, Hispanic, and female. Furthermore, Model 4 explained 18% of the variance for severe pain on POD 1 (0.180, S.E. = 0.022, \( p < .001 \)).

Table 11

Model 4. To preoperatively predict the occurrence of severe postoperative pain on POD 1

<table>
<thead>
<tr>
<th>Variable</th>
<th>Unstandardized Estimate (b)</th>
<th>Standardized Estimate (B)</th>
<th>OR*</th>
<th>( p )-value(^c)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Syst. BP</td>
<td>0.005</td>
<td>0.046</td>
<td>1.005</td>
<td>.167</td>
</tr>
<tr>
<td>Diast. BP</td>
<td>0.001</td>
<td>0.005</td>
<td>1.001</td>
<td>.885</td>
</tr>
<tr>
<td>Heart rate</td>
<td>0.009</td>
<td>0.063</td>
<td>1.009</td>
<td>.021</td>
</tr>
<tr>
<td>Preoperative pain(^b)</td>
<td>0.110</td>
<td>0.085</td>
<td>1.116</td>
<td>.002</td>
</tr>
<tr>
<td>Type of surgery</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lowest Pain</td>
<td>a</td>
<td>a</td>
<td>a</td>
<td>a</td>
</tr>
<tr>
<td>Low Pain</td>
<td>0.624</td>
<td>0.132</td>
<td>1.866</td>
<td>.005</td>
</tr>
<tr>
<td>Moderate Pain</td>
<td>1.181</td>
<td>0.193</td>
<td>3.257</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>High Pain</td>
<td>1.758</td>
<td>0.380</td>
<td>5.802</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Highest Pain</td>
<td>1.936</td>
<td>0.403</td>
<td>6.934</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Age (years)</td>
<td>-0.012</td>
<td>-0.096</td>
<td>0.988</td>
<td>.001</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>a</td>
<td>a</td>
<td>a</td>
<td>a</td>
</tr>
<tr>
<td>Female</td>
<td>0.260</td>
<td>0.065</td>
<td>1.297</td>
<td>.019</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caucasian/Asian</td>
<td>a</td>
<td>a</td>
<td>a</td>
<td>a</td>
</tr>
<tr>
<td>African American</td>
<td>0.181</td>
<td>0.042</td>
<td>1.199</td>
<td>.189</td>
</tr>
<tr>
<td>Hispanic</td>
<td>0.384</td>
<td>0.090</td>
<td>1.468</td>
<td>.004</td>
</tr>
</tbody>
</table>

\(^a\) Reference group  
\(^b\) NRS (0-10)  
\(^c\) Unstandardized  

*Odds ratio greater than 1 indicates higher odds of severe postoperative pain
Figure 13. Model 4 Path Coefficients

Note. Path coefficients are standardized. * Statistically significant.
Model Comparison

The new models ability to discriminate between patients with no severe postoperative pain and patients with severe postoperative pain was estimated by the receiver operating characteristic curve (ROC). The ROC is a single index for measuring the performance of the prediction rule with a larger index indicating a better overall performance of the ability to correctly identify in this study severe pain and non-severe pain. The closer the ROC value is to 1 the more reliable the test is in distinguishes between the individuals who have the outcome. All ROC curve analysis was conducted with SPSS using an empirical non-parametric approach, which does not require any distribution pattern of the test values (Kumar & Indrayan, 2011).

A comparison between Model 1 and Model 4 was conducted to determine the better prediction measurement test. The initial model 1 with the all four significant factors yielded an ROC area of 0.703 (95% confidence interval [CI] 0.677-0.730, \( p < .001 \)). The combined POD 1 model, model 4, with all 9 significant factors yielded an improved ROC area of 0.714 (95% CI 0.689-0.739, \( p < .001 \)) and improving the predictability of the POD 1 model, see Figure 14. Likewise, the area under the curve was significantly different in both models from 0.5 indicating the logistic regression classifies the groups significantly better than by chance. When assessing the ROC values, the larger value of 0.714 indicates stronger evidence for the positive state of severe postoperative pain and has a fair balance between sensitivity and specificity. In addition to an improved model fit, Model 4 is theoretically more pleasing. Therefore Model 4 was utilized as the final prediction model to create the prediction equation outlined in question two.
Figure 14. Graph of sensitivity and specificity of Model to identify severe postoperative pain as measured by the prediction equation.

The threshold for predicting those who will develop severe postoperative pain was created to determine those who develop “severe postoperative pain” and those who have “no severe postoperative pain”. Using the Youden index, a cutoff value of 0.20 was chosen. The optimal cut point of 0.20 resulted in a ROC determined sensitivity of 80% and a specificity of 54.4% to determine severe postoperative pain on POD 1.

Depending on the desire to prevent undertreatment or the prevention of overtreatment, two separate cut points allow for alternative thresholds for predicting individuals at risk for severe postoperative pain. Even though the first choice for a cutoff
value is that value corresponding to the optimal point, in some instances it may be more important to maximize sensitivity, not minimize specificity. The following cut points reflect a few alternate sensitivities and specificities. Using a lower cutoff value of 0.14 resulted in a sensitivity of 89.6% and a specificity of 30.7% to determine severe postoperative pain on POD 1. Alternately a higher cutoff score of 0.33 resulted in a sensitivity of 61% and a specificity of 70%.

The final prediction equation, Figure 15, included baseline heart rate, preoperative pain intensity, age, low through highest expected surgical pain, Hispanics, and females as increasing the risk of severe postoperative pain. The validation of the prediction equation was accomplished through an independent validation sample and explained under Aim 2.

Predicted Severe Postoperative Pain Value = -3.197 + (0.005*Baseline Heart Rate) + (0.110*Preoperative Pain) – (0.012*Age) + (0.624*Low Expected Pain) + (1.181*Moderate Expected Pain) + (01.758*High Expected Pain) + (1.936*Highest Expected Pain) + (0.384*Hispanic) + (0.260*Female)

Figure 15. Prediction Equation for Severe Pain occurring ON POD 1

**Modified Aim 2**

Use the resulting prediction equation from AIM 1 to validate the prediction tool for clinical practice using an independent validation sample.
Modified Research Question for Aim 2

To what extent do the observed factors predict severe postoperative pain?

To validate the prediction rules ability to reliably predict severe postoperative pain, the prediction rule was used to calculate predicted severe postoperative pain and compared to actual observed postoperative pain in an independent validation sample, sample 2. To assess the tools sensitivity and specificity for the risk of developing severe postoperative pain, the cutoff score of 0.2 and alternative cutoff score of 0.14 were chosen for the validation. Both cut points are based on the ROC curve from Model 4.

In an attempt to avoid any verification bias, the same de-identified data, collected from the EHR, was utilized removing any constraints. Using a sample of all patients presenting for surgery during the collection period further prevents any selection bias or over and under estimation of the sensitivity and specificity of the tool. For example, by not using the whole sample of individuals presenting for surgery and including only those individuals from the higher expected pain surgical classification, an over estimation of the sensitivity of the prediction equation would occur.

Predicting factor values from sample 2 was analyzed in relation to the dichotomous pain score for POD 1 by using the receiver operating character (ROC) curve. The initial sample of 1,961 cases was initially examined but 21 cases were excluded from the analysis due to missing values for preoperative pain factor, resulting in a analyzed sample of 1,940 cases. The large sample size of the validation sample was chosen to improve the precision and provide an accurate evaluation of the prediction equation.
Logistic regression analysis, using the prediction equation found during the initial analysis, was used to determine the predicted probability for severe postoperative pain. The area under the ROC curve for predicting severe postoperative pain from baseline heart rate, age, low expected, moderate expected, high expected, and highest expected pain, being Hispanic, and female was 0.703 (95% CI 0.678-0.727, \( p < .001 \)), see Figure 16. The ROC curve is advantageous because the sensitivity and specificity of every cut point is calculated allowing for multiple cut point evaluations. When assessing every cutoff value from the ROC analysis, the point closest to the left hand corner represents the most desirable situation of sensitivity and specificity (McGorray, 2002). The optimal 0.20 cutoff value determined from the initial analysis of the prediction equation corresponded to a sensitivity of 54.4% and a specificity of 73.2% for the equations ability to predict severe postoperative pain on POD 1. Introducing an alternate cutoff point, outlined in aim 1 of 0.14 corresponded to a sensitivity of 73.2% and a specificity of 58.2% for the equations ability to predict severe postoperative pain on POD 1. In addition, the sensitivity, specificity, positive and negative predictive values was analyzed to determine the predictive rules ability to accurately discriminate between those with and without severe postoperative pain.
Figure 16. Graph of sensitivity and specificity of Prediction Equation to identify severe postoperative pain on POD 1 from Sample 2

**Sensitivity and Specificity.** The probabilities of detecting the correct outcome of severe postoperative pain by the prediction equation was assessed by the true severe postoperative pain and the true no severe postoperative pain. For the dichotomous response, the results of the test positive (sensitivity) and test negative (specificity) are summarized in a 2x2 contingency table (Figure 17). The columns represent the true and false positives for severe postoperative pain and the rows represent the prediction tests positive and negative predications of severe postoperative pain. In addition to sensitivity and specificity, the positive and negative predictive values were calculated and included.
The prediction equation using a cut point of 0.20 assigning those as having severe postoperative pain resulted in a 73.33% ability to correctly classify an individual as being at risk for severe postoperative pain, sensitivity. The specificity of the prediction equation to correctly classify an individual as not developing severe postoperative pain was 74.40%. The positive predictive value or the prediction equation's ability to identify patients with a predicted risk of developing severe postoperative pain and actually have observed severe postoperative pain is 48.69%. The percentage of individuals with a negative prediction who do not have severe postoperative pain was 89.37%, negative predictive value. Changing the cut point to 0.14 for assigning those as having severe postoperative pain resulted in an improved sensitivity of 74.19% with a specificity of
57.33%. The positive (44.72%) and negative (82.8%6) predictive value changed but to a small degree.

**Summary**

The preliminary analysis found the quality of the data sufficient. The Physiological and Situational models were revised according to the indices and where evaluated. After determining the inadequacy of the measurement models, the aim was modified and three separate path analyses were conducted to look at the predictability of all the factors for the development of severe postoperative pain at the three time points.

On the basis of the results, Model 4 was chosen as the final model for its improved ability to discriminate between those individuals having pain severe pain and not having severe pain postoperatively. The nine significant predictors of baseline heart rate, preoperative pain, low, moderate, high, and highest expected pain, along with being female and Hispanic were all positively associated with greater postoperative pain on postoperative day one. An increase in age was associated with less severe postoperative pain. Baseline systolic and diastolic blood pressure along with being African American compared to Caucasian did not contribute to the final model. Odds ratios for the association between the predicting factors and severe postoperative pain were calculated. Implications for these findings outlined in this chapter are discussed in depth in the following chapter.

The discharge assessment found preoperative pain to be the only significant factor in predicting severe postoperative pain. Unfortunately, there is no theoretical or empirical evidence to support including this with model 4 and it was subsequently removed from the final model and focus on postoperative day one.
The prediction equation validation found using a cut point of 0.20 resulted in a sensitivity of 73.33% and a specificity of 74.40%. Using a cut point of 0.14 resulted in an improved sensitivity of 74.19% and a worse specificity of 57.33%. Implications for these findings are discussed in length in the following chapter.
Chapter 5: Discussion

Overview

A large number of individuals experience some type of acute pain postoperatively; this chapter will focus on discussing the evidence from this study supporting the early prediction of the development of severe acute pain experienced by individuals receiving surgery. Despite acute pain being a common occurrence postoperatively, it remains inadequately managed.

Each aim and corresponding research question for this study is discussed sequentially with highlights for those findings different than the established literature findings previously discussed.

Discussion of Findings Related to Study Aims

The initial purpose of this study was to test a conceptualized multivariate model of influencing factors comprising the pain experience of severe postoperative pain. This study consisted of 1,794 participants in the first analysis and 1,940 participants for the validation.

Results described in Chapter IV demonstrate that the conceptualized measurement model could not be utilized in the original iteration. After modification of the model to remove the measurement components, the correlation between preoperative factors and severe postoperative pain reflected a number of existing evidence from the literature.

All preoperative predicting factors included in the final model were described previously in the literature and significantly explained the relationship with the outcome of severe postoperative pain.
Aim 1: Assessing the relationship between preoperative predictors and the development of severe postoperative pain.

The first aim of the research study was to develop a tool for predicting severe postoperative pain preoperatively. A lack of empirical evidence was found using the theory of unpleasant symptoms to look at the antecedents or preceding factors and the relationship on the symptom of severe postoperative pain. The lack of theory testing provided no studies to compare the results of this study regarding theory testing. As the analysis unfolded, it was apparent the inability of the theory to fit the measurement model. Given that the intent of the study was to use the uncovered factors in predicting severe postoperative pain, the resulting modifications removed the latent physiological and situational factors. A path analysis showed that baseline heart rate, preoperative pain intensity, age, expected surgical pain, ethnicity, and gender predicted severe postoperative pain.

Very little research has been conducted using ethnicity as a predictor of postoperative pain (Dahmani et al., 2001; Faucett et al. 1994). The previous prediction studies conducted by Kalkman et al. (2003) and Janssen et al. (2008) failed to include ethnicity in their analysis. A similar path analysis by Kinjo et al. (2012) also excluded ethnicity from the analysis. It is worth noting that being Hispanic accounted for more predictive strength than baseline heart rate, preoperative pain, and age combined and after accounting for expected surgical pain, was the strongest remaining predictor. The finding provides evidence supporting the importance of ethical considerations when predicting severe postoperative pain.
As to why the Hispanic ethnicity is related to more severe postoperative pain, it is likely due to a number of cultural and/or sociological factors. While looking at the 2010 U.S. Census (U.S. Census Bureau, 2010), 23% of Hispanics lived below the poverty level in the United States compared to 8% for non-Hispanic white. As reported by Vargas-Willis and Cervantes (1987), ethnic minority status is associated with psychosocial distress. Interestingly, when you look at acculturation of Hispanics to the United States, you find a number of factors accounting for the development of Hispanic Stress. Examples include linguistic differences, changing personal and family values, and perceived discrimination as stressful occurrences (Cervantes, Padilla, & Salgado de Snyder, 1991). The development of stress likely has an impact on the intensity of postoperative pain owing to the large number of research findings linking negative effective states such as stress and depression to pain. Despite the lacking research on the influence being Hispanic has on developing severe postoperative pain, the current findings make theoretical sense when looking at the Hispanic literature.

The strongest group of predictors uncovered in this study is related to the type of surgery. The higher the surgical expected pain in relation to the compare group of lowest expected pain, the higher the strength of the relationship uncovered. These findings are consistent with findings uncovered by both Kalkman et al. (2003) and Janssen et al. (2008). In fact, the regression coefficients found by Janssen et al. (2008) follow a similar increasing strength from low expected pain to highest expected pain in the inpatient setting. The findings provide further validation to the classification of type of surgery for the inpatient setting developed by Janssen et al. (2008), which was used as the basis for the type of surgery classification in the present study. A point worth noting is the surgery
classification places therapeutic laparoscopic procedures into the highest expected surgical pain, a finding that may be surprising to clinicians who often think a smaller incision and thus less invasive procedure means less postoperative pain.

The current study showed that women had a greater likelihood of having severe postoperative pain, after controlling for the type of surgery. This result is consistent with a number of previous studies reporting the importance of gender differences as an important predictor of pain (Cepeda & Carr, 2003; De Cosmo et al, 2008; Gagliese et al., 2008; Janssen, 2008; Kinjo et al., 2012; Lau & Patil, 2004; Thomas et al., 1998; Tsirline et al., 2013). Gender shows a predictive effect similar to the findings reported by Kalkman et al. (2003), showing females are at an increased risk of developing severe postoperative pain in the first hour of recovery following surgery. This was also corroborated in the Janssen et al. (2008) study of the sample of patients in the outpatient setting. More recently a path analysis conducted by Kinjo et al. (2012) found females to be at an increased risk of pain on postoperative day 1, a similar period of time. Although the mechanism for gender differences is unclear there is some evidence suggesting that hormonal differences between genders are associated with differences in endogenous opioid activation and modulation of opioid neurotransmission (Smith et al., 2006; Zubieta et al, 2002). Gender differences may also be attributed to dissimilar ethnical and socialization processes between men and women that influence variations in both the intensity and reporting of postoperative pain.

Blood pressure was not a significant predictor of severe postoperative pain. When reviewing the literature, a number of finding in the literature were tentative at best regarding the predictive nature of baseline hemodynamic parameters predicting
postoperative pain. The study conducted by Kalkman et al. (2003) failed to find both systolic and diastolic blood pressure as significant factors in predicting severe postoperative pain. The lack of significant findings between both systolic and diastolic blood pressure and the development of severe postoperative pain may be due to previously mentioned interarm differences in blood pressure readings (Clark, Taylor, Shore, & Campbell, 2012) resulting in inconsistencies in measurements. Furthermore, it may merely be baseline blood pressure measurements are confounded with other factors already included in the model such as age.

Baseline heart rate findings were positively related to severe postoperative pain. Although the weakest relationship, it contributes to the final prediction equation. Prior research conducted by Kalkman et al. (2003) failed to show baseline heart rate as a significant factor. Although not specific to the postoperative period, heart rate was found by Al’ Absi et al. (2002) to show a relationship with pain perception. In 2002, Logan et al. found heart rate response was one significant factor correlated to maximum pain report. Likely mechanisms between heart rate response and pain reported are the baroreceptor reflex arcs and sympathetic activation. Importantly, the current finding support the impact heart rate plays in the pain process.

The present study shows preoperative pain intensity was associated with severe postoperative pain. Although not as strong a predictor as uncovered in a number of studies, the relationship is a significant finding and consistent with the literature (Bisgaard, Klarskov, Rosenberg, & Kehlet, 2001; Caumo et al., 2002; Janssen et al., 2008; Kalkman et al., 2003; Kinjo et al., 2012; Mamie et al., 2004; Rudin, Wolner-
Hanssen, Hellbom, & Werner, 2008; Taenzer, Melzack, & Jeans, 1986; Thomas et al., 1998; Tsirline et al., 2013).

The current results were consistent with previous research showing that being older is associated with less severe postoperative pain (Bisgaard, Klaraskov, Rosenberg, & Kehlet, 2001; Caumo et al, 2002; Chung, Richie, & Sun, 1997; Gagliese, Gauthier, Macpherson, Jovellanos, & Chan, 2008; Kalkman et al., 2003; Kinjo, Sands, Lim, Paul, & Leung, 2012; Lau & Patil, 2004; Thomas et al., 1998; Tsirline et al., 2013; Voulgari et al., 1991). As to the mechanism to why older individuals have less pain, it is not clear. In fact, age related differences might be related to changes in pain modulation. Research looking at neurochemical changes in the various proteins in the central auditory system has been shown to be associated with aging and a plausible explanation (Gray, Engle, & Recanzone, 2014). These findings along with the literature supports that older and younger individuals experience severe postoperative pain differently. The current study suggests that as age increases severity of severe postoperative pain decreases.

**Aim 2: Validation of the Prediction Equation**

In validating the prediction tool, a separate independent sample of 1,940 cases was found to produce a consistent ROC value implying a similarity in the equations ability to predict severe postoperative pain. The incidence of severe postoperative pain in the validation sample was 31.8%, similar to the 32.4% incidence of severe postoperative pain in the derivation sample. In the current study the outcome of severe postoperative pain has only two possible outcomes, a positive prediction (severe pain) test and a negative test (no pain). A positive prediction indicates a high likelihood that the individual will experience the actual outcome of severe postoperative pain, while a
negative test indicates a low likelihood. The result of the examination of the tests sensitivity and specificity was determined at two separate cut points.

Using the optimal threshold cut point of 0.20 uncovered in chapter 4, resulted in a balanced specific (73.33%) and sensitive (74.40%) tool to predicting severe postoperative pain. In some instances it may be more important to maximize sensitivity not specificity to minimize false negatives. In an attempt to improve sensitivity, the 0.20 cut point was compared to a lower cut point of 0.14 to detect severe postoperative pain. As previously mentioned, if the desire is to prevent undertreatment or the prevention of overtreatment, two separate cut points allow for alternative thresholds for predicting individuals at risk for severe postoperative pain. The cut point of 0.20 has a sensitivity of 73.33% for the presence of severe postoperative pain, which will result in a slightly higher rate of false negatives compared to the use of the 0.14 cut point with a sensitivity of 74.19%. If the most important issue is “not missing” a positive case of severe postoperative pain then a test with a higher sensitivity is more appropriate. As uncovered in this current study, the cut point of 0.20 had a specificity of 74.40% with the smaller cut point of 0.14 being 57.33%. On the other hand high, specific predictability is better for “ruling in” the presence of severe postoperative pain because of a low rate of false positives. An important consideration when developing intervention strategies is tests with higher specificity are critical when making a clinical decision about a definitive action is required, such as the administration of pharmacological agents preoperatively in a response to mitigate the severity or occurrence of postoperative pain.

The creation of a whole number normogram for each individual prediction factor does not make sense in the current practice environment. With the push for
institution and practice adopted electronic health records, an electronic prediction tool becomes more feasible. Ideally, creation of an electronic computer generated prediction tool would be inexpensive and permit automatic calculations at various cut points tailored to the practice environment and interventional strategy. Calculations at various cut points will allow for an innovative way to utilize the prediction equation tailored to the intervention strategy and needed sensitivity and specificity. Lets say one wants to implement an education strategy for at risk individuals, the importance of positively identifying individuals becomes more important than the risk of falsely identifying an individual. Then the use of a lower cutoff point becomes more important. On the flip side, one wants to create an interventional therapy and needs to be more selective in not falsely treating individuals. A need for a more specific prediction would result in using the higher cut point of 0.20.

One may ask, why use a tool that has both a fair sensitivity and specificity? The problem is currently one that is both easily measured and non-invasive to the patient doesn’t exist. With the high incidence and severity of postoperative pain currently occurring following surgery, innovative approaches need to first better identify at risk individuals and the better manage those suffering. The current prediction equation provides both of these functions that will hopefully help impact patients and improve outcomes.

**Implications for The Theory of Unpleasant Symptoms**

The original modified model for the theory of unpleasant symptoms (Lenz et al., 1995; 1997) was not supported by the original measurement and structural model. The data obtained in this study failed to fit the model adequately, resulting in the inability to
test and provide support for the theoretical model depicting the relationship between physiological and situational factors in predicting the symptom of severe postoperative pain.

Unfortunately, few studies have tested the theory of unpleasant symptoms using SEM. A study by Cobb (2007) tested the original theory using SEM but only explained three percent of the variance in the study outcome physical activity. Altering the model from a fully mediated model, the original model based on the theory of unpleasant symptoms, to a partially mediated model (modified model) resulted in improvement of the fit while explaining only sixteen percent of the variability. It is hard to tell in the present study if the exclusion of psychological factors contributed to the failure to retain the model in this study or a result of one or more measured variables inability to measure the latent variables.

Lenz et al. (1997) theory depicts the physiological, situational, and psychological factors interacting to affect the unpleasant symptom. The theoretical basis for the modified model may have unappreciated the influences psychological factors have on the other influencing factors. A point worth noting is the original intention of the research study was determining predictors for the development of severe postoperative pain not testing of the theory. The theory of unpleasant symptoms was utilized as a theoretical framework through which to model the study. In summary, the modified theory of unpleasant symptoms was not utilized when testing this population due to issues in developing a completed measurement model.
Implications for Nursing

The first step discussed in most clinical practice guidelines on acute pain management is the critical step of assessing pain; despite this there are many inconsistencies on what establishes an appropriate pain assessment. Looking as far back as 1992, the clinical practice guideline released by the Agency for Healthcare Policy and Research, outlined a comprehensive pain evaluation, which included a pain history (United States, 1992). An expansion of these earlier guidelines to include preoperative predictors of severe postoperative pain furthers the foundation for a plan for pain management of patients receiving surgery.

By implementing a comprehensive pain management strategy preoperatively, which includes utilizing the preoperative prediction tool completed collaboratively between the healthcare providers and the patient, the identification of patients at risk is ensured at the earliest point prior to the surgical insult. This preoperative identification, when coupled with an acute pain management plan, lays the foundation for early identification and education of patients at risk enhancing the preoperative education and discussions with patients about attitudes and expectations of pain control postoperatively. In fact, evidence supports the effectiveness of preoperative education in significantly reducing experienced pain postoperatively (Giraudet-Le Quintrec et al., 2003; Sjöling et al., 2003).

The objective for adequate management, as outlined by the American Pain Society (APS), is to prevent severe postoperative pain and control pain (Gordon et al., 2005). Currently analgesics are the primary treatment of acute pain, and despite the widespread use of opioids acute pain continues to be poorly managed postoperatively.
Although only one of many factors that contribute to poor management of acute postoperative pain, lack of an inappropriate pain assessment remains an additional major factor in the under treatment of pain. In fact the first step in relieving pain is to prevent the harmful effects of pain. Preoperatively predicting patients at risk for severe postoperative pain allows for a multidiscipline approach tailored specifically for the patient before the insult of surgery and the development of postoperative pain.

Adequate postoperative pain management requires an interdisciplinary approach individualized to the patient to achieve adequate pain management postoperatively. Nurses play a critical role in this interdisciplinary approach by both helping identify those patients at risk and helping determine a strategy to achieve more comfort postoperatively. An example is the use of non-drug methods as comfort measures to compliment conventional methods of pain management. Non-drug methods (music, distraction, relaxation, massage, imagery, and aroma therapy) are within the scope of nursing practice and may be discussed with the at risk patient preoperatively to determine if the techniques are responsive to the patients individual and cultural needs. The plan for postoperative pain relief should consider the patient preferences and past experiences with assurances that acute pain management is a priority.

Predicting individuals at risk for severe acute postoperative pain should raise a “red flag” that attracts nurses attention; prompt education preoperatively on the need to communicate pain and expectations of responsive analgesic care; and coordinate and assess implementation of a “severe postoperative pain protocol” based on the current evidence. By nurses being involved and committing to a multidiscipline multifaceted
approach that includes patient and clinician education, improvements in the treatment of
severe postoperative pain can occur.

With a transition from a paper-based system into a newer format of electronic
health records (EHR) nationwide to meet the federal requirements, it is essential that the
development of new tools be integrated into an electronic format. Doing so is an integral
step in accurately collecting, utilizing, analyzing, reporting, and storing patient data to
promote efficiency and effective decision-making in patient care. Nurses, major
stakeholders in the design, adoption and utilization of the EHR, spend a majority of their
time providing patient care. Not only is nursing documentation an important part for
patient care and efficient communication but evidence has shown favorable time
differences between the paper-based system and the EHR resulting in less time spent on
documentation and more time on patient care (Bosman et al., 2003). Furthermore,
decisions delivered using an electronic tool for predicting severe postoperative pain are
ideally suited to provide nurses with decision support to improve safety (Bates et al.,
2001). As an electronic tool is more robust than a paper-based tool, there is more
potential for nurses to tailor the prediction results into patient specific guidelines taking
into consideration such factors as the patient’s current medications and comorbidities.

Overall, nurse are uniquely qualified with the knowledge and skills needed to
develop, assess, and implement patient centered care as they spend more time at the
bedside with patients. Unrelieved acute pain remains prevalent postoperatively despite
advances in pain management. Nurses have a great opportunity to initiate pain
management protocols established from predicting patients at risk of severe postoperative
pain and initiating and reinforcing patient centered care and education. The introduction
of a prediction tool may help nurses to adequately identifying pain enabling nurses and clinicians to manage pain successfully.

**Study Limitations**

There are a number of limitations to the present study. First, the sample is not reflective of the whole population of patients in the US or the world; this may limit generalizability. Although two different samples were tested, these findings need to be validated in a different setting. There are also a number of methodological limitations to be considered in this current study. Firstly, there are inherent limitations in the analysis of secondary data. The results of this study depended on the reliability of the measured variables and the abstraction process used to obtain the data analyzed. As uncovered in the study, a large number of cases were excluded from the analysis due to both systemic and random missing data. Despite the issues of missing data, both sample 1 and sample 2 resulted in a sufficiently large number of cases. Secondly, the study included only a retrospective sample of patients for analysis. This may have decreased the power of the study, particularly for the severe postoperative pain findings.

Further limitations included methodological issues in the lack of the measurement model fit. However the model fit problems were overcome by modification of the aims and research questions to reflect the removal of the latent variables and regressing the measured variables directly on the observed variable of postoperative pain. Lastly, there is a possibility of confounders among the factors identified for the model. In fact, exclusion of psychological factors, based on the literature findings, will more than likely confound the predictability of preoperative pain on the occurrence of moderate to severe postoperative pain. Psychological factors may be responsible for some of the variability
but was excluded in this study based on the need for more thorough analysis of the role psychological factors play on preoperative pain. Given the lack of a measurement model fit, the psychological factors shown by Kinjo et al. (212) to indirectly influence severe postoperative pain through the existence of preoperative pain may need to be revisited. Additionally, preoperative psychological factors are not easily tested nor currently assessed routinely preoperatively, making the inclusion of psychological factors in a prediction model for clinical practice useless until such testing is performed.

Caution should be taken when looking for causation; rather the data suggests that a number of preoperative predictors are associated with increase odds of severe postoperative pain. Because of these methodological considerations, this study should be considered preliminary work that may need modification in future studies after further exploration of the role psychological factors play in the development of preoperative and postoperative pain. That being said, the research findings add important information to the body of knowledge examining the risk factors predicting the development of severe postoperative pain.

On the other hand, the use of SEM provided to be an ideal method for studying the predicting factors for the development of severe postoperative pain. Despite the removal of the latent variables, SEM allowed the testing of the theoretical model. The analysis was conducive to performing a number of different types of regressions at three separate time points with the creation of a visually depiction of the relationships uncovered through the use of three path models. Furthermore, SEM incorporates the measurement error and adjusts the correlations and path coefficients appropriately.
Recommendations for Future Research

The motivation for conducting this study was early identification through the use of a prediction tool to classify individuals at risk for developing severe postoperative pain. Although this study provides a foundation for ongoing research, an ongoing search for additional factors associated with severe postoperative pain is extremely important to further understand and predict individuals at risk. With future identification of significant factors, the prediction equation can be easily modified to improve both the sensitivity and specificity of the tool's ability to predict severe postoperative pain. The following recommendations for future severe postoperative pain research should be considered.

Psychological Factors

As outlined under the limitations section, the variables of psychological factors were not collected or examined. Research is therefore warranted to expand on the current body of knowledge by exploring the effects psychological factors have on both the physiological factor of preoperative pain as well as the development of severe postoperative pain. Psychological factors need to be studied to not only ferret out their individual roles in predicting pain but also to development management strategies to mitigate any associated risks.

The problem with the existing evidence and an important first step is finding a simple to apply measure to assess the most likely factors of anxiety, depression, and pain catastrophizing. Vranceanu et al. (2014) found depression, posttraumatic stress disorder, catastrophic thinking, and pain anxiety to be strongly associated with pain intensity and disability in patients after skeletal trauma. The researchers utilized five separate measures to assess depression, anxiety, catastrophic thinking, and disability. The problem of
utilizing a similar approach is the feasibility of performing such an extensive assessment preoperatively. With the aim of the prediction tool to use simple to capture measures, a means of simply assessing psychological factors needs to be explored.

A more practical approach may be to follow along with the results of a recent study by Mehling, Ebell, Avins, and Hecht (2015). Utilizing a clinical prediction rule for primary care patients suffering from acute low back pain, the researchers showed the utility of a self-reported survey to identify individuals suffering from acute lower back pain who are at risk for developing chronic pain. Employing a similar approach and implementing a simple questionnaire preoperatively may provide a sufficient means for assessing psychological factors. This will require further research to develop or modify such a measure for inclusion in the current prediction equation.

**Association Between Predicting Acute and Chronic Pain**

Further investigation is likewise needed to understand the association between severe postoperative pain and the development of chronic pain, which has been linked to postoperative pain management. If the existence of severe postoperative pain leads to the development to chronic pain, there may be a commonality in predicting the development of both severe acute postoperative pain and chronic postoperative pain. A commonality of predicting severe postoperative and chronic pain may lead to a number of potential pain management strategies looking at enhancing the management of both acute and chronic postoperative pain.

**Pain Management**

The ultimate goal of this study is to identify individuals at risk. Once at risk individuals are identified then the focus can shift to improving both prevention and
management of severe postoperative pain. Exploring all possibilities for improving postoperative pain should and needs to be explored. The following speculative management strategies may provide benefit in alleviating severe postoperative pain.

Although use of medication is the mainstay of pain management, there are a number of non-pharmacological approaches such as massage therapy, acupuncture, and stress reduction measures that can be utilized to decrease pain intensity. For example, simple measure such as preoperative education focusing on enhancing the patients understanding may help lessen postoperative pain. Additional approaches may be enhancing the individual’s positive coping strategies to treat pain intensity. Further research should focus on these alternative and complementary approaches to treat pain.

While a number of pharmacological approaches have been studied and prescribed to manage pain, the ongoing issue of severe postoperative pain needs to continue until we ultimately solve the problem. Developing additional pharmacological approaches implemented preoperative and/or intraoperative to those individuals identified early may prove beneficial. In fact, the assessment of pain is often cited as a barrier to pain management. Though preliminary, this study provides an encouraging pain prediction tool to provide a more inclusive pain assessment that promises to overcome some of the current barriers.

**Hispanic Ethnicity**

Being Hispanic has important implications for the development of future research. Despite the current findings there is very little research addressing the Hispanic ethnicity and postoperative pain. Implications for research must address the underlying causation so interventional strategies that aim at reducing the effects being Hispanic has on
developing severe postoperative pain can be implemented. For example, Hispanic Stress was found by Gonzalez-Guarda et al. (2013) to be the strongest predictor of Syndemic Factor, a way to describe multiple epidemics that increases the burden of disease among a population. The researchers tested a hypothetical relationship between cultural phenomena and Syndemic Factor. Interestingly, the findings showed familism buffered the relationship between Hispanic Stress and the Syndemic factor. If effective enhancement of familism strategies are employed it is potentially an innovative and effective means to help Hispanic individuals cope with postoperative pain.

**The Pediatric Patient**

Finally, extending this research to younger individuals is warranted to predict the development of severe postoperative pain in children, especially since age has been shown to predict severe postoperative pain. Pediatric patients are known to be extremely vulnerable to underreporting of pain because of a limited ability to verbalize and communicate pain. The resulting underreporting of pain ultimately leads to the under management of their pain.

**Summary**

The purpose of this study was to test and evaluate a conceptualized multivariate model of factors predicting acute severe postoperative pain at a university hospital. Structural equation modeling is a useful methodology, which successfully identified salient variables and constructs leading to the final prediction tool.

Although severe postoperative pain has been shown to be high following surgery, not much has been done to utilize existing knowledge about those factors predicting its occurrence. There is a particular lack of research on utilizing the predictors and
developing a risk stratification tool for clinical practice to identify individuals at risk. Clearly, more studies are needed to further advance the current knowledge to identify, prevent, and better manage the universal, multidimensional experience of severe postoperative pain. Part of the solution involves a commitment to better predict individual at risk to enhance the management or severe postoperative pain. Without the combination of both identifying and managing of severe postoperative pain, another decade will pass with little change in patient pain outcomes.

The current study has conclusively shown that a number of easily and readily captured predictors could easily obtain a prediction score preoperatively, thus improving identification and ultimately management of at risk individuals. Taken together, the results suggest that the nine factors (baseline heart rate, preoperative pain, low, moderate, high, highest expected pain, female gender, and Hispanic ethnicity) identify individuals more likely to report severe postoperative pain following surgery. Although the prediction equation was validated through the use of a large validation sample of 1940 individuals, further validation studies should be conducted in various geographical and clinical practice settings. It is yet to be seen if the application of the prediction equation might improve the management of severe postoperative pain but predicting individuals is an approach that has been utilized by a number of professions improving clinical outcomes.


### APPENDIX A

**SURGICAL CLASSIFICATION SYSTEM**

**Surgical Procedure**

<table>
<thead>
<tr>
<th>Lowest expected pain</th>
<th>Endoscopic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Testicular surgery (including orchidopexy, biopsy, prosthesis implantation, vasoepididymostomy, testis-scrotum exploration)</td>
<td></td>
</tr>
<tr>
<td>Eye surgery (including strabismus)</td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Low expected pain</th>
<th>Pharyngoscopy and laryngoscopy plus biopsy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ear nose throat surgery</td>
<td></td>
</tr>
<tr>
<td>Diagnostic laparoscopy</td>
<td></td>
</tr>
<tr>
<td>Gynecologic surgery (non-abdominal non-laparoscopic)</td>
<td></td>
</tr>
<tr>
<td>Minor rectal surgery</td>
<td></td>
</tr>
<tr>
<td>Oral soft tissue surgery Carotid endarterectomy</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Moderate expected pain</th>
<th>Skin surgery or lymph node biopsy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peripheral vascular procedures (including varicose veins)</td>
<td></td>
</tr>
<tr>
<td>Minor breast surgery</td>
<td></td>
</tr>
<tr>
<td>Procedures on muscle and/or ligaments of extremities</td>
<td></td>
</tr>
<tr>
<td>Upper abdominal surgery with epidural, including hepato-biliary, esophageal, pancreatic and intestinal surgery</td>
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</table>

<table>
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<tr>
<th>High expected pain</th>
<th>Major breast surgery</th>
</tr>
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<tbody>
<tr>
<td>Bone procedures, including cranial/facial, oral, spine, orthopedic/traumatology, procedures on clavicle, extremities, hip and pelvis.</td>
<td></td>
</tr>
<tr>
<td>Instrumentation or removal of instrumentation, including spine,</td>
<td></td>
</tr>
</tbody>
</table>
Arthroscopy of shoulder, hip/pelvis and extremities
Procedures for abdominal wall herniation
Nephrectomy

Highest expected pain

Therapeutic laparoscopic procedures,
including laparoscopic cholecystectomy,
gynecologic laparoscopy and other
therapeutically laparoscopy
Intraabdominal surgery without epidural, including colon,
bladder, prostate, vascular and gynecological surgery
Tonsillectomy (in patients over 16 years)
Herniated disc surgery
Bone procedures including shoulder, thoracotomies, elbow,
ankle/foot (excluding instrumentation or removal of instrumentation)
Thyroid procedures
Peripheral nerve reconstruction
Vaginal hysterectomy

(Janssen et al., 2008)