FACTORS ASSOCIATED WITH MODERATE AND SEVERE POSTOPERATIVE PAIN

by

JACK R. KLESS

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Dissertation Advisor: Marion Good, PhD, RN, FAAN

Frances Payne Bolton School of Nursing
CASE WESTERN RESERVE UNIVERSITY

May, 2010
We hereby approve the thesis/dissertation of

__________________________
Jack R. Kless

candidate for the ___________ PhD ___________ degree*.

(signed) ___________________ Marion Good
/chair of the committee/

__________________________
John Clochesy

__________________________
Elizabeth Madigan

__________________________
Michael Ritchey, MD

__________________________
Christopher J. Burant

(date) ___________________ January 14, 2010

*We also certify that written approval has been obtained for any proprietary material contained therein.
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DEDICATION

This work is dedicated to my mother, Mildred Anne Kless, and my brother, Robert F. Kless Jr. (Chooch), who I lost while completing it.
Factors Associated With Moderate and Severe Postoperative Pain

Abstract

by

JACK R. KLESS

Postoperative pain continues to be a serious consequence of surgical intervention. Understanding the predictive factors of postoperative pain would allow nurses to identify those at increased risk and to better direct resources to ameliorate significantly high levels of postoperative pain. Based on the theory of unpleasant symptoms, the purpose of this research was to identify the factors correlated with moderate and severe postoperative pain. Using a predictive correlational design, this study was a secondary analysis of a randomized controlled trial of nonpharmacological interventions for the treatment of postoperative pain (Good et al., 1999). The sample consisted of 292 participants from the primary study who had pain scores on the first day after major abdominal surgery. Two levels of moderate to severe pain, moderate\textsubscript{30} (30 to 100 mm) and moderate\textsubscript{50} (50 to 100 mm), and one level of severe postoperative pain (70 to 100 mm) were studied. Logistic regression was used to examine the relationship of eight independent variables on moderate and severe postoperative pain: gender, age, chronic preoperative pain, acute preoperative pain, physical status, surgical procedure, length of surgery, and length of incision. The model accounted for 10% of the variance at moderate\textsubscript{30} postoperative pain and predicted 70% of the cases. At moderate\textsubscript{50} postoperative pain only 6% of variance was explained and 60% of cases were correctly classified. At severe\textsubscript{70} postoperative pain, 12% of variance was explained, and 79% of cases were correctly classified. Age and ASA physical status were significant predictors at all three levels of postoperative pain. The model was more accurate at moderate\textsubscript{30} and
severe postoperative pain, but explained variance was low, and -2 log likelihoods were relatively high. The theory of unpleasant symptoms was partially supported by finding that age and ASA physical status were predictive of postoperative pain levels and the major implication for nursing is to increase nurses’ effort to uncover untreated postoperative pain, and to better direct resources to ameliorate it.
Factors Associated With Moderate and Severe Postoperative Pain

Chapter One

Background and Significance

Postoperative pain remains under-treated in many patients. This occurs despite publication of acute pain management guidelines (Acute Pain Management Guideline Panel, 1992; Gordon et al., 2005) and campaigns to increase the awareness of providers about patient pain (Frasco, Sprung, & Trentman, 2005). Anticipating the intensity of pain following a specific surgical procedure is difficult and there is wide variation in the presentation of patients in postoperative pain even when the surgical procedure is the same (Bisgaard, Klarskov, Rosenberg & Kehlet, 2001). Being able to predict or model the character of postoperative pain following a surgical procedure would significantly improve our efforts to achieve better postoperative analgesia, and in turn, reduce the occurrence of multiple complications associated with under-treated postoperative pain (Joshi, 2005). Several studies suggest that predicting moderate and severe postoperative pain is possible by identifying preoperative factors (Ure, Troidl, Spangenberger, Dietrich, Lefering, & Neugebauer, 1994; Puntillo & Weiss, 1994; Thomas, Robinson, Champion, McKell & Pell, 1998; Bisgaard, et al, 2001; Sevensson, Sjostrom & Haljamae, 2000; Caumo et al., 2002; Katz, Poleshuck, Andrus, Hogan. Jung, Kulick, et al., 2005). However, these studies differed in the variables and types of surgical procedures studied. Further evidence is needed following abdominal surgery. The ability to predict severe postoperative pain would allow more appropriate treatment modalities and would potentially prevent significant postoperative complications, such as pulmonary and cardiovascular compromise and prolonged hospitalization.
Purpose

The primary purpose of the study was to identify the factors associated with moderate and severe postoperative pain following abdominal surgery. Using an existing data set, this study was a secondary analysis of a randomized controlled trial of a nonpharmacological intervention for postoperative pain (Good, et al., 1999). The secondary purpose was to use the factors identified and the existing literature to construct a model predicting postoperative pain.

Using dual visual analog scales (VAS) both sensation and distress of postoperative pain were measured in the primary study at four points during ambulation and two points when patients were at rest on postoperative days one and two following abdominal surgery (Good et al., 1999). In the secondary analysis, sensation of pain was studied on the morning of the first postoperative day. Pre rest and pre ambulation pain sensation scores were be recoded into one mid-morning score to evaluate the predictive ability of eight independent factors, controlling for opioid intake.

Moderate postoperative pain was operationally defined for the current study in two ways: 30.0 to 100 mm (Dolin, Cashman, & Bland, 2002) and 50.0 to 100 mm (Serlin, Mendoza, Nakamura, Edwards, & Cleeland, 1995) on a 0-100 VAS. Severe postoperative pain was defined as 70.0-100.0 mm (Serlin, et al., 1995). Day 1 moderate and severe pretest pain scores attained in the morning were regressed against the following variables selected from the data set, based on previous studies: gender, age, chronic preoperative pain, acute preoperative pain, physical status, surgical procedure, length of surgery, and length of incision.
Possible confounders of this secondary study included opioid intake, ambulation before the pretest, analgesics administered in the operating room at the conclusion at surgery and infiltration of local anesthetic into the wound. The only one that could be statistically controlled in this study was opioid intake, as the others were either not recorded or not collected at the time of the original study.

Problem

Efforts to reduce postoperative pain include the publication of several sets of acute pain management guidelines (Rowlingson & Rawal, 2003; Acute Pain Management Guideline Panel, 1992; American Society of Anesthesiologists Task Force on Acute Pain Management, 2004; Gordon et al., 2005), the introduction of the idea of pain as the fifth vital sign (Campbell, 1996), and the Joint Commission on Accreditation of Healthcare Organizations’ standards for pain management on healthcare organizations.
Comission on Accreditation of Healthcare Organizations, 2000). However the reduction of moderate and severe postoperative pain remains an elusive goal (Apfelbaum, Chen, Meta & Gan, 2003; Good, Stanton-Hicks, Grass, Anderson, Makii & Geras, 2000; Chung, Un, & Su, 1996). Researchers continue to find that 80% of surveyed postoperative patients reported acute pain after surgery and 86% of those patients reported moderate, severe, and extreme postoperative pain (Apfelbaum, et al., 2003). The scope of this problem is large, as 44.9 million inpatient operations were carried out in 2005 (Fast stats. National Center for Health Statistics Website).

The problem with this percentage of moderate and severe pain is that in addition to patient suffering, unrelieved pain is associated with a variety of postoperative complications that significantly contribute to postoperative morbidity and mortality (Kehlet, 1998; Acute Pain Management Guideline Panel, 1992; Wu, 2005; Dahl & Kehlet, 2006). The most stress provoking surgical procedures are those that enter the upper abdomen and the thoracic cavity (Kehlet, 1998). It is these procedures that are also associated with high levels of postoperative pain (Parkhouse, Lambrechts & Simpson, 1961; Brown, 1989; Heffline, 1990; Musgrave, 1990; Kehlet & Ferrante, 1995; Carpenter, 1997). Postoperative pain and the associated physiologic stress, delay recovery, extend hospital stay, increase health care costs, and cause a diverse group of potentially life threatening complications (Morrison, et al., 2003).

Thus, there remains a significant segment of the postoperative population at risk for moderate and severe postoperative pain and its negative consequences. This creates both a moral and a pathophysiological issue in perioperative nursing care. The moral issue is, given our current ability to treat postoperative pain, nurses cannot allow the unnecessary
suffering of patients following surgery. The physiological concern is that untreated pain threatens the recovery of the patient following surgery.

Studies of nurses’ ability to assess or sense a patient’s subjective experience of pain reveal that nurses’ ratings of patient pain frequently underestimate patient reports of pain. This observation may be related to the nurse’s education (Kubecka, Simon & Boettcher, 1996), lack of personal experience with pain (Holm, Cohen, Dudas, Medema & Allen, 1989; Wessman & McDonald, 1999), or incomplete understanding of the factors associated with moderate and severe postoperative pain. The aim of this study was to clarify those patient variables that will help nurses to identify those patients at high risk for moderate and severe postoperative pain once clarified, nurses can then better direct pain relieving therapy.

The consequences of under-treated postoperative pain. Under-treated postoperative pain activates the neuroendocrine and sympathoadrenal systems with consequent activation of the hypothalamic-pituitary-adrenocortical axis (HPAA). The net result is to cause a hyper- metabolic catabolic state where metabolism and oxygen consumption are increased and metabolic substrates are mobilized. The negative nitrogen balance and protein catabolism impede recovery and increase the risk of serious complications (Yeager, Glass, Neff & Brinck-Johnsen, 1987). In addition, undertreated postoperative pain may reduce immunity and contribute to cardiac complications and ileus following surgery (Moore & Liu, 1998).

Postoperative respiratory function is markedly decreased especially following upper abdominal and thoracic surgery, due to pain associated with respiration. Reflex splinting of the chest leads to further reductions of lung volumes and inadequate cough. Ateletasis,
with infection (pneumonia) is possible, especially in the elderly or in those with chronic respiratory disease (Cousins & Power, 1999). Control of postoperative pain may attenuate the stress response, sympathetic outflow, and inhibitory spinal reflexes and lead to reductions in morbidity and mortality and other positive outcomes such as health related quality of life (Wu, et al., 2003).

In spite of increasing knowledge of the mechanisms of acute postoperative pain, its treatment and its consequences, the outcome of reducing levels of postoperative pain and therefore the complications associated with it, remains an elusive goal for both medicine and nursing (Dahl, Gordon, Ward, Skemp, Wochos, & Schurr, 2003). Continuing efforts to characterize postoperative pain and the factors associated with moderate and severe postoperative pain are necessary if continuing progress is to be made in reducing the unnecessary patient suffering associated with under-treated postoperative pain.

**Significance**

The significance of the study is that it will confirm or disconfirm results of previous studies that have identified variables that predict moderate and severe postoperative pain. If consistent with previous studies (Thomas et al., 1998; Svensson et al., 2000; Caumo et al., 2002), the findings from this secondary analysis could be used to increase the ability of nurses to anticipate the severity of postoperative pain. This will allow nurses to more effectively intervene in the postoperative pain process. This should increase patient safety and comfort in the postoperative period, and potentially reduce the complications of under treated postoperative pain. Additionally, by constructing a model of postoperative pain, the planning of prospective studies in this area will be facilitated.
Theoretical Framework

The conceptual framework for this study is based on the middle-range theory of unpleasant symptoms as first proposed by Lenz, Suppe, Gift, Pugh, and Milligan (1995), and subsequently revised (Lenz, Pugh, Milligan, Gift, & Suppe, 1997). The theory of unpleasant symptoms posits that unpleasant symptoms (dyspnea, fatigue, pain) are preceded by physiological, psychological and situational factors that influence the duration, intensity, quality, and distress of the unpleasant symptoms; and that unpleasant symptoms can influence performance. Performance includes physical activity, activities of daily living, and social and role performance. The originally proposed theory was focused on one symptom and three antecedent factors (physiologic, psychologic, situational), and did not include relationships between antecedent factors. The revised model allows the inclusion of several unpleasant symptoms, their interrelationships and three antecedent factors as well as interrelationships between the antecedent factors. (Figure 2).


The Theory of Unpleasant Symptoms proposes in part, that physiological factors affect the intensity of symptoms. Physiological factors include both normal and abnormal
functioning of body systems. This study examined eight antecedent physiological factors available in the original data set (gender, age, chronic preoperative pain, acute preoperative pain, physical status, surgical procedure, length of surgery, and length of incision) for their contribution to the occurrence of the unpleasant symptom, moderate and severe postoperative pain. The conceptual framework for the study is shown in Figure 3.

Figure 3. Conceptual Framework.

**Mid-Range Theory Concepts**
- Physiological Factors
  - Gender
  - Age
  - Chronic Preoperative Pain
  - Acute Preoperative Pain
  - Physical Status
  - Surgical Procedure
  - Length of Surgery
  - Length of Incision

**Research Concepts**
- Symptom Intensity
  - Moderate Postoperative Pain
  - Severe Postoperative Pain

**Operational Definitions**
- Gender: male, female
- Age: Continuous
- Chronic Preoperative Pain, pain of greater than 1 month duration, yes/no
- Acute Preoperative Pain, yes/no, ≤ 1 mo
- Physical Status, ASA status, I-II, = 0; III-V, = 1
- Surgical Procedure, Colorectal & general = 0, gynecological & urological = 1
- Length of Surgery (in hours/minutes)
- Length of Incision (in centimeters)

**Opioid Intake**
- Moderate VAS ≥ 30.0 to 100 mm
- ≥ 50.0 to 100 mm
- Severe VAS ≥ 70.0 to 100 mm
- Opioid Intake 24 hours
**Summary of Literature**

Seven studies examined variables and constructed a model to better predict moderate and severe postoperative pain (Puntillo & Weiss, 1994; Ure et al., 1994; Thomas et al., 1998; Bisgaard et al., 2001; Caumo et al., 2002; Kalkman et al., 2003; Katz et al., 2005). Statistically significant factors which emerged, by variance explained and odds ratio, as being predictive of moderate and severe pain include gender (Ure et al., 1994; Puntillo & Weiss, 1994; Thomas et al., 1998), age (Thomas et al., 1998; Bisgaard et al., 2001; Caumo et al., 2002; Kalkman et al., 2003; Katz et al., 2005) acute preoperative pain (Ure et al., 1994; Thomas et al., 1998; Caumo et al., 2002) and surgical procedure (Puntillo & Weiss, 1994; Katz et al., 2005). Predictors less frequently found include physical status (Caumo et al., 2002), chronic preoperative pain (Thomas et al., 1998; Caumo et al., 2002), length of surgery (Caumo et al., 2002), and length of incision (Kalkman et al., 2003). While there are areas of agreement in these studies, there are also many inconsistencies. The inconsistencies may be related to methodological issues (different surgical procedures, different definitions for moderate and severe pain and different postoperative times of pain measurement). The secondary analysis is proposed to use vigorous methods and to add to the already existing body of knowledge in defining the factors associated with moderate and severe postoperative pain. Answers to the following research questions will be compared to findings of previous postoperative pain studies.

**Research Questions**

Research Question 1. Which of the following, gender, age, chronic preoperative pain, acute preoperative pain, physical status, surgical procedure, length of surgery, and
length of incision, are associated with moderate (30.0 to 100 mm and 50.0 to 100 mm on a 100 mm VAS) and severe (70.0 mm to 100 mm on a 100 mm VAS) postoperative pain sensation.

Research Question 2. How much variance in moderate and severe pain, is explained by the following factors: gender, age, chronic preoperative pain, acute preoperative pain, physical status, surgical procedure, length of surgery, and length of incision?

Research Question 3. Which of the following factors, gender, age, chronic preoperative pain, acute preoperative pain, physical status, surgical procedure, length of surgery, and length of incision, are most important/influential in predicting moderate and severe postoperative pain?

**Conceptual and Operational Definitions**

*Sensation of pain.* The sensation of pain was conceptually defined in the proposed study, as the unpleasant physical perception of hurt in and around the surgical incision.

Operational Definition: Sensation of pain in and around the surgical incision, was measured using a 100 mm visual analog scale (VAS), (Good et al., 1999; 2001), with anchors of ‘none’ to ‘most sensation’.

*Moderate postoperative pain.* Moderate pain will be conceptually defined as pain that passes a threshold that makes it difficult for the patient to ignore (Serlin et al., 1995).

Operational Definition: In the proposed study, moderate pain will be conceptually defined in two ways: as sensation of pain that is ≥ 30 to 100 mm (Dolin, et al., 2002) and ≥ 50 to 100 mm (Serlin, et al., 1995), indicated by the patient, on a 100 mm VAS).
**Severe postoperative pain.** Severe postoperative pain will be conceptually defined as pain that becomes the primary focus of the patient and prohibits most patient activity (Serlin et al., 1995).

Operational Definition: For the secondary study, severe postoperative pain will be operationally defined as sensation of pain that is $\geq 70$ mm, indicated by the patient, on a 100 mm VAS (Dolin, et al., 2002).

**Gender.** A complex genetic, social and cultural condition assigned to a sexual group.

Operational Definition. In the primary study gender was the decision on the part of the research assistant, as to which of the two groups, male or female, the research subject belonged.

**Age.** Age is the number of years that the subject has been alive.

Operational Definition: Age was reported by participants in the original study in years, and will be analyzed as a continuous variable.

**Acute preoperative pain.** Acute preoperative pain is of recent onset and is associated with illness or injury. It will be defined as pain that has lasted one month or less.

Operational Definition: Acute preoperative pain will be defined in the study for secondary analysis, by the response to the question, asked at the preoperative visit in the primary study, “Are you having pain today or in the last two days?” If the answer was yes, it was followed by a question concerning the duration of the pain. All those who responded yes to the first question of pain in the last two days, and having a duration of one month or less, will be considered as having acute preoperative pain.

**Chronic preoperative pain.** Chronic preoperative pain is pain that has persisted beyond the normal healing process or is due to an ongoing disorder. Chronic pain was
defined by the primary study using a > 1 month duration. However, that is not consistent with existing literature which defines chronic pain duration of at least 3-6 months (Caumo, et al., 2002; Dunajcik, 1999).

Operational Definition: For purposes of the secondary analysis, any patient who responded affirmatively to the question regarding daily pain, moderate or greater, for over one month will be considered to have chronic preoperative pain.

*Physical status.* Physical status is defined as health, in terms of systemic disease, functional limitations, and threat to life.

Operational Definition: The American Society of Anesthesiologists physical status is a grading or assessment system used by anesthesia providers preoperatively to assess the severity of preexisting comorbidities in patients coming to surgery (Fleisher, 1997). The American Society of Anesthesiologists physical status was assigned by the anesthetist prior to the surgical procedure, and was listed on the anesthetic record. (Table 1).

Table 1

*American Society of Anesthesiologists Physical Status*

<table>
<thead>
<tr>
<th>Status</th>
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<tr>
<td>I</td>
<td>A normal healthy patient</td>
</tr>
<tr>
<td>II</td>
<td>A patient with mild systemic disease that results in no functional impairments</td>
</tr>
<tr>
<td>II</td>
<td>A patient with severe systemic disease that results in functional limitations</td>
</tr>
<tr>
<td>IV</td>
<td>A patient with severe systemic disease that is a constant threat to life</td>
</tr>
<tr>
<td>V</td>
<td>A moribund patient who is not expected to survive with or without the operation</td>
</tr>
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Surgical procedures. Surgical procedures in the primary study were major operative procedures which involved incision of the abdominal wall. Because they may vary in their degree of invasiveness and the area of the body involved, their ability to disrupt physiological homeostasis, and cause postoperative pain, varies (Kehlet, 2005).

Operational Definition: Surgical procedures from the primary study were categorized as colorectal and general, and gynecological and urological, in the present study.

Length of surgery. Length of surgery was defined as length of time required to complete the surgical procedure.

Operational Definition: Length of surgery was measured in the primary study by noting the start time recorded on the anesthesia record and subtracting it from the admission time on the PACU data sheet. This was then defined on the data collection sheet as “length of surgery from start to end.”

Length of incision. Length of incision was defined as the length of the surgical opening required for completion of the surgical procedure.

Operational Definition: The length of surgical incision was measured in the primary study in centimeters by the nurse data collector and recorded on the data collection sheet.

Summary

In spite of improved understanding and treatment of postoperative pain, many patients still have unacceptable levels of pain associated with surgical intervention. This study was designed to identify those factors associated with moderate and severe postoperative pain. This information will then be used to construct a model to predict postoperative
pain. The findings were expected to help nurses identify patients at risk so they can intervene more effectively and prevent unnecessary suffering in patients following surgery.
Chapter Two

Literature Review

The literature review begins with a description of the neurophysiology of postoperative pain. It continues with a review of the literature on the proposed predictor variables and pain. This is followed by a review of the current literature on postoperative pain models and a discussion regarding defining moderate and severe postoperative pain. The chapter concludes with a consideration of possible confounding variables and threats to internal validity.

_Neurophysiology of Pain Perception._

Nociception is the general term for the formation, transmission, and perception of painful stimuli (Polomano, Dunwoody, Krenzischek, & Rathmell, 2008). Following injury (surgical incision), neuropeptides (substance P (SP) and calcitonin gene related peptide (CGRP)) are released from the ends of specific afferent nociceptive pain fibers (A delta and C-fibers). The local injury, activates local inflammatory cells which release hormones, including bradykinin, leukotrienes, prostaglandins, cytokines and K+, H+, into the tissues near the injury. These result in increased sensitivity (decreased threshold and increased response) of free nerve endings. Activation of phospholipase A₂ activates the arachidonic acid cycle which further contributes to the postoperative pain. This is described as primary hypersentization (Woolf & Chong, 1993).

The pain fibers differ in the type of pain experienced. A delta-fiber (myelinated) stimulation results in a brief prickling sensation (first pain), C-fiber (unmyelinated) activation results in a localized burning sensation (second pain) (Sorkin & Wallace,
After injury, depolarization, and sensitization of the nerve, the noxious impulse travels along the nerve fibers to the dorsal root ganglion of the spinal cord. A delta-fibers enter the dorsal horn via Lissauer’s tract and terminate in Rexed’s Laminae I (marginal zone), II (substantia gelatinosa), V (nucleus proprius), and X (central canal) (Siddall & Cousins, 1998). Most C-fibers enter the dorsal horn and synapse with second order neurons primarily in laminae I, II, and V. Unlike A delta-fibers, up to 30% of C-fibers enter the dorsal horn per the ventral root (Costigan & Woolf, 2000).

The secondary neurons in the dorsal root ganglion (DRG) are of two types. The first type is a nociceptive-specific neuron (NS) which responds to A delta and C-fiber nociceptive input and the second is a wide-dynamic range neuron (WDR) which responds to both noxious and nonpainful stimuli. If WDR and NS pain stimuli persist, receptors in the DRG are activated. These receptors include the N-methyl D-aspartate (NMDA) and non-NMDA receptors. It is the stimulation of the NMDA receptor that is responsible for “wind up” or the phenomena of central sensitization that occurs. Wind-up is due to persistent A delta and C-fiber afferent stimulation. Central sensitization is an enhanced responsiveness of central pain transmission with facilitated responsiveness and reduced inhibition (Dahl & Kehlet, 2006).

As a result of NMDA stimulation, depolarization is prolonged and the action potential increases and results in hyperalgesia. This occurs due to the release of prostaglandins in the dorsal horn (Brune & Zeilhofer, 2006). This is followed by increases in the area of receptive fields (areas in and around the surgical incision), with reduced thresholds for stimulation and the recruitment of A beta-fibers, that are not usually involved in the pain transmission (Cohen, 2004). A beta-fiber recruitment occurs
due to persistent A delta and C-fiber pain transmission, NMDA stimulation and the occurrence of central sensitization. A beta-fiber involvement is responsible for the occurrence of allodynia, which is the conversion of normally painless stimulation to that of painful noxious transmission. This manifests itself when the postoperative patient complains of pain even when touching an area remote to the surgical incision. The presence of allodynia, confirms central sensitization, because it establishes the recruitment of A beta-fibers (Woolf & Chong, 1993).

Activation of NMDA receptors is also responsible for structural and functional changes in the central nervous system (CNS). This process is facilitated by the formation of C-Fos, a proto-oncogene, which produces new proteins that restructure the CNS (neuroplasticity). This restructuring creates the situation where pain can occur in the absence of the primary lesion, and has been established in the conversion of acute to chronic pain (Sinatra & Bigham, 1998).

After stimulation of the NMDA and non-NMDA receptors in the dorsal horn, fiber tracts projecting from the dorsal horn, and the various laminae ascend primarily through the spinothalmic tract, crossover to the contralateral side and ascend to the thalamus. Projection then proceeds from the somatotopically lateral thalamus to the somatosensory cortex (Cross, 1994). Pain can be perceived at both the level of the thalamus and the higher cortical regions. This process of nociceptive pain generation and transmission should be more extensive in more invasive surgery (longer duration and length of incision), and in certain types of surgical procedures (upper abdominal, thoracotomy). Additionally, these pain generating processes would be most intense the closer they are in time following the surgical injury.
Modification of incoming pain information occurs in two ways. The first process is segmental and occurs in the dorsal horn as pain impulses are altered by stimulation of other afferent sensory impulses (position and vibration), that inhibit incoming pain fibers. Additionally, the substantia gelatinosa contains interneuronal systems, opioid receptors and other peptide substances, which alter incoming pain signals (Cross, 1994). The second part of the modulation system is supraspinal and consists of several descending pathways. Three areas in the brain have been identified as the origins of pain modulating descending tracts, the cortex, thalamus, and the brain-stem. Neurotransmitters for these systems include epinephrine, norepinephrine, serotonin, and various opioids (Cross, 1994). Stimulation of the sensory and motor cortex can inhibit, excite, or have mixed effects on both WDR and NS dorsal root neurons.

These effects may be mediated by direct descending fibers or via intermediary brain-stem structures. In the brain-stem, descending inhibitory tracts originate in the reticular formation; in the midbrain, they originate in the ventral portion of the periaqueductal grey area (PAG) (dorsal raphe nucleus); and in the medulla, they originate in the nucleus raphe magnus (NRM) and the nucleus raphe centralis superior. Stimulation of the dorsal raphe nucleus of the PAG, markedly inhibits the response of the dorsal horn neurons to nociceptive transmission of C-fibers (Siddall & Cousins, 1998). This occurs through the release of endogenous opioids (Simpson, Meyerson, & Linderoth, 2006). The projections of the NRM-PAG tract traverse the dorsolateral cord and the neurotransmitter is serotonin. Stimulation of the dorsolateral cord inhibits dorsal horn nociceptive neurons, either through the release of endogenous opioids or the stimulation of other inhibitory systems or both. The ventromedian medulla (VMM) is a combination of nuclear groups
which also serve as the origin of descending inhibitory pain fiber tracts that rely on serotonin as a neurotransmitter. The exact receptors and tracts involved are unclear at this point (Fields, Basbaum, & Heinricher, 2006).

Nucleus raphe nucleus stimulation also releases norepinephrine which has a pronounced tonic inhibitory effect on nociceptive neurons in the dorsal horn. Norepinephrine projections also arise in the area of the locus coeruleus in the Pons. This area can be stimulated by the PAG or the VMM. Stimulation of the area of the locus coeruleus causes analgesia and inhibits spinal nociceptive transmission. The mechanism of this inhibition is due to the release of gamma-aminobutyric acid (GABA), a spinal inhibitory neurotransmitter (Fields, et al., 2006). Opioid receptors in the dorsal horn and brain-stem respond to endogenous opioids, including enkephalin, beta-endorphin, and dynorphin (Cross, 1994). These substances also act to reduce incoming afferent pain sensation. The endogenous opioids, as well as exogenous opioid substances bind with specific opioid receptors in the central nervous system which mitigate the level of pain (Pasero, Paice, & McCaffery, 1999).

It is these pain modulating mechanisms that provide a rational basis for the diversity of pain scores seen in different patients following the same surgical procedure. Patients with better pain inhibitory systems would have reduced levels of pain while those with less complete systems would have more postoperative pain. As time passes from the original surgical insult, endogenous modulation systems are more successful in reducing the levels of postoperative pain (Bisgaard, et al., 2001). This is very apparent as day 2 postoperative pain scores are usually less than those on day 1, and even less on day 3 (Bisgaard et al., 2001).
Modulation of incoming pain impulses also provides a rationale for many well-known pain relief techniques, which include transcutaneous nerve stimulation, acupuncture, placebo, suggestion, hypnosis, distraction, cognition (Woolf & Salter, 2006), and counterirritation (Cross, 1994). Indeed, it is the pain modulating mechanism which gives us some of the scientific support for the gate control theory of pain (Melzack, 1996). It is proposed that the balance between the pain generating (tissue damage), and modulating mechanisms, patient factors (age, gender, acute or chronic preoperative pain, physical status) and surgical factors (surgical procedure, length of surgery, length of incision), and postoperative pain treatment, that results in the variation of postoperative pain into mild, moderate and severe levels.

**Moderate and Severe Postoperative Pain**

Determining moderate and severe postoperative pain is an important part of effectively treating postoperative pain. This was clearly demonstrated by the work of Cepeda, Africano, Polo, Alcala, and Carr (2003), who found that improvement in acute pain (minimal, much & very much), depends on the baseline level of pain when clinicians start to treat the patient. They found for patients in moderate pain (between 4 and 6 on a 0-10 Numerical Rating Scale (NRS), a decrease of 35% (2.4 units) was required for ‘much’ improvement, and a 45% (3.5 units) reduction was required for ‘very much’ improved pain. Patients in severe pain (greater than 6 on a NRS), required larger decreases in pain levels to obtain these same degrees of pain relief.

In a unique study of cancer pain, Serlin, et al., (1995) quantified moderate and severe pain. They measured pain with the Brief Pain Inventory (BPI) (Cleeland, 1989), and categorized the 0-10 pain scores as mild, moderate or severe. The sample for this
study was large (N = 1,897), and included both inpatients and outpatients from four
countries (United States, Philippines, France, and China). The researchers compared
these pain scores with indicators of functional interference with normal activity. Patient
reported “worst” pain had the highest correlation with the interference items (activity,
enjoyment, mood, relating to others, sleeping, walking, work ability), and not current
pain severity or pain “now.” Therefore, the mean pain interference score was compared
to each of four commonly used models or upper boundaries of mild, moderate, and severe
cancer pain, using them as abbreviations in a model of cut points (CP), of 36, 37, 47, 46.
For example, a cut point of 36 means that the upper boundary of mild pain is at a NRS
level of 3, and the upper limit of moderate pain is at a NRS pain level of 6 (Table 2).

Table 2

Cutpoints for Mild, Moderate and Severe Pain

<table>
<thead>
<tr>
<th>Cutpoints</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td>CP36</td>
<td>1-3</td>
<td>4-6</td>
<td>7-10</td>
</tr>
<tr>
<td>CP37</td>
<td>1-3</td>
<td>4-7</td>
<td>8-10</td>
</tr>
<tr>
<td>CP47</td>
<td>1-4</td>
<td>5-7</td>
<td>8-10</td>
</tr>
<tr>
<td>CP46</td>
<td>1-4</td>
<td>5-6</td>
<td>7-10</td>
</tr>
</tbody>
</table>

*Note. CP = Cutpoints for four commonly used boundaries of mild, moderate and severe pain, labeled 36, 37, 47, 46, which defines the higher end of the mild and the moderate boundaries on the 0-10 numerical rating scale of the BPI. i.e., a cut point of 36 means that mild pain ends at a NRS level of 3, and moderate pain ends at a NRS level of 6. Adapted from “When is Cancer Pain Mild, Moderate or Severe? Grading Pain Severity by its Interference with Function,” by R. C. Serlin, T. R. Mendoza, Y. Nakamura, K. R. Edwards, and C. S. Cleeland, 1995, Pain, 61, p. 280. Copyright 1995 by Elsevier Science B. V. Used with permission from The International Association for the Study of Pain.*
which mild pain equals 1-4; moderate pain equals 5-6; and severe pain equals 7-10 (Table 2). This differentiation quantified the terms mild, moderate and severe cancer pain, by associating a level of functional interference with each pain level designation.

In a continuation of Serlin et al.’s work, Jensen, et al., (2001) applied the criteria found in cancer pain to non-cancer pain. Jensen et al used amputation pain, phantom limb pain, back pain and general pain and found that the criteria used for cancer pain corresponded only to back pain. Different cut-points were found for phantom limb pain, and general pain. The authors summarized this study, by stating that as found by Serlin, et al. (1995), they found non-linear cut-points indicating that non-cancer pain also has certain thresholds that interfere with function, and that optimal cut-points varied according to the pain site. Nevertheless, Jensen et al. concluded that the cut-points as expressed by Serlin, et al. (1995), fit the pain sites included in their study reasonably well, as the F ratios were similar.

Mendoza et al. (2004) directly applied Serlin’s criteria to postoperative open heart patients. The boundaries of mild (1-4), moderate (5-6), and severe (7-10), were optimal to describe postoperative open heart pain on 5 out of 11 postoperative study days. The time points that Mendoza et al. used started on the fourth day post open heart and continued to day fourteen. Pain levels decreased greatly after day six (the sixth postoperative day), making it difficult to correlate pain levels with functional impairment.

Dolin et al. (2002) reviewed a number of studies of abdominal, major gynecological, major orthopedic and thoracic patients. Dolin et al. also defined severe pain as 7.0 out of 10.0, but defined moderate pain as greater than 3.0. Based on the cancer pain criteria of Serlin et al. (1995), and the adaptation of this work by Mendoza et al.
(2004), to postoperative pain, the secondary analysis will extrapolate to the 0-100 mm scale and examine the following defined levels of postoperative pain: mild (0 to < 30 mm and 0 to < 50 mm), moderate (30 to 100 mm and 50 to 100 mm), and severe (70-100 mm). As some controversy exists in the definition of moderate pain, lower boundaries of both 30 mm and 50 mm will be studied and outcomes will be compared in the secondary analysis.

Independent Variables and Their Relation to Pain

Gender

Females have demonstrated significant differences from males in the way they respond to acute experimental pain (Rollman, Lautenbacher, & Jones, 2000; Sheffield, Biles, Orom, Maixner, & Sheps, 2000; Myers, Robinson, Riley, & Sheffield, 2001). While some of these studies reveal that women have lower pain thresholds, rate similar pain stimuli as more painful than men, and have reduced pain tolerance for intensely painful stimuli, these findings are not consistent, and appear to be related to the method of inducing experimental pain (Rollman, et al, 2000).

Females also suffer from a variety of painful conditions, some of which occur with a higher frequency in females, i.e.; migranes, temporomandibular joint disorders, fibromyalgia and irritable bowel syndrome (Rollman, et al, 2000). Females also report higher levels of daily pain in chronic pain conditions (Holtzman, Saleh, & Kane, 2002). Differences in pain levels between males and females in chronic osteoarthritis vary, with 72% of females reporting higher pain levels versus males (Affleck, et al., 1999). In studies of postoperative pain in patients with osteoarthritis who have undergone total hip
and knee replacement, females reported higher levels of postoperative pain and less satisfaction with pain treatment than males (Thomas et al., 1998).

Additionally, females have better analgesia from kappa receptor opioids (Gear, Gordon, Heller, Paul, Miaskowski, & Levine, 1996; Miaskowski, Gear, & Levine, 2000). The physiological basis for this is due to hormonal differences (Berkley, 2000). Further, women recover 50% faster than males from propofol/alfentanil/nitrous oxide anesthesia and have a threefold greater potential for experiencing awareness under anesthesia (Gan, et al., 1999). In addition, during pregnancy the anesthetic requirement, as measured by the Minimum Alveolar Concentration (MAC) is reduced by one-third compared to the unpregnant state and returns to the unpregnant level in the late postpartum period (12-25 hours) (Zhou, Norman, DeLima, Mehta, & Bass, 1995). All of this strongly suggests that there are gender differences in pain and analgesia which may provide differences in postoperative pain levels.

Research findings demonstrate that women use different coping styles for dealing with pain. They reported significantly more problem-solving, social support, positive self-statements, and palliative (sustaining) behaviors, compared to men when dealing with both acute and chronic pain (Unruh, Richie, & Mersky, 1999). Women also used different parts of the brain to deal with chronic pain (Naliboff, et al., 2003). Explanations for these female gender differences have been based on socialization or psychosocial factors, hormone levels (estrogen and progesterone) (Berkley, 2000), and differences in reproductive status (Ciccone & Holdcroft, 1999) and phase of the menstrual cycle (Cepeda & Carr, 2003).
While these studies establish gender differences in experimental and chronic pain, the focus of this study is acute postoperative pain. The following studies are more related to the area of acute or postoperative pain. In a study of 8-17 year old children (N = 65), who underwent thoracic (23%), orthopedic (23%), abdominal (23%), urologic (12%), neurological (11%), and miscellaneous (8%) operations, girls had a significantly higher pain intensity on day 1 following surgery, $F(1,44) = 5.1, p = 0.03$, (Savedra, Holzemer, Tesler, & Wilkie, 1993). In a study of 3rd molar extractions in 242 people 15-44 years of age, Faucett, Gordon, and Levine, (1994), found that females (n = 301) had significantly (7-35%) greater pain than males, $t(300) = -4.21, p < .001$, across four different ethnic groups, in a study of postoperative dental pain following third molar extraction. Significantly greater pain intensity was also reported in females following laparoscopic cholecystectomy, 5-9 mm on a 0-100 mm VAS, $p < .05$ (Ure, et al., 1994), and on day 1 following cardiac, and abdominal vascular surgery, $F(1,71) = 3.21, p < .05$, (Puntillo & Weiss, 1994).

In a surgical study of hip replacement (n = 30), knee replacement (n = 31) and spinal nerve root decompression (n = 30), researchers found that female gender was a significant predictor of severe postoperative pain (odds ratio = 1.73, $p = 0.01$), (Thomas, et al., 1998). In another study of 166 patients, 18-65 years of age, undergoing surgical procedures of less than three hours duration, females had greater levels of pain intensity than males, $p = 0.02$, 95% CI, 0.2-1.6 (0-10 NRS), and .3 points less pain relief after controlling for surgical procedure, $p = 0.04$, 95% CI, 0.02-0.6, (Cepeda, et al., 2002).

While there is support for a gender difference in postoperative pain, with females having higher pain intensity, there is also some conflict found in the literature. Good et
al., (1999) found no gender related differences in post-test pain after interventions, but did not report gender differences at pretest. In a study of preschool immunizations (n = 200, males = 50%), postsurgical wound packing (n = 75, males = 45%), and chronic pain (n = 78, males = 38%), researchers found no gender difference in pain levels across these three groups (Lander, Fowler-Kerry, and Hill, 1990).

To illustrate the confounding factors among studies, two will be compared. In a prospective cohort study conducted in Bogota, Colombia, Cepeda and Carr (2003) found that female patients experienced more postoperative pain (0.4 unit on a 0-10 NRS) than males, p = 0.001, and required 30% more morphine, p = 0.02. In a prospective study conducted in Taiwan, gender was not a factor when comparing rest pain, but men had more movement related pain on day 2, and consumed 24-43% more PCA morphine than females in the study (Chia, et al., 2002). The difference in these two studies may well be related to the very different clinical conditions chosen for testing. The surgical procedures carried out in each study were comparable. In the Cepeda and Carr (2003) study, all patients admitted to the post-anesthesia unit with a 5.0/10.0 or greater VAS were included in the study. Patients were then given IV morphine boluses until the VAS pain level was 4.0/10.0 or less. The result was that women, after controlling for surgical procedure and age, had higher levels of pain and required more morphine. In the 2-year Taiwanese study, all patients (N = 2,298) were followed for three postoperative days and pain was assessed at both rest and with movement. While Cepeda and Carr suggest that the difference in the results of these two studies may be due to the fact that the Taiwanese patients are different culturally, the difference in research conditions, recovery room versus 3 days at ambulation and rest may also account for the divergent findings.
Among researchers who attempted to construct a model of postoperative pain, female gender was predictive of the higher levels of postoperative pain in three studies (Ure et al., 1994; Puntillo & Weiss, 1994; Thomas et al., 1998) and not significant in three other studies (Bisgaard et al., 2001; Kalkman et al., 2003; Caumo et al., 2002). The explanation for these different findings is not readily apparent. Although the effect size of gender on postoperative pain is small ($f^2 = .055$) (Puntillo & Weiss, 1994), the studies that found differences had relatively smaller sample sizes than those studies that did not find a significant difference. The proportion of males in each sample also did not impact the findings, as small percentages of men (25-26%) were found in both significant and non-significant studies. It does appear that controlling for surgical procedure allows gender differences to emerge, as comparable studies of laparoscopic cholesteotomies came to opposite conclusions regarding the effect of gender on postoperative pain. The only obvious difference in this comparison of studies is the year the study was carried out; the studies which show gender as a significant predictor of postoperative pain were conducted earlier (1994-1998) than those that found no difference (2001-2003). The implications of this are not clear.

Age

The evaluation of the relationship between older age and postoperative pain is complex. Studies of the relationship between postoperative pain and age are compounded by issues of the aging nervous system, changes in response to analgesics, and the existence of barriers to effective treatment. Factors in older patients suggest rationale for both decreases and increases in expected postoperative pain. Factors that support decreased postoperative pain include reduced nerve conduction and physiologic
changes that alter the action of analgesics. Factors that would increase the intensity of postoperative pain in the elderly are usually psychological, like stoicism and not wanting to bother the doctor or nurse with pain complaints.

*Reduced nerve density and conduction as a person ages.* In a review discussed by Harkins (2002), studies have demonstrated an increase in experimental pain threshold in the aged due to changes in A delta and C-fiber nerve conduction (Chakour, Gibson, Bradbeer, & Helme, 1996), reduced pain sensitivity to low-intensity noxious stimuli, and delay in central sensitization (Gibson & Farrell, 2004; Wu, 2005), but this work has not been confirmed in clinical postoperative pain studies. Studies have also demonstrated that the elderly shift from both A delta and C-fiber pain transmission, to predominately C-fiber pain transmission as part of the aging process (Chakour et al., 1996). This is significant as C-fiber transmitted pain sensation is more amenable to opioids than A delta-fibers (Rakel & Frantz, 2003; Hall, Tarala, Tapper, & Hall, 1996).

Additionally, it is A delta-fiber transmission that is related to movement related postoperative pain (Rakel & Frantz, 2003), which is the most intense form of postoperative pain (Gilron et al., 2005). It is movement related postoperative pain that prevents patients from ambulation, coughing and deep breathing and leads to significant postoperative complications (Kehlet & Dahl, 1993). These findings would suggest that the elderly may have less movement related pain and therefore less overall postoperative pain than younger patients following identical surgical procedures, but the basis for these findings is largely experimental pain studies (Harkins, 2002) and retrospective studies (Ready, 1999).
In several predictive studies, reduced postoperative pain in the elderly holds across several types of surgery: abdominal surgery, odds ratio = 4.7, p = .0081, (Caumo et al., 2002), laparoscopic cholecystectomy, p = .03, (Bisgaard, et al., 2001), hip replacement, knee replacement, and spinal nerve root decompression, odds ratio = .98, p = .001, (Thomas, et al., 1998) and a variety of surgical procedures, odds ratio = .98, p = .001 (Kalkman et al. 2003). Ready (1999) in a record review of older women > 75 years of age (n = 23), and younger women < 40 years of age (n = 54), undergoing abdominal hysterectomy, found that older women had considerably less movement related pain (4.3 versus 7.1 points on a 0-10 scale) than younger women, and used less morphine (8 versus 22 mg per 24 hours). The author cautions that these findings are from a record review and are not the result of a formal prospective study.

*Altered pharmacology in the elderly patient.* Changes in what the body does to the drug (pharmacokinetics), and what the drug does to the patient (pharmacodynamics) occur in the elderly patient. Most studies support less postoperative opioid intake in older adults which is attributed to pharmacokinetic and pharmacodynamic differences from physiological changes (Parkhouse, et al., 1961; Bonica, 1990; Macintyre & Jarvis, 1995; Wu, 2005; Bellville, Forrest, Miller, & Brown, 1971; Woodhouse & Mather, 1997). However, one study reported no difference in opioid consumption across all ages following surgery (Dahmani, Dupont, Mantz, Desmonts, & Keita, 2001). Mixed results are most probably related to different operational definitions for the term elderly, and the fact that all of these studies had retrospective designs.

Pharmacokinetic changes (what the body does to the drug) include elevated blood levels of opioids and decreased metabolism and elimination of the dose administered.
Pharmacodynamic changes (what the drug does to the body) include increased sensitivity of the central nervous system to the effects of opioids. These changes combine to increased side-effects and toxicity of opioids in the elderly (Wu, 2005).

Total body water and lean body mass decrease in the elderly and this in turn, reduces the volume of distribution of hydrophilic drugs (e.g., morphine). These changes along with a reduction in glomerular filtration in the kidneys and reduced hepatic blood flow, increase the elimination half-life of opioids. This leads to a higher peak effect and a longer duration for opioids in the elderly adult. This translates into not only more efficacy with regard to pain relief, but to a greater incidence of side-effects as well (Pasero & McCaffery, 1996). These side effects include respiratory depression, constipation, pruritus, sedation, and urinary retention. Nausea and vomiting are the only opioid side effects that occur less in the elderly than in younger adults (Pasero & McCaffery, 1996).

**Central nervous system changes.** These changes in older adults include a reduction in the efficacy of the endogenous pain system, reduced pain tolerance and slower resolution of post injury hyperalgesia (Gibson & Farrell, 2004; Wu, 2005). These changes have been implicated in the higher incidence of chronic pain in the elderly (Wu, 2005).

**Psychological issues within elderly patients following surgery.** Elderly adult patients are at risk for under-treatment of postoperative pain due to their reluctance to complain of pain, their stoic nature, their respect for the caregiver, their reluctance to bother nurses for pain medication and their concern that they may become addicted to pain relieving drugs (Pasero & McCaffery, 1996). Zalon (1997) reports that the behavior of frail elderly
patients is to endure pain and to trust physician and nurses to provide analgesics without requesting them. Clinicians reported that many elderly adults have sensory deprivation (hearing and sight), are cognitively impaired and may be confused about the use of patient-controlled analgesia for postoperative pain control (Pasero and McCaffery, 1996). More recent studies reported that cognitive problems, confusion or postoperative delirium is observed in one out of four patients greater than 60 years of age after major surgery (Mann, et al., 2003). In patients greater than 70 years of age, researchers found that 17.5% of patients had problems initiating Patient Controlled Analgesia (PCA) bolus doses on the first postoperative day because of mild confusion (Pasero & McCaffery, 1996). The combination of opioid side effects and postoperative confusion, may act additively to prevent the elderly patient from communicating pain and receiving effective treatment.

The literature regarding acute pain and postoperative pain in the elderly is mixed, and ranges from no significant differences in the quality and quantity of postsurgical pain across different adult age groups (Harkins, 2002), to increased rest pain in the elderly (≥ 70 versus < 70 years of age) following surgery, p = .02, (Lynch et al, 1997), to reduced levels of postoperative pain in the elderly versus younger patients following a variety of surgical procedures (Thomas, et al, 1998; Bisgaard, et al, 2001; Caumo, et al, 2002; Kalkman, et al, 2003). The mixed results may well lie in the differences in type of pain studied (experimental versus clinical), and the definition of elderly. Harkins’s work is a review of pain in the elderly with a strong emphasis on experimental pain studies. The Lynch, Bisgaard, Caumo, Thomas, and Kalkman studies vary most importantly in the way age is defined. For example, Caumo, et al dichotomize age into younger and older at
52 years of age, while Lynch, et al. only sampled patients older than 50 years of age and used 70 years of age as the dichotomous point between older and younger patients. Kalkman et al. and Bisgaard et al. entered age as a continuous independent variable. These methodological differences may have contributed substantially to the mixed results.

Most studies show lower levels of postoperative pain in the elderly (Thomas et al., 1998; Bisgaard et al., 2001; Caumo et al., 2002; Kalkman et al., 2003; & Katz et al., 2005). This finding occurs even across very different definitions of elderly. In clinical studies that controlled for surgical procedure and defined elderly as about ≥ 50 years of age (n = 587), the finding of reduced levels of postoperative pain in the elderly is fairly consistent (Thomas et al., 1998; Ready, 1999; Bisgaard et al., 2001; Caumo et al., 2002).

**Chronic Preoperative Pain**

Pain that has persisted beyond the normal healing process or due to an ongoing disorder, is referred to as chronic. Pain is usually considered chronic if its duration is six months or greater (Caumo, et al, 2002; Dunajcik, 1999; Joint Commission on Accreditation of Healthcare Organizations, 2000). Chronic pain in the primary and this secondary study was defined as pain that has persisted for greater than one month, a definition consistent with that of Bonica (1990). Only one study was found that supported a correlation between the severity of postoperative pain and the existence of preoperative chronic pain and it used a six month duration to define chronic pain (Caumo, et al, 2002). Caumo attributes the relationship between more intense postoperative pain and preoperative acute or chronic pain to neuroplastic changes in the central nervous system (Kehlet, Jensen, Woolf, 2006). These neuroplastic changes take place within 20 minutes
of the injury or incision (Carr & Goudas, 1999). The primary study failed to find a
relationship between chronic pain (n = 180, 38%) and postoperative pain at posttest,
however relationships at pretest were not reported (Good et al, 1999).

**Acute Preoperative Pain**

While acute pain has been defined in various ways (Bonica, 1990; Joint
Commission on Accreditation of Healthcare Organizations, 2000; Kumar & Smith, 2003;
Pasero, Paice, & McCaffery, 1999; Craig, 2006), there are several features common to
these definitions: acute pain is of recent onset, and is associated with illness or injury.
Three studies predicted increased severity of postoperative pain based on the existence of
pain preoperatively using regression and logistic regression (Kalkman, et al, 2003;
Caumo, et al., 2002; Thomas, et al., 1998). In six studies acute pain was not differentiated
from chronic pain (Ure et al., 1994; Ready, 1999; Slappendel et al., 1999; Bisgaard et al.,
2001; Kalkman, et al., 2003; Katz et al., 2005).

In the Thomas et al study, 91 patients underwent one of three surgical procedures, hip
replacement, knee replacement or spinal nerve root decompression. Patients were
interviewed preoperatively to document pain, using both a VAS scale (0-10) and the 0-5
Present Pain Intensity scale (PPI) from the McGill Pain Questionnaire (Melzack, 1975).
The PPI is a verbal/numerical pain assessment scale with 0 indicating no pain, 1 = mild
pain, 2 = discomforting pain, 3 = distressing pain, 4 = horrible pain and 5 = excruciating
pain. As the correlation between the VAS and the PPI was high (r = 0.84-0.91, p <
0.001), only the PPI scores were reported. Postoperative pain was assessed on days 1-5
and compared with preoperative measures. Preoperative pain was dichotomized into low
(0-1) and high (2-5) levels. High preoperative pain levels significantly predicted severe
pain with an odds ratio of 3.09, p < 0.01, over the duration of the study (five days).

Patients with high levels of preoperative pain were three times more likely to have severe postoperative pain than patients with low or absent preoperative pain.

Caumo et al., (2002), studied 346 subjects, all undergoing elective abdominal surgery. Pain was assessed with a VAS (0-100 mm) and was then averaged over two time periods, 12 and 24 hours postoperatively. Pain was dichotomized into ≤ 30 mm, for absent or mild pain and > 30 mm for moderately intense or worst possible pain. Preoperative moderate intense or worst possible pain significantly predicted moderate to intense postoperative pain and had an odds ratio of 2.96 (95% CI, 1.32-6.60, p = .0081). Patients with preoperative moderate to intense worst pain were almost 3 times as likely to have moderate to intense postoperative pain.

Another group (Kalkman et al., 2003), studied 1,346 subjects undergoing all types of surgical procedures except cardiac and intracranial neurosurgery. Trained nurse researchers used the pain domain of the Short Form 36 (SF 36), to measure pain levels in the recovery room every 15 minutes for the first hour. Scores were transformed, 0 = no pain to 10 = worst pain. The outcome variable was severe pain, defined as ≥ 8, on the NRS. The incidence of severe pain in the first hour following surgery was 25.8%. Preoperative pain had an odds ratio of 1.15, p < .001, for severe postoperative pain probability. In those with acute preoperative pain, there was 15% more severe pain per unit of preoperative pain (0-10).

While all three studies found preoperative pain as a significant predictor of postoperative pain severity, they differed widely in their definition and measurement of preoperative acute pain. Kalkman et al. used a 0-10 NRS and regressed per unit of
preoperative pain. Caumo et al., (2002) dichotomously defined moderately severe
preoperative pain as ≥ 3.0 on a 0-10 VAS, and Thomas et al, (1998), used the PPI, a 0-5
scale. These differences make it difficult to draw robust conclusions. In addition, acute
and chronic preoperative pain, were not always differentiated. The proposed study will
evaluate the relationship between preoperative pain and moderate and severe
postoperative pain using logistic regression. Moderate postoperative pain will be defined
in two ways; according to Caumo et al. (2002), and Dolin et al. (2002), as 30 to 100 mm,
and according to Serlin et al. (1995), and Mendoza et al. (2004), as 50 to 100 mm, will be
used to define and categorize moderate pain. The purpose of defining moderate pain in
both ways reflects the lack of consistency in the literature regarding the level at which
most researchers agree represents moderate pain. The advantage of this approach is that it
allows a contrast of both levels of pain in assessing moderate precedent factors and can
be compared to the literature in a more specific way. Severe pain will be defined
according to Serlin et al. (1995), and Dolin et al. (2002), as 70 to 100 mm.

Surgical Procedure

Bonica (1990) lists the site of surgery, duration of operation, type of incision and
the amount of intraoperative trauma as important factors with regard to the intensity,
quality, and duration of postoperative pain. Bonica states that postoperative pain occurs
more often and is more severe following intrathoracic, intra-abdominal, extensive surgery
of the spine, major joints, and large bones in the hand and foot, and other major surgical
procedures. Bonica (1990) also compares types of incision in relation to postoperative
pain. The subcostal incision used for cholecystectomy, is followed by less postoperative
pain than a midline one, and a transverse abdominal incision damages fewer nerves and
therefore causes less postoperative pain. Bonica (1990) also points out that underlying muscles go into reflex spasm contributing to elevated levels of incisional pain.

Using published and unpublished reports Bonica (1990) constructed a table showing the percentage of patients with moderate and severe pain, as well as the mean duration and range of days of moderately to severe postoperative pain. Moderate to severe pain duration in days, is as follows for the following surgical sites: intrathoracic (8), upper abdominal (4), renal (5), major joint (3), lower abdominal (2), bladder/prostate (2), and skin (2.5). Bonica warns that these numbers are “rough estimates.” Additionally, Bonica collected this data prior to 1990. It is reasonable to suggest that postoperative pain management has changed since 1990, with the more frequent use of epidural analgesia, patient controlled techniques as well as regional blocks and catheters that deliver continuous local anesthetics to the surgical site (Rowlingson, 2005).

Many authors have suggested that upper abdominal and thoracic surgical procedures are the most painful postoperatively (Parkhouse, et al., 1961; Bonica, 1990; Simpson & Parkhouse, 1961; Brown, 1989; Heffline, 1990; Musgrave, 1990; Kehlet and Ferrante 1995; Carpenter, 1997). It is possible that operative procedures carried out in these two body areas are modified by movement and breathing which make them inherently more painful and/or that the sensory nerves stimulated (vagus and phrenic) transmit increased levels of impulses, resulting in more postoperative pain following surgery, as it reflects a very deep penetration (stimulation of vagal and phrenic nerve branches) of the body’s integrity (Kehlet, 1998).

Thomas et al. (1998) found differences in pain following orthopedic surgery. They studied postoperative pain following three operative procedures (knee and hip
replacement, and spinal decompressive surgery (N = 91). Researchers used a VAS and the Present Pain Inventory, a 0-5 verbal descriptor scale (Cleeland, 1989). Pain was measured by self-assessment and as a daily peak score (recall over the past 24 hours) over the course of five days. At the exit interview with each patient, overall pain control and patient satisfaction were evaluated. Pain for each of the three procedures decreased over the course of the five days with each operation, demonstrating a distinctive trend of pain decrease. Postoperative pain was less for patients undergoing hip replacement versus those who underwent knee and spinal procedures.

The relationship between surgical procedure and pain was investigated in two other studies (Dahmani, et al., 2001; Caumo, et al., 2002). In the first of these (Dahmani, et al., 2001), orthopedic, general, urological, gynecological, and ear, nose and throat surgical procedures were included, while cardiac procedures were excluded (N = 149). Pain was evaluated using a VDS (none = 0, mild pain = 1, moderate pain = 2, and severe pain = 3) in patients complaining of pain upon entry to the recovery room. Morphine was then administered by the nurse according to standard procedure until the patient was comfortable (VAS = 0 or 1). As a measure of pain intensity, morphine consumption in the first hour in the recovery room was recorded. Surgical procedures were classified as major, intermediate, and minor. Major procedures included, gastrectomy, splenectomy, liver/pancreatic, esophageal, laparotomy/bowel resection, laparotomy/cholecystectomy, laparotomy/hysterectomy, thoracic surgery, spinal fusion, renal surgery, total knee replacement or arthrolysis, and adenoidectomy. Intermediate procedures included: appendectomy, laparoscopic procedures, mastectomy, inguinal hernia, vaginal hysterectomy, thyroidectomy, ear, nose and throat surgery (other than adenoidectomy),

Using this classification and logistic regression, Dahmani et al demonstrated that undergoing major surgery was predictive of the morphine requirements in the early postoperative period, \( \text{odds ratio} = 2.4, 95\% \text{ CI} = 1.1-5.8, p = 0.04 \). Patients who underwent surgical procedures classified as major were twice as likely to have higher morphine requirements, than those undergoing intermediate or minor procedures. This contrasts with the study by Caumo et al., (2002), which classified major surgical procedures into upper abdominal and lower abdominal and found no significant relationship between surgical procedure and the severity of postoperative pain.

The invasiveness of the surgical procedure and its relationship to postoperative pain has been evaluated in both breast surgery (Katz, et al., 2005), and knee surgery (Williams, et al., 2003). In both studies, higher levels of postoperative pain were significantly correlated with more invasive surgery. Because the primary study included only major abdominal procedures, the proposed secondary study will segregate surgical procedures from the primary study into two categories. The first group was composed of colorectal and general surgery patients, while the second group consisted of gynecological and urological patients.

*Physical Status*

The American Society of Anesthesiologists (ASA) physical status classification (Saklad, 1941) is a system used to grade or evaluate the preoperative physiological condition of patients presenting for surgery (Owens, Felts, & Spitznagel, 1978). The
rankings are as shown in Table 1. The American Society of Anesthesiologists (ASA) physical status has been used clinically to predict anesthesia and surgical risk and postoperative outcome (Cullen, Apolone, Greenfield, Guadagnoli, & Cleary, 1994; Klotz et al., 1996; Wolters, Wolf, Stutzer, & Schroder, 1996), in spite of assertions that it was not created for that purpose (Keats, 1978; Owens, 2001; Lema, 2002). Caumo et al. (2002) used ASA physical status as a predictor of moderate to intense postoperative pain following abdominal surgery and found that patients with an ASA ranking of III had twice the occurrence, odds ratio = 1.99, 95% CI, 1.30-3.03, p = .0052, of moderate to intense pain following abdominal surgery compared to those with ASA I and II. Two other studies (Chung et al., 1996; Bisgaard et al., 2001) also used ASA status as a predictor of the severity of postoperative pain and were unable to find any correlation. The primary study included 139/500 or 28% ASA physical status level III patients (ASA I = 12%, ASA II = 63%, ASA IV = 1%, and ASA V = 0.2 %). The proposed study used ASA physical status as a variable in the regression to ascertain its possible role in moderate and severe postoperative pain. I and II and III, IV and V, will be dichotomized into < III and ≥ III.

Length of Surgery

In one observational study, the length of surgery has been found to correlate with the intensity of postoperative pain, (data not included in report) but not when adjusted for additional factors of younger patient age, larger mean end-tidal anesthetic concentration, and larger doses of fentanyl per kilogram (Pavlin, Chen, Penaloza, Polissar, & Buckley, 2002). Others found that surgery exceeding 100 minutes, odds ratio = 7, 95% CI, 1.5-33, p = .01, and pain score on arrival to the recovery room, odds ratio = 5, 95% CI, 2.6-10, p
= .0001, were predictive of morphine requirements in the first hour following surgery (Dahmani, et al., 2001). However a third study did not find a correlation between length of laparoscopic cholecystectomies and intensity of postoperative pain measured 5 hours postoperatively and 8 a.m. and 6 p.m., for three days postoperatively, in laparoscopic cholecystectomy (Ure et al. 1994). The lack of correlation in the Ure et al. study may well be related to waiting five hours to measure postoperative pain following this procedure and to its lower levels of postoperative pain. In another study of laparoscopic cholecystectomy patients, they found that at six hours postoperatively only 39% of patients had pain greater than 50 mm on a 100 mm VAS. The lower level of pain associated with laparoscopic procedures and the reduction of pain over five hours makes it more difficult to find correlations with predictors. Due to the strength (odds ratio = 7) of the finding in the Dahmani et al. study, and the open incisions included in the primary study, length of surgery was analyzed as a possible predictor of moderate and severe postoperative pain.

Length of Incision

Researchers in only one study found a correlation between the length of the incision and the intensity of postoperative pain in a variety of surgical procedures (Kalkman et al., 2003). Ure et al., (1994) was not able to correlate incision length with postoperative laparoscopic patients. This most probably reflects the consistently small incisions required for this procedure and the fact that the surgical incision or trocar sites in laparoscopic surgery are just one of several possible sources of postoperative pain (Ure et al., 1994).
Prior Work in Building a Model of Postoperative Pain

Early attempts in constructing a model of postoperative pain include a prospective correlational study (N = 74), which examined pain following abdominal vascular and cardiac surgery in the intensive care unit (Puntillo & Weiss, 1994). This study found that gender, $R^2 = .052$, $F = 3.21$, $p < .05$, type of surgery (abdominal vascular surgery versus cardiac surgery), $t = 2.58$, $p = .02$, and analgesic consumed, $F = 8.74$, $p < .004$, were significant predictors of the intensity of pain on the first postoperative day. Independent variables that were not significant in the model included age and personality adjustment. Overall, the model accounted for 28% of the variance in intensity of postoperative pain. The researchers expressed the opinion that this was a very low variance for the model and suggested that additional factors, family support, patient ethnicity, mode of analgesic administration (systemic versus epidural), nursing comfort measures, and amount of perioperative analgesics, could be evaluated in the regression model in an attempt to increase the variance explained (Puntillo & Weiss, 1994).

In a prospective observational study that included only laparoscopic cholecystectomy patients (N = 382), postoperative pain was higher in females, $p < .05$. Patients who required opioids or had postoperative pain greater than 50 VAS points, also had higher preoperative pain levels (mean intensity = 51 VAS points), $p = .018$. Three variables, gender, opioid treatment required for postoperative pain, and preoperative pain were found to be predictive of the level of postoperative pain, 5 hours following surgery (Ure, et al., 1994). In an observational cohort study (N = 91), of total hip replacement, knee replacement, and spinal surgery patients, four variables, gender, OR = 1.73, $p = .01$; age, OR = .98/year, $p = .01$; chronic preoperative pain, (> 6 months), OR = 1.70, $p = .01$;
and acute preoperative pain, OR = 3.09, p = .01, were significant as multivariate predictors of severe postoperative pain (PPI > 2.5) (Thomas, et al., 1998).

In another study of laparoscopic cholecystectomy (N = 150), researchers measured (patient self-reports) both a daily total pain score and a maximum pain score using a VAS over the first week postoperatively. They found two predictors: younger patients (r = -.2) and those with preoperative pain (biliary attacks) (r = -.3) had more daily pain, p = .02 (Bisgaard, et al., 2001). Gender and physical status were not predictive of postoperative pain in this study and length of surgery and length of incision were not studied.

In a prospective cohort correlational study of upper and lower abdominal surgery (N = 346), age (≥ 52 years, < 52 years) younger age (<52 years) was related to more moderate intense or worst possible postoperative pain (> 30 mm), OR = 4.72, 95% CI, 2.69-8.32, p < .001. Additionally, the presence of chronic preoperative pain, OR = 1.75, p = .0393; acute preoperative pain, OR = 2.96, 95% CI, 1.32-6.60, p = .0081; and physical status (ASA III), OR = 1.99, 95% CI, 1.30-3.03, p = .0052, were significant predictors of ≥ 3.0 cm (0-10 cm VAS) “moderate intense or worse possible” postoperative pain. Gender and surgical procedure were not significant predictors of the level of postoperative pain (Caumo, et al., 2002).

In a secondary analysis of data used for a study of nausea and vomiting following eye, laparoscopic, orthopedic, and abdominal surgery, Kalkman et al. (2003) studied factors associated with the incidence of severe pain (≥ 8.0 cm on a 0-10 cm VAS) in the first hour following surgery using logistic regression. There were five significant predictors of severe pain: age, OR = .98/year, p < .001, acute preoperative pain, OR = 1.15, p < .001; orthopedic surgery, OR = 2.64, p = .006; abdominal surgery, OR = 3.56, p
< .001, and length of incision, OR = 1.26, p = 0.15. The researchers, used a Receiver Operating Characteristics (ROC) Curve, to produce an area under the curve of 0.71 (95% CI: 0.68-0.74) (Kalkman, et al., 2003). The “fit” or area under a ROC curve is a statement of the exactness of the model’s ability to predict severe pain in the first hour following surgery, with 1.0 being a perfect fit (Swets, Dawes, & Monahan, 2000). It is interesting that the OR for age (.98/year) found by Kalkman et al. was the same as that found by Thomas et al. (1998). Gender was not significant in predicting severe pain in the first hour following surgery.

A prospective correlational study of breast surgery found three predictors more likely to result in persistently meaningful clinical pain (≥ 5.0 cm on a 0-10 cm VAS) at 2, 10 and 30 days following surgery (Katz et al., 2005). The first factor was age (≤ 49, ≥ 50 years), younger patients had more pain, p = .04. The second factor was more invasive surgery (node dissection, mastectomy), OR = 7.53 (95% CI: .67-84.78) p = .10, and the third factor was preoperative anxiety as measured by the Spielberger State-Trait Anxiety Inventory (STAI), OR = 1.08 (95% CI: 1.01-1.17), p = .03.

In summary, three of the seven model studies found that female gender significantly predicted increased postoperative pain (Ure et al., 1994; Puntillo & Weiss, 1994; Thomas et al., 1998), and three did not find gender significant in the prediction of postoperative pain (Bisgaard et al., 2001; Caumo et al., 2002; Kalkman et al., 2003), and one study (Katz et al., 2005) did not study gender as a predictive factor. In the three studies that found gender as a predictor, sample size was considerably less than in the three studies that failed to find gender predictive. The total sample size for the three studies that found female gender predictive was 533. The total sample size for the three
studies that did not find female gender predictive of postoperative levels was 1912. This is unexpected as the larger sample would have been expected to allow gender to emerge as a predictor. However, the diversity of surgical procedures was greater in the studies that found no gender difference. This is expected, as limiting the types of surgical procedure in the study should have allow predictors to more readily emerge. Finally, the studies which failed to show gender as a predictor of the intensity of postoperative pain were more recent (2001-2003) than those that identified gender as a predictor (1994-1998). It is tempting to suggest that more effective postoperative treatment (PCA, epidural techniques) has eliminated gender differences, but this is unsubstantiated.

In five out of seven studies, age was inversely related to levels of postoperative pain. In the other two (laparoscopic cholecystectomy studies), age was not predictive of postoperative pain levels. In the first of these two studies patients underwent laparoscopic cholecystectomy and pain levels were not measured until five hours after surgery (Ure et al., 1994). The second had a majority of patients with mild pain which would considerably reduce the ability of the researcher to find correlations between predictors and postoperative pain levels (Bisgaard et al., 2001).

Chronic preoperative pain was a predictor of higher levels of postoperative pain in two studies (Thomas et al., 1998; Caumo et al., 2002), and not studied in four of the seven studies. Acute preoperative pain was predictive of postoperative pain intensity in five of six studies (Ure et al., 1994; Puntillo & Weiss, 1994; Thomas et al., 1998; Bisgaard et al., 2001; Kalkman et al., 2003). In one study, preoperative breast pain was not classified as either acute or chronic and it was not found to be predictive of postoperative pain (Katz, et al., 2005).
Physical status was predictive of postoperative pain in only one of seven studies (Caumo et al., 2002), not predictive in one study (Bisgaard, et al., 2001), and not studied in five of the seven studies. Differences in surgical procedure were diverse in three of seven studies (Thomas et al., 1998; Caumo et al., 2002; Kalkman et al., 2003), and two of the studies limited their surgical procedures to laparoscopic cholecystectomy (Ure et al., 1994; Bisgaard et al., 2001) and therefore did not allow a contrast of surgical procedures. In a contrast of hip replacement, knee replacement, and spinal surgery, knee replacement was the most painful, hip replacement the least painful, and spinal surgery intermediate (Kalkman et al., 2003). More invasive breast surgery was associated with more postoperative pain (Katz et al., 2005), and abdominal vascular surgery patients had more postoperative pain than cardiac patients (Puntillo & Weiss, 1994). Increased levels of postoperative pain are associated with orthopedic, abdominal surgery, and other invasive procedures. In the secondary analysis, major abdominal surgical procedures will be examined in an effort to segregate those that are associated with the greatest levels of postoperative pain. These results will then be contrasted with prior model findings.

Length of surgery was predictive of higher levels of postoperative pain in only one of seven studies (Puntillo & Weiss, 1994) and that was at a univariate level only. Two studies (Ure et al., 1994; Kalkman et al., 2003) did not find a relationship between length of surgery and the intensity of postoperative pain and four studies did not study length of surgery as a predictor. Length of incision was not a predictor of postoperative pain in two studies (Ure et al., 1994; Kalkman et al., 2003), and not studied in the remaining five studies.
In reviewing variables most likely to be associated with moderate and severe postoperative pain, four predictors, have the most support; these are gender, age, acute preoperative pain and surgical procedure. Physical status, chronic preoperative pain, length of surgery, and length of incision have been studied less, with none or only one study that supported their inclusion in a model of postoperative pain. The difficulties in comparing these studies are different pain measurement techniques and time points for measurement, different definitions for the terms moderate and severe pain, and a wide variety of surgical procedures. Additionally, not all the researchers included the same variables in the models, or defined them the same when they did (e.g. age dichotomized or used as a continuous variable). In spite of these difficulties, a potential model will be studied based on previous research. It includes; gender, age, chronic preoperative pain, acute preoperative pain, physical status, surgical procedure, length of surgery, and length of incision. The final model created by the secondary analysis, may not contain all of these factors, as the researcher will try to explain the largest amount of variance in the incidence of moderate and severe postoperative pain. Independent variables which are highly related to each other will be considered for collapsing into one variable to eliminate multicollinearity.

Potentially Confounding Variables

The attribution of a relationship or causality between two variables may be confounded by a third variable that can lead to threats to internal validity of a study that significantly alter the results. A review of potential classification of confounders is considered to reduce their potential for reducing the validity of the secondary study.
The major confounding variable of pain scores levels following surgery is opioid consumption. Opioid consumption varies widely across different genders (Cepeda & Carr, 2003), ages (Macintyre & Jarvis, 1995) and surgical procedures (Dahmani et al., 2001). It is of interest that very early studies of postoperative pain severity used opioid consumption as a measure of pain severity. The premise of these studies was that not requesting pain relief was the equivalent of “No” pain, a statement we know to be not true today (Apfelbaum, Chen, Mehta, & Gan, 2003). These early pain studies found up to one-third of patients in severe pain, one-third in moderate pain, and one-third without pain, based on opioid consumption (Papper, Brodie, & Rovenstine, 1952).

Patient ambulation is also a potential confounder as movement increases postoperative pain levels. This was readily apparent in the primary study control group, as a comparison of post ambulation and post rest sensation scores revealed a difference of 8 mm (47-39 mm) (Good et al., 1999). Movement and its effect on pain will be partially controlled for by using only pretests prior to rest and ambulation in the primary study. Ambulation at other times was not recorded in the primary study and cannot be controlled. Analgesics administered at the conclusion of the surgical procedure and other techniques, i.e., local infiltration of the wound by the surgeon, were also not recorded and cannot be controlled.

Threats to Internal Validity

Threats to internal validity can occur singly or in combination and may confound both the primary study and secondary analysis (Shadish, Cook, & Campbell, 2002; Higgins & Straub, 2006)
1) Ambiguous temporal precedence is a threat regarding the sequence of cause and effect. Cause must precede effect, effect cannot precede cause. The sample characteristics were measured prior or during surgery (independent variables) and the pain levels were measured after surgery (dependent variables). Therefore this is not considered an issue with the secondary analysis.

2) Selection is defined as including or excluding participants in the study in a manner that could influence the outcome. The primary study sample was a convenience (nonprobability) sample. Women (83%) and younger patients less than 52 years of age (72%) are overrepresented in both the primary sample and the sample for the secondary analysis. In the secondary analysis, age will be evaluated as a continuous variable and dichotomized: older patients will be ≥ 52 years of age and younger patients will be < 52 years of age (Caumo et al., 2002). In addition, the demographics of potential participants who refused to enter the study and reasons for refusal are unknown. It is not possible to know if those who refused to participate differed from those who did participate. This lack of information regarding those who chose not to participate in the study introduces the possibility that had they been included in the study the results would have differed from those obtained. This is a study limitation.

3) History refers to events occurring concurrently with the study that could influence the outcome. Treatment of postoperative pain is a historical threat to the validity of the primary study. Documentation of 24-hour opioid intake on day one will be entered into the logistic regression to control for opioid intake as a historical threat to the internal validity of the study. In the primary study, testing was done
at the second ambulation on day 1. This helped to control for the very intense
level of pain noted directly after surgery, the residual effects of anesthesia, and
the establishment of postoperative pain relief. Ambulation at non-test times is a
potential historical confounder, but as it would be unknown to those conducting
the study, it cannot be controlled.

4) Maturation is change, such as growing older, wiser, or in this case, a reduction in
pain levels with the passage of time that can occur in participants during the
course of a study that can influence outcomes. Postoperative pain levels normally
decrease over time. Data in the original study shows a reduction in all pain scores
on day one. This will reduce the numbers of participants who have moderate and
severe pain on day one p.m, which will reduce the variability of the dependent
variable and the precision of the regression (Polit & Beck, 2008). Additionally
pain levels at pretest were measured two times on day 1, sequence 1-ambulation
first and rest second. Pain was also measured two times on day one for
participants assigned to sequence 2-rest first and ambulation second. On day two,
the sequences were reversed. Those in sequence 1 had pain measured at rest first
and ambulation second. Those in sequence 2, had pain measured at ambulation
first and rest second. A preliminary analysis revealed statistically different pain
scores based on sequence of testing at two of the four pretest points. This most
probably reflects that pretest pain scores measured in the original study included
both a.m. and p.m. pain scores and that in order to reduce confounding in the
original study, ambulation pretests were delayed relative to the rest pretest scores.
To reduce maturation as a threat to the secondary analysis, two new variables
were constructed from the ambulatory and rest pretests, which are segregated into am and pm pain scores and the regression is confined to day one a. m. data only.

5) Regression towards the mean implies that extreme scores will, on retesting, move towards the mean or be less extreme. Participants with initial high levels of pain will on subsequent testing have lower levels of pain. Randomization of the original study is a method of controlling for this threat.

6) Attrition is a loss of study participants who are different from the remaining sample. Attrition has the potential for changing the outcome and the results of the study. First, it is the attrition of the primary sample that is of concern to the secondary analysis. Of the original sample, 117 were lost (no longer qualified, did not feel well, did not want to use treatment, wanted to rest or gave no reason) from the study, leaving 500 to participate in the study. A demographic comparison of those who left the study will be compared to those who remained to ascertain if differential attrition occurred. Additionally, participants who are missing am pretest pain scores will be compared to those whose scores are not missing.

7) Testing is participant acquisition of knowledge or familiarity with the testing instrument, due to prior exposure to a measure. Participants in the primary study were exposed to the VAS pain scale to measure sensation of pain over 12 times. Randomization in the original study is an effort to partially control for this validity threat.

8) Instrumentation is a change in the nature of the measure or a shift in criteria or conditions over time. No changes in the methods of pain measurement or the
instrument occurred during the primary study; therefore, instrumentation should not be a threat to the internal validity of the secondary analysis.

9) Additive and interactive effects-Factors or conditions may become additive or reach levels which enable other factors to threaten validity. An example of interaction in the proposed study is that postoperative pain decreases over the course of the first day (maturation) and opioid treatment lowers pain levels (history).

Summary

Several factors, gender, age, chronic preoperative pain, acute preoperative pain, physical status, surgical procedure, length of surgery, and length of incision, have emerged from the literature as possible predictors of moderate and severe postoperative pain. The relative strength of these factors as predictors may be directly related to the quality of studies cited. The creation of a model to predict moderate and severe postoperative pain will require additional documentation and further study. The literature reveals fair to good support for gender, age, acute preoperative pain, and surgical procedure while only poor to weak support for physical status, chronic pain states, length of surgery, and length of incision. The proposed secondary analysis, seeks to increase the amount of evidence available in an effort to continue the effort to better understand predictors of the phenomena of postoperative pain.
Chapter Three

Methods

The primary purpose of this study was to identify factors associated with moderate and severe postoperative pain in a secondary analysis of the data set of a randomized controlled trial (Good et al., 1999). The second purpose was to use the associated factors, along with those identified in the existing literature, to construct a model of postoperative pain.

Design

The study was a predictive correlational design (Burns & Grove, 2005). Eight independent variables (age, gender, chronic preoperative pain, acute preoperative pain, physical status, surgical procedure, length of surgery, and length of incision) were regressed with the dependent variable, pain sensation. Pretest pain mid morning on postoperative day one was categorized as moderate pain measured in two ways, moderate$_{30}$, 30.0 to 100 mm and moderate$_{50}$, 50.0 to 100 mm, and severe pain, $\geq$ 70 mm on a 100 mm VAS).

The original study found that music, relaxation and their combination used on patients undergoing major abdominal surgery procedures significantly reduced posttest pain compared to those who did not receive these interventions. To identify predictors that affect pain, and that were not influenced by the intervention, day one, 10 a.m. pretest pain scores were used as the dependent variable.

Sample for the secondary analysis. In the primary study, the initial convenience sample of 617 subjects, were recruited in the pre-admission testing departments of three tertiary medical centers and two suburban community hospitals in a large Midwestern city. Participants
were scheduled for major abdominal surgery, expected to use patient controlled analgesia (PCA), and to ambulate postoperatively. Participants who were scheduled for laparoscopic or vaginal surgery, epidural analgesia, or had a diagnosis of psychosis, mental retardation or opioid dependence were excluded. Due to attrition, there were 500 participants in the final sample.

The sample for the secondary analysis was a non-probability, convenience sample, and was obtained from the 337 participants who completed the mid-morning rest or ambulation pretests on day 1 and had no missing independent variables. The final number of participants for the secondary analysis was less than the total number that completed mid-morning rest or ambulation pretests due to missing values and list wise deletion (N = 292).

**Power analysis.** Based on Cohen’s calculation method (1988) and the mean and standard deviation of mid-morning pretest pain sensation scores, using G-Power, the effect size was calculated to be .21. An effect size of .15 is considered to be moderate in regression (Cohen, 1988). Using effect size of .21, power of .8, alpha of .05, the a priori calculated sample size was 177. Based on this calculation and the actual number of participants (N=292) in the morning, the calculated power is .96. Therefore, the sample is adequately powered to prevent a Type II error.

**Measures**

**Sensation of pain.** Postoperative pain is defined and conceptualized as an unpleasant sensory experience in the incisional area. Sensory pain was operationally defined in the primary study as the unpleasant physical perception of hurt, and was measured with the 100 mm Sensation of Pain Visual Analog Scale (VAS), adapted by Good et al., (2001), from Johnson’s numerical rating scales (1973). Verbal anchors were
“none” to “most sensation.” In the primary study, the scale was introduced preoperatively. Postoperatively sensation was measured before and after tests of the interventions at rest and ambulation on postoperative day 1 and again on day 2.

For the secondary study, the dependent variables were the pretest intensities of sensation pain, measured in the mid-morning, day 1, in the primary study. They were measured in some (n = 211) before testing at rest and in others (n = 224) before testing at ambulation, at different times on day 1 following surgery. The testing conditions of ambulation and rest were randomly assigned. In order to control for maturation, i.e. normal pain decrease after surgery, only day 1 mid-morning pretest sensation scores were used. The pre-rest and pre-ambulation scores were reconfigured into new variables which separated pain in the a.m. from that in the p.m.

_Moderate postoperative pain._ Moderate pain was theoretically defined according to Serlin et al., (1995) as pain that passes a threshold that makes it difficult for the patient to ignore it. In the proposed study, moderate pain was operationally defined and analyzed in two ways: (a) sensation of pain that is 30 to 100 mm (moderate<sub>30</sub>) (Dolin et al., 2002), and (b) 50 to 100 mm (moderate<sub>50</sub>) (Serlin et al., 1995), on a 100 mm visual analog scale (VAS). Moderate pain was measured at two levels because the literature is not definitive regarding the exact range of pain scores associated with the term “moderate postoperative pain.” Some have defined moderate postoperative pain as the level at which treatment should begin (Dolin et al., 2002), while others have looked at the limitation of activity associated with a particular level of pain (Serlin et al., 1995). Moderate<sub>30</sub> and moderate<sub>50</sub> pain scores were dichotomously coded for the logistic regression. Moderate<sub>30</sub>, VAS = 30-100 mm = 1, <30 mm = 0; moderate<sub>50</sub>, VAS = 50-100 mm = 1, <50 = 0.
Severe postoperative pain. Severe postoperative pain is defined as pain that becomes the primary focus of the patient and prohibits most patient activity (Serlin et al., 1995). For the secondary study, severe postoperative pain was sensation of pain that is ≥ 70 mm on a 100 mm VAS (Serlin et al., 1995; Dolin, et al., 2002). Pretest sensation scores of 70.0-100 mm, were considered as severe pain and coded as yes = 1. Scores of < 70 mm were coded as not severe pain, no = 0, and did include mild and moderate pain.

Construct validity of the original scale was supported by Johnson (1973). Concurrent validity was established by comparing post ambulatory scores on the original scales to scores on the McGill Pain Questionnaire’s Pain Rating Scale (Melzack, 1975). Strong positive correlations were found for pain sensation ($r = 0.44$, $p < 0.001$) and distress ($r = 0.55$, $p < 0.001$) (Good, 1995). During rest in the primary study, correlations with the original Johnson’s scales and VAS sensation and distress scales ranged from $r = 0.89 - 0.92$ (Good et al., 1999). Reliability of these single item measures in change states was not established in the report of the primary study, but a subsequent analysis reported reliability, validity and sensitivity for that study (Good et al., 2001). On postoperative days one and two, 15-minute test-retest reliability at rest was .73 to .82 for the VAS. Construct validity of sensation and distress ranged from $r = .72$ to .85, and convergent validity of the scales ranged from $r = .90$ to .92, and discriminant validity ranged from $r = .65$ to .78. Both instruments measured significantly less pain in the treatment groups, $p < .05$ to .01.

The independent variables were: gender, age (defined as a continuous variable), the presence or absence of acute pain (yes, to pain today or last two days, duration, one month or less) or chronic pain (yes to pain today or last two days, duration, greater than
one month), preoperative pain, the patient’s physical status as defined by the American Society of Anesthesiologists, and surgical procedure, segregated into two groups. Group 0 consisted of those patients who underwent colorectal and general surgery, and group 1 consisted of those patients who underwent gynecological and urological surgery.

**Gender.** Gender is a complex genetic, social and cultural condition that is assigned to a sexual group. In the primary study, the decision on the part of the research assistant, as to which of the two groups, male or female the participant belonged, based on face value, was indicated on the data collection instrument. Gender was coded as it was in the primary study, male = 0, female = 1.

**Age.** Age was defined as the chronological number of years that the subject has been alive. Age was studied as a continuous variable.

**Chronic preoperative pain.** Chronic preoperative pain was defined as pain that has persisted beyond the normal healing process or is due to an ongoing disorder. Chronic pain as defined by the primary study, using only 1 month duration, is not consistent with the existing literature which defines chronic pain as lasting more than 3-6 months (Caumo, et al., 2002; Dunajcik, 1999). One author did use a one month duration for chronic pain (Bonica, 1990). For purposes of the proposed study, the existence of chronic preoperative pain was based on the judgment of the primary study data collector after confirming by questioning, and was defined as daily moderate or greater pain of > 1 month duration. The presence of preoperative chronic pain was coded, yes = 1, no = 0.

**Acute preoperative pain.** Acute preoperative pain is of recent onset, and is associated with illness or injury. Acute preoperative pain was identified in the proposed study in two stages. First, by an affirmative response to the question, asked at the
preoperative visit, “Are you having pain today or in the last two days?” This was followed by a question concerning the duration of the pain. All those who responded yes to the first question of pain in the last two days, and who reported a duration of one month or less, were considered as having acute preoperative pain, yes = 1. Those participants who responded negatively to the question, “Are you having acute pain today or in the last two days”, or those responding yes who have acute pain with a duration of pain exceeding one month, were considered to not have acute preoperative pain, coded as no = 0.

**Physical status.** Physical status is defined as health in terms of systemic disease, functional limitations, and threat to life. Physical status was operationalized by using the American Society of Anesthesiologists (ASA) physical status which is a grading system used preoperatively to compare the severity of preexisting comorbidities in patients coming to surgery (Fleisher, 1997). The American Society of Anesthesiologists (ASA) physical status was assigned by the anesthesia provider prior to the surgical procedure, according to the five levels shown in Table 1. ASA physical status was coded as in the primary study, using Roman numerals I-V. Higher scores indicate worsening physical status (Table 1). Due to low numbers in some classifications of ASA physical status, classifications I-II were coded as 0, and III-V were classified as 1.

**Surgical procedures.** Surgical procedures are defined as major operative procedures which involve incision of the abdominal wall, and they vary in their degree of invasiveness. Surgical procedures from the primary study were segregated into two groups, colorectal and general surgeries were coded as 0, and gynecological and urological surgery patients were coded as 1. Procedures carried out in the lower abdomen
(gynecological, urological), generally result in less postoperative pain versus those carried out in the upper abdomen (colorectal and general) (Bonica, 1990). Because the surgical procedures were all considered to be major in the primary study, they were categorized for the secondary study according to the surgical specialty, as described in the operational definition,

*Length of surgery.* Length of surgery was defined as the difference between the time anesthesia started (anesthesia record) and the time patients were admitted to PACU (from PACU flowsheet). It was recorded as “length of surgery, start to finish,” in minutes.

*Length of incision.* The length of the incision was the length of the surgical incision, measured by the data collector, in centimeters.

*Opioid intake.* The amount of opioid a patient consumes following surgery could result in a reduction in postoperative pain (Wu, 2005; Slappendel, et al., 1998). The mean 24 hour (0600, day 1 to 0600, day 2) opioid consumption was 45 mg or approximately 2 mg of morphine equivalent per hour on day 1 (Good et al., 1999). Opioid intake was a potential confounder of postoperative pain levels and an attempt was made to control for it by entering the number of milligrams of morphine equivalent per 24 hours, as an independent variable in the logistic regression, and testing for interactions (Tabachnick & Fidell, 2001). This was not done, as there were too many missing values for 24-hour opioid intake to carry out the regression.
Table 3

*Coding-Independent and Dependent Variables.*

<table>
<thead>
<tr>
<th>Variable</th>
<th>Independent/Dependent</th>
<th>Level of Data</th>
<th>How Coded</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td>Independent</td>
<td>Dichotomous</td>
<td>Female = 1, Male = 0,</td>
</tr>
<tr>
<td>Age</td>
<td>Independent</td>
<td>Dichotomous &amp; Continuous</td>
<td>≤ 52 years of age = 0, &gt; 52 years of age = 1</td>
</tr>
<tr>
<td>Chronic preoperative pain</td>
<td>Independent</td>
<td>Dichotomous</td>
<td>Daily moderate or greater pain &gt; 1 month, no = 0, yes = 1</td>
</tr>
<tr>
<td>Acute preoperative pain</td>
<td>Independent</td>
<td>Dichotomous</td>
<td>Acute pain &lt; 1mo, No = 0, yes = 1,</td>
</tr>
<tr>
<td>Physical status</td>
<td>Independent</td>
<td>Ordinal</td>
<td>1, 2 = 0, 3, 4, &amp; 5 = 1</td>
</tr>
<tr>
<td>Surgical procedure</td>
<td>Independent</td>
<td>Categorical</td>
<td>Colorectal and General surgery = 0, Gynecological and Urological surgery = 1</td>
</tr>
<tr>
<td>Length of surgery</td>
<td>Independent</td>
<td>Continuous</td>
<td>Minutes</td>
</tr>
<tr>
<td>Length of incision</td>
<td>Independent</td>
<td>Continuous</td>
<td>Centimeters</td>
</tr>
<tr>
<td>Moderate pain_{30}</td>
<td>Dependent</td>
<td>Dichotomous</td>
<td>&lt; 30 = 0, 30.0 to 100 = 1</td>
</tr>
<tr>
<td>Moderate pain_{50}</td>
<td>Dependent</td>
<td>Dichotomous</td>
<td>&lt; 50 = 0, 50.0 to 100 = 1</td>
</tr>
<tr>
<td>Severe pain</td>
<td>Dependent</td>
<td>Dichotomous</td>
<td>&lt; 70 = 0, ≥ 70.0 to 100 = 1</td>
</tr>
<tr>
<td>Opioid intake</td>
<td>Independent</td>
<td>Continuous</td>
<td>mg of morphine equivalent from 0600 day 1 to 0600 day 2</td>
</tr>
</tbody>
</table>
Procedure

The original data were collected according to the procedure outlined in Good et al., (1999). Preoperative factors, gender, age, chronic preoperative pain, acute preoperative pain and physical status, along with postoperative factors, surgical procedure, length of surgery and incision, were entered into a logistic regression, using the newly constructed dependent variable, mid-morning, day one, pain sensation.

Table 4

<table>
<thead>
<tr>
<th>Variable</th>
<th>Preop</th>
<th>Surgery</th>
<th>Day 1, a. m.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chronic preop pain</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute preop pain</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical status</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surgical procedure</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Length of surgery</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Length of incision</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Sensation of postoperative pain</td>
<td></td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

Note. a. m. = a new variable containing mid-morning pretest ambulation and rest pain levels, day 1, from the original study.

Data Cleaning and Management

Missing data. Missing data were assessed during a preliminary analysis, using SPSS frequencies and is reported here.
Table 5

*Missing Data*  *N = 337*

<table>
<thead>
<tr>
<th>Variable</th>
<th>Cases Missing (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td>None</td>
</tr>
<tr>
<td>Age</td>
<td>None</td>
</tr>
<tr>
<td>Chronic preoperative pain</td>
<td>None</td>
</tr>
<tr>
<td>Acute preoperative pain</td>
<td>None</td>
</tr>
<tr>
<td>Physical status</td>
<td>3 (&lt;1%)</td>
</tr>
<tr>
<td>Surgical procedure</td>
<td>None</td>
</tr>
<tr>
<td>Length of surgery</td>
<td>None</td>
</tr>
<tr>
<td>Length of incision</td>
<td>42 (12.5%)</td>
</tr>
<tr>
<td>Opioid Intake</td>
<td>Day 1, 159 (47%)</td>
</tr>
<tr>
<td>a.m. pain levels d1</td>
<td>None</td>
</tr>
</tbody>
</table>

As shown in Table 5, there were minimal missing data in the eight independent variables. Opioid intake during day one did have significant missing values, as did length of incision. Even with this level of missing values, an SPSS missing values analysis, using all eight independent variables and the dependent variable, allowed 292 pain assessments with complete data. The calculated power of this number of complete assessments was .96. Therefore missing data was not a limitation to this secondary analysis.

The data set was obtained from the principal investigator of the primary study. Relative to the level of data, errors in data were evaluated by examining the following descriptive statistics, frequencies, means, standard deviations, range, out of range
numbers, minimum and maximum values, and missing data codes, of all independent and
dependent variables. Dichotomous data were screened by checking for yes/no and
missing codes (Roberts, Anthony, Madigan, & Chen, 1997). Using SPSS crosstabs,
logical order and sequence of response was checked in the data set (i.e., preoperative
duration of pain should not have a response if initial response to the presence of pain is
negative.

The outcome of logistic regression is to generate a model of the independent
variables’ ability to predict the dependent variable. Therefore, the specification of the
model is important. The model may or may not contain all the relevant variables that are
possible. To the extent that the model does contain as many relevant variables as
possible, its ability to predict the phenomenon (dependent variable) is enhanced. The lack
of inclusion or exclusion of relevant variables from the model is referred to as
specification error by Pedhazur and Schmelkin (1991). The model as specified in the
secondary analysis had only two of eight independent variables that were significant, so it
is probable that a specification error occurred.

Data Analysis

Participant sensory pain levels and variables were described by measures of central
tendency and dispersion consistent with their level of measurement. Moderate pain was
considered at both 30-100 mm and 50-100 mm, and severe pain was considered at 70-100
mm. Univariate correlations were carried out on all independent variables prior to
multivariate logistic regression. Independent variables were identified from the literature
with particular attention to citations of those investigators who used logistic regression to
develop a model of acute postoperative pain sensation (Ure et al., 1994; Chung et al.,
Opioid intake per 24 hours on day 1 was to be added as an independent variable to control for potential confounding, but due to a large number of missing values, this could not be carried out.

After checking for outliers, multicollinearity, and overfitting, a direct logistic regression (Alpha = .05, Power = .8), was carried out using SPSS, entering all independent variables at the same time, as there is no theoretical a priori reason to alter the method of entry. The eight independent variables were regressed across one postoperative time point (mid-morning pain levels, day 1). Sensation pain levels will be regressed at three levels, moderate³₀ (≥ 30 to 100 mm), moderate₅₀ (≥ 50 to 100 mm), and severe (≥ 70 to 100 mm). Therefore, there were six logistic regressions, one time period (mid-morning), times three levels of pain, times two, due to entering age as both a dichotomous and continuous variable.

The SPSS output was analyzed for overall model fit and its ability to predict the levels of postoperative pain encountered in the primary study. In addition, the SPSS output was used to answer the three research questions proposed.

Identification of potentially confounding variables

The 24-hour opioid intake on day 1 (0600, day 1, to 0600, day 2) was to be included as an independent variable to control for the possible confounding influence of opioids on postoperative pain levels, but due to missing values, this was not carried out. A Pearson product-moment correlation was carried out to determine if a relationship exists between opioid intake and postoperative pain levels (Tabachnick & Fidell, 2001).
The statistical technique chosen for this study was direct logistic regression (Tabachnick & Fidell, 2001). Logistic regression was selected because it does not require adherence to distributional assumptions (Munro, 2001). This is important as five out of eight of the independent variables in the study were dichotomous (gender, chronic preoperative pain, acute preoperative pain, ASA physical status, surgical procedure), and three were continuous (age, length of surgery, length of incision). Six of eight independent variables did not have normal distributions. In addition, when defining moderate pain as ≥ 30 mm to 100 mm and ≥ 50 mm to 100 mm, and severe pain as ≥ 70 to 100 mm, the dependent variable was coded dichotomously, as required for logistic regression. Logistic regression provided odds ratios which allow the researcher to predict the odds that a patient would fit into, moderate\textsubscript{30}, moderate\textsubscript{50}, or severe\textsubscript{70}, postoperative pain, based on the predictors (independent variables). More importantly, it allows the researcher to see how well the selected independent variables or predictors fitted the overall model generated by the logistic regression, of moderate or severe postoperative pain. Several of the researchers who have studied the relationship between predictors and moderate and severe pain have used direct logistic regression as the primary statistical test (Ure et al., 1994; Chung et al., 1996; Thomas et al., 1998; Caumo et al., 2002; Kalkman et al., 2003; Katz et al., 2005).

*Human Subjects Protection, Secondary Analysis*

The primary study was approved by the IRBs of the five institutions where data was collected and written informed consent was obtained from all participants (Good et al., 1999). As all data was anonymized by the primary researcher, the secondary analysis
has been exempted from the complete IRB process (Copy of exemption appended as Appendix A).

Summary

Re-examination of the primary study data set offered a unique possibility of uncovering preoperative attributes that correlate to moderate and severe postoperative pain. Pretest assessments of pain allowed control for the interventions used in the primary study. Logistic regression as a statistical technique lent itself well to this analysis by providing an assessment of model fit and the reporting of an odds ratio for each of the independent variables. This allowed meaningful assessment of the accuracy of the model and the individual contribution of each of the independent variables to moderate and severe postoperative pain. This study increased our understanding of the phenomena of postoperative pain and a model was constructed which allows better prediction of those patients at risk for moderate and severe postoperative pain, which allows nurses to better prevent high postoperative pain levels and prevention of complications associated with moderate and severe postoperative pain.
Chapter Four

Results

This section summarizes the results of the study to examine moderate and severe postoperative pain in a sample of abdominal surgical patients. First the subjects will be described. Second, the independent and dependent variables will be described. Both will be compared to those from the primary sample, who were not included. Finally, the results of the analysis of the research questions will be presented.

Sample

The sample was composed of all participants who had a morning pretest pain score and who also had complete data on all eight independent variables. A total of 292 participants met these criteria on day 1 after surgery and were included in the analysis. The continuous demographic and health related variables will be described first.

The mean and standard deviation for the continuous variables were, age, (M = 45.71 years, SD = 11.3, range, 20-70 years, $t(498) = .81, p = .42$), body mass index (M = 28.78 Kg/m², SD = 7.6, range, 17-65 Kg/m², $t(497) = -.209, p = .83$), length of incision (M = 17.4 cms. SD = 5.5, range, 2-40 cms, $t(438) = -1.597, p = .11$), and length of surgery (M = 191.1 minutes, SD = 71.6, range, 45-510 minutes, $t(498) = .916, p = .36$). Using t-tests, these were not significantly different than the primary sample. Categorical demographic and health-related variables are displayed in Table 6.

The majority of the secondary sample was Caucasian, employed, married, had an income of $3000/mo or less, and a lower abdominal incision. One-half were Protestant,
smoked and had a vertical incision. Steroids were used by one-tenth, while one-sixth used benzodiazepines or antidepressants (Table 6).
Table 6  
*Categorical Demographic and Health-Related Variables*  

<table>
<thead>
<tr>
<th>Variable</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Race</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>234</td>
<td>80.1</td>
</tr>
<tr>
<td>African American</td>
<td>56</td>
<td>19.2</td>
</tr>
<tr>
<td>Hispanic</td>
<td>2</td>
<td>.7</td>
</tr>
<tr>
<td><strong>Religion</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Protestant</td>
<td>145</td>
<td>49.7</td>
</tr>
<tr>
<td>Catholic</td>
<td>105</td>
<td>36.0</td>
</tr>
<tr>
<td>Jewish</td>
<td>9</td>
<td>3.1</td>
</tr>
<tr>
<td>Atheist</td>
<td>1</td>
<td>.3</td>
</tr>
<tr>
<td>None</td>
<td>16</td>
<td>5.5</td>
</tr>
<tr>
<td>Other</td>
<td>15</td>
<td>5.1</td>
</tr>
<tr>
<td><strong>Employment</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Full Time</td>
<td>164</td>
<td>56.2</td>
</tr>
<tr>
<td>Part Time</td>
<td>38</td>
<td>13.0</td>
</tr>
<tr>
<td>Retired</td>
<td>25</td>
<td>8.6</td>
</tr>
<tr>
<td>Full Time Homemaker</td>
<td>38</td>
<td>13.0</td>
</tr>
<tr>
<td>Student</td>
<td>7</td>
<td>2.4</td>
</tr>
<tr>
<td>Disabled</td>
<td>9</td>
<td>3.1</td>
</tr>
<tr>
<td>Unemployed</td>
<td>11</td>
<td>3.8</td>
</tr>
<tr>
<td><strong>Smoke</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>146</td>
<td>50.0</td>
</tr>
<tr>
<td><strong>Use Benzodiazepines</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>/antidepressants</td>
<td>47</td>
<td>16.0</td>
</tr>
<tr>
<td><strong>Steroids</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>30</td>
<td>10.3</td>
</tr>
<tr>
<td><strong>Marital Status</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>180</td>
<td>61.6</td>
</tr>
<tr>
<td>Never Married</td>
<td>38</td>
<td>13.0</td>
</tr>
<tr>
<td>Separated</td>
<td>7</td>
<td>2.4</td>
</tr>
<tr>
<td>Divorced</td>
<td>57</td>
<td>19.5</td>
</tr>
<tr>
<td>Widowed</td>
<td>10</td>
<td>3.4</td>
</tr>
<tr>
<td><strong>Monthly Income</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Under $500</td>
<td>14</td>
<td>4.8</td>
</tr>
<tr>
<td>$500-$1000</td>
<td>18</td>
<td>6.2</td>
</tr>
<tr>
<td>$1,001-$1,500</td>
<td>24</td>
<td>8.2</td>
</tr>
<tr>
<td>$1,501-$2,000</td>
<td>49</td>
<td>16.8</td>
</tr>
<tr>
<td>$2,001-$2,500</td>
<td>27</td>
<td>9.6</td>
</tr>
<tr>
<td>$2,501-$3,000</td>
<td>37</td>
<td>12.7</td>
</tr>
<tr>
<td>Over $3,000</td>
<td>83</td>
<td>28.4</td>
</tr>
<tr>
<td><strong>Incision location</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lower abdominal</td>
<td>207</td>
<td>71.9</td>
</tr>
<tr>
<td>Upper abdominal</td>
<td>7</td>
<td>2.4</td>
</tr>
<tr>
<td>Both</td>
<td>74</td>
<td>25.3</td>
</tr>
<tr>
<td><strong>Incision direction</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vertical</td>
<td>164</td>
<td>57.0</td>
</tr>
<tr>
<td>Horizontal</td>
<td>119</td>
<td>40.8</td>
</tr>
<tr>
<td>Oblique</td>
<td>2</td>
<td>0.7</td>
</tr>
<tr>
<td>Round</td>
<td>3</td>
<td>1.0</td>
</tr>
</tbody>
</table>
Using chi-square, there were no significant differences in any of the categorical demographic variables between those in the secondary sample and those in the primary sample who did not meet the criteria, there were no differences in race, religion, employment status, smoking behavior, use of benzodiazepines/antidepressants, use of steroids, marital status, and incision location and direction. Additionally, there were no significant differences found between the two samples in 24-hour total morphine equivalents consumed on day one \( t(288) = .237, \ p = .813 \), two-tailed.

**Independent Variables**

The categorical independent variables are shown in Table 7. The secondary sample included only 43 males (14.7%). Over three-quarters of the sample was classified as ASA physical status I or II, and one-fourth was ≥ ASA III. One-sixth of the participants (16%) were in acute pain prior to surgery, and more than one-third (41.4%) were in chronic pain prior to surgery. Over 70% underwent gynecological/urological surgery and 28% underwent colorectal or general surgery. There were significantly more participants with chronic pain preoperatively in the secondary (41%) versus the primary sample (31%), \( \chi^2 (1, \ N = 500) = 5.397, \ p = .024 \), and there were more gynecological/urological surgeries in the secondary sample (72% versus 59%) \( \chi^2 (1, \ N = 500) = 8.427, \ p = .004 \).

As shown in Table 8, about one-third of the sample had mild postoperative pain, when considering moderate pain at 30 mm. Two-thirds of the secondary sample had moderate or greater pain, and nearly half had moderate or greater pain, and one-fifth had severe pain levels on the morning of day one after major abdominal surgery.
Table 7

*Categorical Independent Variables (N = 292)*

<table>
<thead>
<tr>
<th>Independent variable</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Males</td>
<td>43</td>
<td>14.7</td>
</tr>
<tr>
<td>Females</td>
<td>249</td>
<td>85.3</td>
</tr>
<tr>
<td>Physical status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ASA I-II (I = 36)</td>
<td>226</td>
<td>77.4</td>
</tr>
<tr>
<td>ASA ≥ III (IV = 4, V = 1)</td>
<td>66</td>
<td>22.6</td>
</tr>
<tr>
<td>Acute pain</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>48</td>
<td>16</td>
</tr>
<tr>
<td>Chronic pain</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>121</td>
<td>41.4</td>
</tr>
<tr>
<td>Surgical specialty</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Colorectal/general</td>
<td>83</td>
<td>28.4</td>
</tr>
<tr>
<td>Gyn/urological</td>
<td>209</td>
<td>71.6</td>
</tr>
</tbody>
</table>

The mean of the low moderate through severe group (Table 8) reached almost 60, and the high moderate group through severe had a mean of 70, while the severe pain group had a mean above 80.

Table 8

*Dependent and Comparison Variables: Frequency, Mean, and SD (N = 292)*

<table>
<thead>
<tr>
<th>Pain levela</th>
<th>N</th>
<th>%</th>
<th>Mean (mm)</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comparison scores</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 30</td>
<td>92</td>
<td>32</td>
<td>16.2</td>
<td>8.8</td>
</tr>
<tr>
<td>&lt; 50</td>
<td>163</td>
<td>56</td>
<td>26.6</td>
<td>14.1</td>
</tr>
<tr>
<td>&lt; 70</td>
<td>232</td>
<td>79</td>
<td>36.3</td>
<td>19.5</td>
</tr>
<tr>
<td>Dependent variable</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30-100 , moderate30 pain</td>
<td>200</td>
<td>68</td>
<td>59.4</td>
<td>18.6</td>
</tr>
<tr>
<td>50-100, moderate50 pain</td>
<td>129</td>
<td>44</td>
<td>70.1</td>
<td>13.8</td>
</tr>
<tr>
<td>70-100, severe70 pain</td>
<td>60</td>
<td>20</td>
<td>82.3</td>
<td>9.0</td>
</tr>
</tbody>
</table>

Note. Percentages do not sum to 100% as moderate30 and moderate50 pain levels overlap with severe70 pain levels.

a100 mm VAS
Testing the assumptions of logistic regression

1. Adequate variance- Using SPSS frequencies, all continuous independent variables were evaluated for adequate variance by examining the range, skewness (< 3), and kurtosis (<8 to 20). Dichotomous independent variables were examined for adequate variance by ensuring that no dichotomous category exceed 90% (Tabachnick & Fidell, 2001).

2. Absence of influential cases (outliers)- Independent variables were entered into a logistic regression and Cook’s Distances were calculated and found to be less than 1.0, indicating the absence of influential cases (Tabachnick & Fidell, 2001). Frequencies were checked using SPSS and no extreme outliers were found.

3. No multicollinearity-A linear regression was carried out using all the independent variables included in the logistic regression. No tolerance was found ≤ .1, therefore multicollinearity was not a concern in this study (Tabachnick & Fidell, 2001).

4. Missing completely at random (MCAR)- As described in Table 6 (Chapter Three) the only independent variable with significant missing data was length of incision with 42 or 12.5% of the sample missing. To determine if there was randomness to the missing values, a variable was constructed using SPSS that consisted of the missing values for the length of incision. This new variable was then correlated, using Pearson’s Correlations, with each independent variable, as well as moderate30, moderate50, and severe70 postoperative pain. All correlations were non-significant. Additionally, a Pearson chi-square test was
carried out to assess the possible role of the individual data collector in the missing length of incision values. All chi-squares were not significant. These findings suggest that missing values were missing completely at random.

Model Evaluation

Using the dependent and independent variables as described above, a direct logistic regression was carried out at each level of postoperative pain (moderate$_{30}$, moderate$_{50}$ and severe$_{70}$). The three models, which corresponded to the three levels of pain, were generated by entering all variables at once at each level. The models are compared across the three levels of pain, Table 9.

Table 9

Comparison of Logistic Models Generated

<table>
<thead>
<tr>
<th>Model</th>
<th>-2 LL</th>
<th>Chi-square</th>
<th>df</th>
<th>P</th>
<th>Correct Classification % patients</th>
<th>Nagelkerke</th>
<th>Hosmer-Lemeshow</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moderate$_{30}$</td>
<td>342.84</td>
<td>21.05</td>
<td>8</td>
<td>.007**</td>
<td>71%</td>
<td>.098</td>
<td>P = .535</td>
</tr>
<tr>
<td>Moderate$_{50}$</td>
<td>386.57</td>
<td>14.3</td>
<td>8</td>
<td>.075</td>
<td>56%</td>
<td>.064</td>
<td>P = .613</td>
</tr>
<tr>
<td>Severe$_{70}$</td>
<td>273.34</td>
<td>23.3</td>
<td>8</td>
<td>.003**</td>
<td>79%</td>
<td>.12</td>
<td>P = .934</td>
</tr>
</tbody>
</table>

*Note.* -2 LL = -2 Log Likelihood, an indices of model fit. **p < .01.

The -2 log likelihood (-2 LL) is an indication of the predictor’s ability to predict the outcome (dependent variables). The closer the value of the -2 LL is to zero the more accurate the model is in predicting the actual data. The lowest -2 LL is -273.34 for severe$_{70}$ postoperative pain. The difference between the constant only model and the model with all independent variables included is 23.3 and is called the chi-square, as its distribution follows a chi-square distribution. The overall model for severe$_{70}$ pain was
significant, \( p = .003 \), and accurately predicted 79\% of cases, and accounted for only 12\% of variance. The Hosmer-Lemeshow value was not significant for any level of pain, indicating that the model proposed is not reliably different from the perfect model. The Hosmer-Lemeshow is a chi-square based statistic, and as such is sensitive to sample size (Hair, Black, Babin, Anderson, & Tatham, 2006). The fact that the Hosmer-Lemeshow was non-significant at the moderate\(_{50}\) model of postoperative pain, was most probably due to the large sample size (\( N = 292 \)).

The model at moderate\(_{30}\) postoperative pain was second best with a -2 LL of -342.84, chi-square = 21.05, \( p = .007 \), and correctly predicts 71\% of cases, but explains only 9.8\% of the variance. The model at moderate\(_{50}\) pain was not significant, \( p = .075 \), had a very negative -2 LL (-386.57), a chi-square of 14.3, classified only 56\% of cases, and explained only 6.4\% of variance.

The validity of measures of the current eight independent variables may also be important to moderate\(_{30}\) and severe\(_{70}\) models; where in spite of significance and the ability to predict greater than 71 to 79\% of cases, respectively, the -2 LL was still high, indicating that the models may improve by either adding independent variables, or defining those already existing more precisely.

Possible Confounding of the Dependent Variable due to Opioid Intake

Twenty-four hour milligrams of morphine equivalents was chosen as a measure of opioid consumption because it was readily available in the primary study for the secondary analysis. There was a large number of missing values for 24 hour (0600, day 1 to 0600, day 2) (47.2 \%). In the secondary analysis the total 24 hour milligrams of morphine equivalent intake was negatively correlated with the day 1 a. m. pretest pain
scores. Mid-morning pain levels were correlated with total morphine equivalents on day 1, \( r = -0.24, p = 0.01 \). Opioid intake could be ruled out as a potential confounder, although the only available measure of opioid intake was a twenty-four hour total, in which only four hours preceded the pain measurement at 10 a.m. The twenty-four hour opioid intake was not included in the analysis due to a large number of missing values (47%).

Analysis of Research Questions

Research Question 1. Which of the following, gender, age, chronic preoperative pain, acute preoperative pain, physical status, surgical procedure, length of surgery, and length of incision, are associated with moderate (30.0 to 100 mm and 50.0 to 100 mm on a 100 mm VAS) and severe (70.0 mm to 100 mm on a 100 mm VAS) postoperative pain sensation?

A logistic regression was carried out and as detailed in Tables 10-12, age and ASA physical status were significantly associated with and predicted moderate\(_{30}\), moderate\(_{50}\), and severe\(_{70}\) postoperative pain. At moderate\(_{30}\) pain, the odds ratio for age was 1.036, indicating that for every one year increase in age there was about a 4% increase in the number of cases who had moderate\(_{30}\) postoperative pain. Physical status was dichotomized as ASA I and II = 0, and ASA III to V = 1. The odds ratio of .391 for moderate\(_{30}\) pain implied that at ASA physical status III and above there was 61% decrease in the odds of having moderate\(_{30}\) pain of 30-100 mm, compared to ASA physical status I and II (Table 10). The finding for the ASA status was in the unexpected direction. The other independent variables, gender, chronic preoperative pain, acute preoperative pain, physical status, length of surgery, and length of incision, were not significantly associated with moderate and severe pain.
There was a smaller (2.5%) increase of those participants in moderate postoperative pain for every one year increase in age. The odds ratio for ASA physical status was .514, which implied there was a 49% decrease in the odds of having pain at moderate at 50 mm or greater at ASA physical status III and above, when compared to better physical status I and II (Table 11). None of the other independent variables were significant predictors of moderate postoperative pain.

Table 10

Logistic Regression Moderate (n = 71) Postoperative Pain (N = 292)

<table>
<thead>
<tr>
<th></th>
<th>B</th>
<th>S. E.</th>
<th>Wald</th>
<th>Df</th>
<th>Sig.</th>
<th>OR</th>
<th>95.0% C I</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute pain</td>
<td>-.051</td>
<td>.393</td>
<td>.017</td>
<td>1</td>
<td>.897</td>
<td>.951</td>
<td>.440 .2053</td>
</tr>
<tr>
<td>Age</td>
<td>.036</td>
<td>.013</td>
<td>7.822</td>
<td>1</td>
<td>.005**</td>
<td>1.036</td>
<td>1.011 .1062</td>
</tr>
<tr>
<td>Physical status</td>
<td>-.940</td>
<td>.319</td>
<td>8.673</td>
<td>1</td>
<td>.003**</td>
<td>.391</td>
<td>.209 .730</td>
</tr>
<tr>
<td>Chronic pain</td>
<td>-.421</td>
<td>.289</td>
<td>2.126</td>
<td>1</td>
<td>.145</td>
<td>.656</td>
<td>.373 1.156</td>
</tr>
<tr>
<td>Gender</td>
<td>.222</td>
<td>.385</td>
<td>.333</td>
<td>1</td>
<td>.564</td>
<td>1.248</td>
<td>.587 2.653</td>
</tr>
<tr>
<td>Surgical specialty</td>
<td>.282</td>
<td>.338</td>
<td>.696</td>
<td>1</td>
<td>.404</td>
<td>1.325</td>
<td>.684 2.570</td>
</tr>
<tr>
<td>Length of incision</td>
<td>.041</td>
<td>.026</td>
<td>2.459</td>
<td>1</td>
<td>.117</td>
<td>1.042</td>
<td>.990 1.096</td>
</tr>
<tr>
<td>Length of surgery</td>
<td>-.001</td>
<td>.002</td>
<td>.337</td>
<td>1</td>
<td>.561</td>
<td>.999</td>
<td>.995 1.003</td>
</tr>
<tr>
<td>Constant</td>
<td>-1.258</td>
<td>.856</td>
<td>2.163</td>
<td>1</td>
<td>.141</td>
<td>.141</td>
<td>.284</td>
</tr>
</tbody>
</table>

Note. B = unstandardized regression coefficient, S. E. = standard error of B, Wald statistic is a measure of significance of B, Sig. = significance of Wald, OR = odds ratio. CI = confidence interval: LL = lower limit; UL = upper limit. **p < .01.

For severe postoperative pain there was a 3% increase in number of participants with severe pain for every year increase in age. ASA physical status III and above were
associated with 78% fewer participants with severe pain than those with ASA physical status I and II (Table 13). The other independent variables were not significant predictors of severe postoperative pain.

Table 11

Logistic Regression Moderate\textsubscript{50} (n = 69) Postoperative Pain (N = 292)

<table>
<thead>
<tr>
<th></th>
<th>B</th>
<th>S. E.</th>
<th>Wald</th>
<th>Df</th>
<th>Sig.</th>
<th>OR</th>
<th>95.0% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute pain</td>
<td>.157</td>
<td>.356</td>
<td>.196</td>
<td>1</td>
<td>.658</td>
<td>1.170</td>
<td>.585 - 2.349</td>
</tr>
<tr>
<td>Age</td>
<td>.024</td>
<td>.012</td>
<td>4.366</td>
<td>1</td>
<td>.037*</td>
<td>1.025</td>
<td>1.002 - 1.048</td>
</tr>
<tr>
<td>Physical status</td>
<td>-.665</td>
<td>.310</td>
<td>4.593</td>
<td>1</td>
<td>.032*</td>
<td>.514</td>
<td>.280 - .945</td>
</tr>
<tr>
<td>Chronic pain</td>
<td>-.266</td>
<td>.266</td>
<td>.995</td>
<td>1</td>
<td>.319</td>
<td>.767</td>
<td>.455 - 1.292</td>
</tr>
<tr>
<td>Gender</td>
<td>.188</td>
<td>.374</td>
<td>.253</td>
<td>1</td>
<td>.615</td>
<td>1.207</td>
<td>.580 - 2.512</td>
</tr>
<tr>
<td>Surgical specialty</td>
<td>.106</td>
<td>.318</td>
<td>.111</td>
<td>1</td>
<td>.739</td>
<td>1.112</td>
<td>.596 - 2.072</td>
</tr>
<tr>
<td>Length of incision</td>
<td>.013</td>
<td>.024</td>
<td>.297</td>
<td>1</td>
<td>.586</td>
<td>1.013</td>
<td>.967 - 1.062</td>
</tr>
<tr>
<td>Length of surgery</td>
<td>-.003</td>
<td>.002</td>
<td>2.884</td>
<td>1</td>
<td>.089</td>
<td>.997</td>
<td>.993 - 1.001</td>
</tr>
<tr>
<td>Constant</td>
<td>-.935</td>
<td>.813</td>
<td>1.321</td>
<td>1</td>
<td>.250</td>
<td>.393</td>
<td></td>
</tr>
</tbody>
</table>

*Note. CI = confidence interval; LL = lower limit; UL = upper limit.
*p < .05.

Research Question 2. How much variance in moderate and severe postoperative pain is explained by the following factors: gender, age, preoperative pain (acute and chronic), physical status, surgical procedure, length of surgery, and length of incision? To answer research question 2, the quality of the predictive model (-2LL), and the variance (Nagelkerke), were examined. The Nagelkerke varied across the three different pain levels (Table 9). Using these factors to construct a model, 9.8% of variance in the number
of cases with moderate 30 postoperative pain was explained by the predictors, 6.4% of variance in the number of cases with moderate 50 postoperative pain was explained, and 12% of variance in severe 70 pain was explained.

Table 12

*Logistic Regression Severe 70 (n = 60) Postoperative Pain (N = 292)*

<table>
<thead>
<tr>
<th></th>
<th>B</th>
<th>S. E.</th>
<th>Wald</th>
<th>Df</th>
<th>Sig.</th>
<th>OR</th>
<th>95.0% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>LL</td>
</tr>
<tr>
<td>Acute pain</td>
<td>.393</td>
<td>.415</td>
<td>.896</td>
<td>1</td>
<td>.344</td>
<td>1.482</td>
<td>.656</td>
</tr>
<tr>
<td>Age</td>
<td>.030</td>
<td>.015</td>
<td>4.229</td>
<td>1</td>
<td>.040*</td>
<td>1.031</td>
<td>1.001</td>
</tr>
<tr>
<td>Physical status</td>
<td>-1.501</td>
<td>.510</td>
<td>8.661</td>
<td>1</td>
<td>.003**</td>
<td>.223</td>
<td>.082</td>
</tr>
<tr>
<td>Chronic pain</td>
<td>-.382</td>
<td>.343</td>
<td>1.239</td>
<td>1</td>
<td>.266</td>
<td>.683</td>
<td>.349</td>
</tr>
<tr>
<td>Gender</td>
<td>.228</td>
<td>.515</td>
<td>.195</td>
<td>1</td>
<td>.659</td>
<td>1.256</td>
<td>.457</td>
</tr>
<tr>
<td>Surgical specialty</td>
<td>.472</td>
<td>.432</td>
<td>1.192</td>
<td>1</td>
<td>.275</td>
<td>1.603</td>
<td>.686</td>
</tr>
<tr>
<td>Length of incision</td>
<td>-.006</td>
<td>.031</td>
<td>.035</td>
<td>1</td>
<td>.852</td>
<td>.994</td>
<td>.935</td>
</tr>
<tr>
<td>Length of surgery</td>
<td>-.002</td>
<td>.003</td>
<td>.591</td>
<td>1</td>
<td>.442</td>
<td>.998</td>
<td>.993</td>
</tr>
<tr>
<td>Constant</td>
<td>-2.534</td>
<td>1.111</td>
<td>5.197</td>
<td>1</td>
<td>.023</td>
<td>.079</td>
<td></td>
</tr>
</tbody>
</table>

*Note. CI = confidence interval; LL = lower limit; UL = upper limit.*

* p < .05. ** p < .01.

The variance or pseudo-variance in logistic regression is different from “variance explained” in linear or multiple regressions (Pampel, 2000). Variance or pseudo-variance in logistic regression is an expression of how well the model predicts the dependent variable, which in turn is a reflection of how well the model components, the independent variables, function to predict the dependent variable. This is readily apparent in Table 9, as the model fit is significant at moderate 30 postoperative pain, 30 mm or greater, (p =
correctly predicting 71% of cases, with variance of 9.8% explained. At moderate postoperative pain, 50 mm or greater, model fit is not significant, \( p = .075 \), and the model only predicts 56% of cases (6% over chance), and explains only 6.4% of variance. The model at severe postoperative pain, has the best model fit (lowest -2LL), is significant (\( p = .003 \)), correctly classifies 79% of cases, and explains 12% of the variance.

Research Question 3. Which of the following factors, gender, age, acute and chronic preoperative pain, physical status, surgical procedure, length of surgery, and length of incision, are most important/influential in predicting moderate and severe postoperative pain?

Z-scores or Standardized Beta (\( \beta \)) coefficients were used to answer research question three, about the relative importance of each of the independent variables in predicting the outcome, level of postoperative pain. Standardized Betas were calculated prior to the analysis, by dividing the unstandardized beta by its standard deviation, thereby making it comparable to all other independent variables in magnitude and predictive power (Hair, Black, Babin, Anderson, & Tatham, 2006). For moderate postoperative pain, 30 mm or greater, age had the highest standardized beta of significance (\( \beta = .401, p = .005 \)). Also at moderate pain, ASA physical status has the second highest standardized Beta of significance (\( \beta = -.393, p = .003 \)). At moderate postoperative pain, 50 mm or greater, both age and ASA physical status have the largest standardized Beta’s of significance (\( \beta = .274, p = .037; \beta = -.278, p = .032 \), respectively).
Table 13

*Logistic Regression Moderate*30 Postoperative Pain Standardized

<table>
<thead>
<tr>
<th>Independent Variable</th>
<th>β</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute pain</td>
<td>-.019</td>
</tr>
<tr>
<td>Age</td>
<td>.401</td>
</tr>
<tr>
<td>Physical status-.</td>
<td>-.393</td>
</tr>
<tr>
<td>Chronic pain</td>
<td>-.206</td>
</tr>
<tr>
<td>Gender</td>
<td>.080</td>
</tr>
<tr>
<td>Surgical specialty</td>
<td>.128</td>
</tr>
<tr>
<td>Length of incision</td>
<td>.228</td>
</tr>
<tr>
<td>Length of surgery</td>
<td>-.088</td>
</tr>
<tr>
<td>Constant</td>
<td>.840</td>
</tr>
</tbody>
</table>
Table 14

*Logistic Regression Moderate* 50 *Postoperative Pain Standardized*

<table>
<thead>
<tr>
<th>Independent Variable</th>
<th>β</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute pain</td>
<td>.059</td>
</tr>
<tr>
<td>Age</td>
<td>.274</td>
</tr>
<tr>
<td>Physical status</td>
<td>-.278</td>
</tr>
<tr>
<td>Chronic pain</td>
<td>-.130</td>
</tr>
<tr>
<td>Gender</td>
<td>.068</td>
</tr>
<tr>
<td>Surgical specialty</td>
<td>.048</td>
</tr>
<tr>
<td>Length of incision</td>
<td>.072</td>
</tr>
<tr>
<td>Length of surgery</td>
<td>-.242</td>
</tr>
<tr>
<td>Constant</td>
<td>-.242</td>
</tr>
</tbody>
</table>

Again for severe 70 pain, age and ASA physical status were significant standardized predictors of the number of cases with this level of pain (β = .341, p = .040; β = -.627, p = .003, respectively).
Table 15

*Logistic Regression Severe\textsubscript{70} Postoperative Pain Standardized*

<table>
<thead>
<tr>
<th>Independent Variable</th>
<th>$\beta$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute pain</td>
<td>.148</td>
</tr>
<tr>
<td>Age</td>
<td>.341</td>
</tr>
<tr>
<td>Physical status</td>
<td>-.627</td>
</tr>
<tr>
<td>Chronic pain</td>
<td>-.187</td>
</tr>
<tr>
<td>Gender</td>
<td>.082</td>
</tr>
<tr>
<td>Surgical specialty</td>
<td>.214</td>
</tr>
<tr>
<td>Length of incision</td>
<td>-.032</td>
</tr>
<tr>
<td>Length of surgery</td>
<td>-.138</td>
</tr>
<tr>
<td>Constant</td>
<td>-1.524</td>
</tr>
</tbody>
</table>

Summary

The assumptions of logistic regression were met, allowing correct use of this statistical technique. The primary sample differed from the secondary sample in two areas. There was statistically significant more participants with chronic preoperative pain in the secondary sample (41.4\% versus 31.3\%), and the secondary sample included more participants who underwent gynecological/urological surgery (71.6\% versus 59.1\%), otherwise the two samples were similar.

The overall fit of the model was best at severe\textsubscript{70} postoperative pain as evidenced by the lowest -2 log likelihood (-273.34), although this is still large. The model for severe\textsubscript{70}
postoperative pain allowed correct classification of 79% of cases. The model worked best at high levels (severe) levels of postoperative pain.

The potential confounding of the results of the secondary analysis by 24-hour opioid use was not ruled out because of missing values and the lack of precision of the available 24-hour time frame as a predictor. As detailed in Tables 10-15, continuous age and ASA physical status were consistent predictors of postoperative pain at all levels measured, even when standardizing the results.
Chapter Five

Discussion

This chapter begins with a summary of the results, a contrast with existing studies, a discussion of non-significant independent variables, limitations of the study, and implications for theory, research, and nursing practice.

Summary of the Study

Nurses need to be able to predict in advance which postoperative patients are likely to have pain that is moderate or greater so that appropriate interventions can be made. A secondary analysis of a published study of postoperative pain (Good, et al., 1999) was carried out to evaluate the ability of eight independent variables to predict patients who would have postoperative pain that was moderate and severe on day 1 after major abdominal surgery. Two levels of moderate to severe pain (30 to 100 mm, 50 to 100 mm), and one level of severe postoperative pain (70 to 100 mm) were studied. The Theory of Unpleasant Symptoms (Lenz, et.al, 1997) and a predictive correlational design were used. The sample size was 292 and included all postoperative participants from the primary study who had both a mid-morning pretest pain score and data on all eight independent variables. The majority of the sample was Caucasian, employed, married, had an income of $3000/mo or less, and a lower abdominal incision. Half were Protestant, smoked, and had a vertical incision. Statistically significant differences from the primary study included more participants with chronic preoperative pain and more who underwent gynecological/urological surgery in the secondary sample. Eight independent variables were selected on the basis of their support in the literature as predictors of the severity of postoperative pain: gender, age, chronic preoperative pain,
acute preoperative pain, physical status, surgical procedure, length of surgery, and length of incision.

Summary of Findings

There was a low level of opioid consumption for the reported pain levels noted in the overall study. Quite simply, those patients that used less opioid had more pain while those that used more, had less pain. What accounts for patient opioid use was not a focus of this study and could be a focus for future quantitative or mixed methods research. As explained below there were hospital differences in the twenty-four hour morphine equivalents which may either reflect practitioner’s reluctance to give opioid or patients’ reluctance to use the PCA.

Using logistic regression, the variables were regressed across two levels of moderate to severe pain (moderate\textsubscript{30} and moderate\textsubscript{50}), and one level of severe postoperative pain (severe\textsubscript{70}). Hereafter for conceptual clarity, the terms, “moderate\textsubscript{30}” and 30-100 mm will be considered the same. Similarly, the terms “moderate\textsubscript{50}” and 50-100 mm will be considered the same.

The model consisting of the eight independent variables was significantly predictive of moderate\textsubscript{30} and severe\textsubscript{70} postoperative pain, but not moderate\textsubscript{50} postoperative pain. Possible explanations for lack of model significance at moderate\textsubscript{50} include the moderating effects of opioid consumption (Baron & Kenny, 1986). Depending on the level of pain, and opioid level, age and ASA physical status become predictive of membership in moderate\textsubscript{30} and severe\textsubscript{70} postoperative pain but not moderate\textsubscript{50} pain. This explanation is enhanced by the concept of minimum effective analgesic concentration (MEAC) (Grass, 2005). The possibility exists that the MEAC was achieved at moderate\textsubscript{30}
and severe_{70}, but not at the moderate_{50} pain level. Additional study would be required to test the possible moderating role of opioids in postoperative pain and the impact it would have on the factors used to predict moderate or severe postoperative pain.

Another possible explanation includes the selection of 50/100 as a cut point for moderate pain. The mean of moderate_{30} pain was closer to 60 and this may well be a better cut-point for moderate pain as it would maximize higher levels of pain and reduce the influence of lower levels of postoperative pain. The findings of this study would support redefining moderate pain at 60/100 and undertaking a subsequent study to determine whether this cut point is clinically relevant.

The results further showed that continuous age increased the potential to be in one of the pain levels and ASA physical status III and higher had a reduced potential to be in one of the pain levels (moderate_{30}, moderate_{50}, and severe_{70}). The finding with regard to ASA physical status was not consistent with the literature, as two studies found no relationship between ASA physical status and postoperative pain (Chung, et al., 1996; Bisgaard, et al., 2001), while another study found an odds ratio of 1.65 with regard to the ability of ASA physical status III to predict higher levels of postoperative pain (Caumo et al., 2001). While no single explanation is obvious for the finding regarding ASA physical status, several factors emerge as possible explanations. The simplest explanation may lie in the subjectivity of assigning ASA physical status. It is possible that there are differences in the way anesthesiologists assign the upper levels of ASA status obscuring differences through subjective ASA status assignment.

Second, Caumo et al. (2002) found that the diagnoses of cancer reduced postoperative pain. One-third of the ≥ ASA III participants in this study had a diagnosis
of cancer. Surgery in patients with cancer may actually reduce postoperative pain levels if it relieves an obstruction or pressure on organs. Another possible explanation for the ASA physical status finding was that there were differences in the type of surgery undergone by the ≥ ASA III cohort and the overall study sample. Only one-half of the ≥ ASA III participants underwent gynecological or urological surgery, whereas 72% of the entire sample underwent gynecological or urological surgery. If the gynecological or urological group contained more extensive or invasive procedures, it is possible that less invasive surgical procedures could have reduced pain levels in the ≥ ASA III cohort.

Finally, it is possible that ≥ ASA III participants had higher levels of preoperative pain and that the surgical intervention may have reduce the pain level following surgery.

The finding of more pain with older age is in contrast with the existing literature, that supports a consistent small reduction in postoperative pain as age increases (Bisgaard et al., 2001; Caumo et al., 2001; Kalkman et al., 2003; Ready 1999; Thomas, et al., 1998). Kalkman used a much larger sample size (N = 1,957), and a wider age range (18-85 years) and found that younger age was a predictive factor for severe postoperative pain. Thomas et al. used > 60 years as a cut-off for older age and ages ranged from 25-88 years. They found that patients undergoing total hip, total knee, and spinal surgery had less postoperative pain if they were > 60 years of age. Bisaagard et al. studied patients undergoing laparoscopic cholecystectomy (N = 150) and found that age as a continuous variable was inversely related to postoperative pain with younger patients having more pain during the first week following surgery and also complaining of higher peak pain.

There are several possible explanations for the finding of older age being associated with more pain. It may reflect the fact that the secondary sample included a
small number of participants (9%), who were 65 years age or older. Caumo et al. found an odds ratio of 2.0 for age and postoperative pain levels. Caumo et al. dichotomized age at 52 years, with 33% > 52 years of age, and used 30/100 as a measure of moderate to intense postoperative pain. Caumo et al. measured pain at 12 and 24 hours following major abdominal surgery, and used a sample size of N = 346, and an age range of 18-60. A sub-sample analysis in the present study found no significance when age was dichotomized at 52 years, as described by Caumo et al. However, pain levels for moderate\textsubscript{50} and severe\textsubscript{70} postoperative pain were higher in the present study and pain was measured later following surgery.

The findings with regard to age may be related to sampling as one of the four primary study hospitals gave statistically ($p < .001$) more opioid to their patients and had the lowest mean age (M = 40). This confined most of the older participants to the other three hospitals that gave lower levels of opioid to patients who therefore had higher levels of pain. Other considerations include the presence of more comorbidities with older patients and therefore reluctance on the part of providers to administer opioids. Additionally, because of the number of older female patients, there were more gynecologic and invasive surgical procedures which may result in more pain.

Additional explanations for the finding of increased pain in the elderly include their stoic nature and their reluctance to complain of pain to physicians and nurses (Pasero & McCaffey, 1996; Zalon, 1997) and the fact that older patients suffer more cognitive dysfunction and difficulties using PCA (Pasero & McCaffey, 1996). In designing a prospective study, the sample should include 40% of participants who are 65 years or greater, in order to more accurately reflect the larger surgical population (Fast Stats:
National Center for Health Statistics Website). This would be important to establishing the external validity of any future study.

The Six Remaining Independent Variables

The next section deals with each of the remaining six independent variables and contrasts them with the way they were established in the primary study as well as their use in the secondary analysis. The purpose was to redefine them in a way that could improve the overall model fit and therefore, the accuracy of the model, with regard to its ability to predict levels of postoperative pain.

Gender. Gender differences did not reach significance in the logistic regression across all three levels of pain. These findings are inconsistent with two previous studies that also used logistic regression and found that females had greater postoperative pain (Thomas et al., 1998; Ure et al., 1994). The results were consistent with those of Ready (1999) who found no difference in postoperative pain scores based on gender (Ready, 1999). One possible explanation for gender not predicting postoperative pain in the present study may be the high level of pain noted in the study. The mean level of pain in the moderate\textsuperscript{50} cohort was 70/100, and the mean pain level of those in the severe pain cohort was $\geq 82/100$. Sixty participants or one out of five had severe pain. At these high levels of pain, gender may not be an issue. Additionally, only 43 males (14.7\%) were included in the study sample. Thus, there may have been inadequate numbers of males in each pain level for a meaningful analysis. It is also possible that males underwent less invasive surgery (minor colorectal or general surgery).

Chronic preoperative pain. Chronic preoperative pain was not a significant predictor of any of the three postoperative pain levels in this study. This is most probably
related to the difference in classifying chronic pain in the primary study versus the literature. Studies that found chronic preoperative pain as a predictor of postoperative pain levels used six months as the length of time before it was considered chronic pain (Caumo et al., 2002; Lynch et al., 1997; Thomas et al., 1998), whereas the primary study used one month. The neuroplastic changes required for the formation of chronic pain can take seconds to months to complete and so the duration of pain used to identify chronic pain may need to be increased to accurately study its impact. (Woolf & Salter, 2006).

*Acute preoperative pain.* Acute preoperative pain was also not a significant predictor of the three postoperative pain levels. This was not expected as the relationship between acute preoperative pain and increased postoperative pain has been well established in the literature (Bisgaard et al., 2001; Caumo et al., 2002; Kalkman et al., 2003; Lynch et al., 1997; Slappendel et al, 1998; Thomas et al., 1998; Ure et al, 1994). Clearly the criteria used in the primary study were a valid way of assessing the presence of acute pain and over 16% or 48 participants were found to be in acute pain, which is more than adequate for a valid analysis. It is possible that this group had low levels of preoperative pain as it was not measured at the time the presence of acute pain was documented. Higher levels of preoperative pain may have impacted postoperative pain more significantly. It is also possible that acute preoperative pain was reduced or eliminated by the surgical intervention, and this would significantly reduce any effect it may have on the level of postoperative pain.

*Surgical procedure.* There was no relationship between surgical procedure and the level of postoperative pain. This is most probably related to the lack of precision of the method used to approximate the surgical procedure. Two choices existed in the primary
study for surgical procedure, a list of 25 different surgical procedures and a breakdown according to surgical service, colorectal, general, gynecological, and urological. The present study used the surgical service, and further collapsed it into two groups, colorectal and general or gynecological and urological. Evidence continues to accumulate that more invasive/intensive surgery results in increased postoperative pain (Katz et al., 2005; Williams et al., 2003), but in this secondary study, the investigators were not able to demonstrate this due to the lack of precision of the proxy for surgical procedure.

**Length of surgery.** Only two studies looked at the length of surgery and the severity of postoperative pain (Kalkman et al., 2003; Ure et al., 1994). Similar to the present study findings, there was no correlation between length of surgery and postoperative pain in these studies. This occurred in the present study in spite of more than adequate variance (127 to 263 minutes), and a more than adequate sample size. The length of surgery is a reflection of the total time in the operating room, and may or may not be directly related to the invasiveness of the surgical procedure, and therefore the amount of postoperative pain.

**Length of incision.** In the present study, length of incision was not related to the level of postoperative pain. This is similar to two previous studies (Kalkman et al., 2003; Ure et al., 1994) Kalkman et al. found no correlation between length of incision and level of postoperative pain. Thus, the relationship between larger incisions causing greater postoperative pain has not been established. Where the incision is on the body may turn out to be more important than the length. Additionally, close inspection of the length of incision data revealed that the variation was more homogeneous than the range (2-40
cms) would suggest. Ninty-six percent of the values fell between 6.4 cms and 28.4 cms. Thus, it is possible that the range was restricted, influencing the relationship.

Limitations of the Study

As this was a descriptive correlational study design, causal relationships cannot be demonstrated. Additionally, due to the nature of secondary data analysis, definition of variables had to be as outlined in the primary study. For instance, the definition of chronic pain in the primary study had a duration of one month. This was in conflict with the literature which supported a 3-6 month duration. Another limitation is that the primary study was completed in 1999. Technology and surgical operations are very different today versus the time of the primary study. More aggressive pain management is in place today versus in 1999. Incisions today are smaller and the technology for treating postoperative pain is more comprehensive (regional blocks, local anesthetic infiltration). Therefore study results would vary accordingly.

Other limitations included the sample selection of the primary study which only included 9% of participants who were 65 years of age or older; this compares with 40% in the national surgical population (Fast Stats: National Center for Health Statistics Website). Only 15% of the secondary sample was male, whereas 30% of the national sample is male. Finally, over 70% of the secondary sample had gynecological surgery; this compares with a national level of 17% gynecological surgery (Fast Stats: National Center for Health Statistics Website). These sample differences would limit generalization of the findings.
Implications for Theory

The study was framed in the mid-range Theory of Unpleasant Symptoms (Lenz, Pugh, Milligan, Gift, & Suppe, 1997). This theory is a clinical theory that proposed that nurses prevent or ameliorate unpleasant symptoms (postoperative pain) by better understanding the circumstances associated with the symptom (postoperative pain intensity). In the present study, age and ASA physical status were found to be associated with moderate and severe postoperative pain. These findings partially support the theory in that two of eight antecedent physiologic factors were able to predict or model postoperative pain levels. The theory is mid-range and at a very low level of abstraction. Further elaboration of the theory may require additional elaboration of predictive factors and the linking of the unpleasant symptom to pathological consequences and patient outcomes.

Implications for Research

The model has some ability to predict levels of postoperative pain but would benefit from further refinement. Efforts to refine the model should include redefining chronic pain to be pain that has lasted longer than six months, increasing the percent of males to 30%, and using surgical procedures classified by surgical or anesthesia codes, that include surgical procedures with wide degrees of invasiveness or alternatively, surgical procedures that are the same. In a redesigned prospective study, six months (Pasero, Reed, & McCaffery, 1999) would be the threshold for deciding if a participant has chronic preoperative pain. Additionally, the current study could be replicated using only females to define their role in moderate and severe postoperative pain. Other areas of research are suggested by this study.
**Patient use of patient controlled analgesia (PCA).** The correlation between the eight independent variables and the use of PCA could be explored and this, in turn, could be correlated with fear of side effects and addiction. Studies have shown that older patients use PCA less than their younger cohorts (Grass, 2005). This could provide explanation for the higher pain levels found in the current study. Additionally, does gender influence the use of PCA? Answers to these questions would increase insight into the quality of postoperative pain relief and possibly suggest other interventions to reduce postoperative pain and its complications.

**The possible role of opioids as a moderator of postoperative pain.** As suggested by the lack of model significance at 50-100 mm pain, it is possible that opioids modify the independent variables and their ability to predict moderate and severe postoperative pain. While it appears that opioids moderate the independent variables, it is not certain. Therefore, both mediation and moderation should be tested for. A hierarchical multiple regression with opioid as a variable could test for mediation, while the creation of an interaction term (opioid and independent variable) could test for the moderating role. It is possible that depending on the level of pain, opioid level could be a mediator or a moderator of postoperative pain.

**Using 60 mm as a measure of moderate pain.** The mean pain level of 30-100 mm moderate pain was 59.4 mm. This suggests that this level of pain may serve as a demarcation point for moderate pain. Carrying out the logistic regression using 60 mm as moderate pain would allow evaluation of the model fit and determination of the significance of the eight independent variables.
Implications For Nursing Practice

There is wide variation in pain following surgery. Not every patient has significant pain following the same operative procedure. Interestingly, the one-third with mild pain corresponds with early studies that used opioid use as an indication of pain level, and found that about one-third did not request pain medication following surgery. It may reflect the fact that some patients may have better developed endogenous pain modifying systems than others (Grass, 2005) or underwent less extensive surgeries. Alternatively, it may reflect reluctance on the part of some patients to request pain medication or to request sufficient pain medication. This variation is indicative of the complex nature of predicting postoperative pain severity. At a minimum this complexity includes patient factors (levels of endogenous opioid), system factors (ability to use PCA) and intraoperative factors (local infiltration of the wound) that determine the severity of postoperative pain.

Two factors (age, ASA physical status) predicted 71% of low moderate pain and 79% of severe pain. This information would allow nurses to better identify patients at risk for severe pain and to better direct resources to relieve postoperative pain. The threshold for nursing intervention would appear to be around 3.0 cm or 30.0 mm, as those above 30.0 mm had a mean pain level of near 60 mm. Postoperative assessment and reassessment of pain should be initially frequent and comprehensive, given that 20% of the study sample, were in severe pain. The number with pain greater than 50 mm becomes even more relevant when one considers that this was rest pain, and that with movement, these pain levels would have to increase. The implications for nursing practice include the realization on the part of the nurse, that after asking a patient’s pain
level two more questions need to be asked, “do you require more pain medicine?” and “what happens to your pain when you move about?”. Additionally, the significant negative correlation between morning pain levels and 24-hour opioid consumption, emphasize the under-treatment of postoperative pain. Patients need to be encouraged by nurses not to tolerate high levels of postoperative pain and to use their PCA pumps, or to secure additional pain treatment resources. The level of patient pain correlates with functional impairment (Mendoza et al., 2004), and therefore the risk of postoperative complications. Lowering the level of postoperative pain by encouraging the patient to use the PCA, using rescue doses, or contacting the pain service, if present, may reduce postoperative pain levels and the related complications.

Summary

The model as constructed for the present study, significantly predicted moderate (30-100 mm) and severe pain (70-100 mm). Age and ASA physical status were significant predictors in the model, allowing correct classification of 71% of moderate (30-100 mm) pain and 79% of severe (70-100 mm) pain. Gender, chronic and acute preoperative pain, surgical procedure, length of surgery, and length of incision, were not significant as predictors of moderate and severe postoperative pain. Limitations of the study include its definition of variables and sample selection. The study partially supports the Theory of Unpleasant Symptoms, in that two of the eight independent variables were significant predictors of moderate and severe postoperative pain. Implications for research include better definition of variables and further refinement of the model. Future studies suggested include evaluation of opioid therapy in pain management as a moderator, and patient reluctance to use PCA technology. Implications for nursing
practice include that nurses could predict 71% of low moderate and 79% of severe pain allowing better direction and utilization of resources to relieve postoperative pain and that as 20% of the sample had severe postoperative rest pain, nurses need to aggressively look for under-treated postoperative pain and better direct pain-relieving resources.
Appendix A

Institutional Review Board Exemption

Case Western Reserve University Institutional Review Board
NOTICE OF EXEMPTION (#4)
Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
This protocol is exempt under the #4 category because this involves existing retrospective de-identified data. Prospective data are NOT included in this exemption. De-identified pre-existing data to be collected on 03/10/2009 and after are NOT covered by this exemption. PLEASE NOTE THAT THIS ONLY APPLIES TO EXISTING DATA. THE RI MUST ENSURE DATA REMAIN COMPLETELY DE-IDENTIFIED.
If you wish to change the protocol in any way, you must an addendum request PRIOR to implementing any protocol change.
Responsible Investigator: Marion Good
Department: Nursing -General IRB Protocol Number: 20090220
Title: Factors Associated with Moderate and Severe Postoperative Pain
Exemption Date: March 9, 2009
Co-Investigator: Jack Kless
The Institutional Review Board (IRB) has deemed the above protocol EXEMPT under 45 Code of Federal Regulations (CFR) part 46.101b. The IRB will not conduct subsequent reviews of this protocol.
Any changes to the protocol that put it under the purview of the IRB would require a formal application to, and approval of, the IRB prior to implementation of the change IRB applications are available at the CWRU IRB Pages, or from the Office of Research Compliance (ORC) at Sears Library Building, #657.
Appendix B

Description of Sample from Primary Study

A minimization program (Zeller, Good, Anderson, & Zeller, 1997) was used to randomize subjects to three treatment groups and one control group (n = 152, 25%) and two testing sequences, ambulation first (n = 318, 52%) or rest first (n = 299, 49%). The minimization program controlled for gender, surgical specialty, intestinal surgery, chronic pain, first surgery, and antidepressant/benzodiazepine use between the groups.

Following surgery, 76 (12%) no longer qualified for the study and 33 (5%) withdrew. Reasons for disqualifying include: epidural anesthesia/analgesia, surgical procedure changed or cancelled, illness or other factors. Reasons for withdrawal included: (a) did not feel well, (b) did not want to use the treatment (n = 8), (c) wanted to rest or (d) provided no reason. Of the 500 subjects in the final sample, most, (n = 413, (83%) were women from the three tertiary care hospitals. The subjects who withdrew did not differ across the four groups $\chi^2 (3, n = 33) = 4.21, p = 0.24$) or between the two testing sequences $\chi^2 (1, n = 33), = 3.67, p = 0.06$) or between sequences per group $\chi^2 (3, n = 33) =1.09, p = 0.78$.

On day 1, 340 participants were tested at ambulation and 458 participants were tested at rest by a trained research assistant. The number of participants who missed one test on day 1, was 221 (44%), and 28 participants (6%) missed more than one test. Reasons for missed test included: (a) adverse symptoms (n = 80), (b) condition at time of test (n = 36), (c) refusal to ambulate (n = 41), (d) early discharge (n = 14), (e) too much
pain (n = 10), (f) did not like the music (n = 3), or (g) miscellaneous/no reason (n = 37). All subjects who completed one out of four tests were included in the original analysis.

In the final sample of the primary study, there were 87 (17%) men and 413 (83%) women; 350 (70%) were from the three tertiary care centers, and 150 (30%) from the two community hospitals. The mean age was, 45.37 years SD = 11.03, range, 20-70 years, the majority were Caucasian (81%), Protestant (52%), married (61%), employed (69%), completed a year or more of college (64%), and had a monthly household income of 3000 US $ or less (57%). More than half (52%) smoked, 94% had previous surgery, 86% did not drink alcohol, 64% did not have chronic pain, 85% did not take benzodiazepines or antidepressants, and 89% did not take steroids. The mean body mass for the sample was 28.84 Kg/M2, SD = 7.94. The final sample underwent gynecological (50%), gastrointestinal (28%), exploratory (18%), and urinary (4%) surgery. Subjects spent an average of 3h 15m, SD = 1h 8m, in surgery.

During surgery, cancer was found in 19%, surgical incisions were in the lower abdomen for 62%; 54% had vertical incisions and 35% had horizontal incisions. Most (93%) of subjects had initial postoperative orders for PCA with a lockout range of 5-10 minutes, 4% received intramuscular analgesia as needed, 2% received intravenous opioids and 1%, other routes. A small percentage, 13% of subjects progressed to oral medications by the first postoperative day, 35% more did so on day 2, for a total of 48% by day 2. On day 1, within each group, half were tested first during ambulation and half were tested during rest; the order was reversed on day 2, $\chi^2 (1, N = 500) = 0, p = 0.84$. Carryover effects between data points were controlled for by spacing tests at least one hour apart or by doing the tests the next day (Good et al., 1999).
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