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FENTANYL ADMINISTRATION ON EMERGENCE FROM SURGERY AND POST
ANESTHESIA CARE UNIT DISCHARGE TIMES AND PAIN SCORES

by

Andrew Ernst Wetzel

A Capstone Project
Submitted to the Graduate School
and the Department of Advanced Practice
at The University of Southern Mississippi
in Partial Fulfillment of the Requirements
for the Degree of Doctor of Nursing Practice

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ABSTRACT

FENTANYL ADMINISTRATION ON EMERGENCE FROM SURGERY AND POST ANESTHESIA CARE UNIT DISCHARGE TIMES AND PAIN SCORES

by Andrew Ernst Wetzel

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Problem: Pain has been historically mismanaged potentially leading to a host of negative physiological consequences. Today's dynamic health care reform offers an opportunity to increase satisfaction with care. Utilizing the PICO question, in adults undergoing laparoscopic cholecystectomy over a 12 month period, does medication with fentanyl during emergence versus not medicating during emergence reduce the need for pain medications and discharge times? *Evidence/Background:* Two national studies surveyed patient perception of pain management following surgery. The first, conducted by Apfelbaum et.al (2003) showed that 80% of patients experienced acute pain after surgery with 86% rating that pain as moderate to severe or extreme. The second national survey, by Tong et.al (2014) showed similar results with 86% experiencing pain following surgery and 76% rating that pain as moderate to severe. Despite standards released in 2001 by Joint Commission on Accreditation of Healthcare Organizations (JCAHO), and recommendations by the American Society of Anesthesiologist Task Force on Pain Management more needs to be done. *Strategy:* A quantitative retrospective chart review was used to evaluate patients between the age of 19-60 who underwent a laparoscopic cholecystectomy surgery who either received fentanyl on emergence or did not receive fentanyl on emergence from surgery. A convenience sample of 503 charts were obtained with 256 charts being excluded from the study. The remaining 247 charts

were included in the study with 170 not given fentanyl and 77 given fentanyl. A systematic random sample ($k = N/n$) was obtained from the remaining charts. An independent samples t-test analyzed the group differences of administering fentanyl on emergence on the following: (a) PACU length of stay, (b) time to first analgesic administration in PACU, and (c) how much morphine was given in PACU. *Results:* An independent samples T-test showed no statistically significant outcomes related to giving fentanyl on emergence on the following: (a) PACU total length of stay ($p = 0.066$), (b) the time to first analgesic administration in PACU ($p = 0.172$) or (c) the amount of morphine given in PACU ($p = 0.080$) versus those who did not receive fentanyl.

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LIST OF ABBREVIATIONS

ACA	Affordable Care Act
ACTH	Adrenocorticotrophic hormone
AHCPR	Agency for Health Care Policy and Research
AHRQ	Agency for healthcare Research and Quality
ASA	American Society of Anesthesiologist
cAMP	Cyclic adenosine monophosphate
CMS	Centers for Medicare and Medicaid Services
CNS	Central nervous system
COPD	Chronic obstructive pulmonary disease
DNP	Doctor of Nursing Practice
eMAR	Electronic medication administration record
EMR	Electronic medical record
ERCP	Endoscopic retrograde cholangiopancreatography
GPCR	G-protein-coupled receptor
HCAHPS	Hospital consumer assessment of healthcare providers and systems
HIPPA	Health Insurance Portability and Accountability Act
HR	Heart Rate
ICU	Intensive care unit
IL	Interleukin
IM	Intramuscular
IRB	Institutional review board

IV	Intravenous
MAP	Mean arterial blood pressure
NSAID	Non-steroidal anti-inflammatory
ORADE	Opioid related adverse drug events
PACU	Postanesthesia care unit
PCA	Patient controlled analgesia
PEN	Patient encounter number
PHI	Protected health information
PICOT	Problem, Intervention, Comparison, Outcomes
ROS	Reactive oxygen species
SNS	Sympathetic nervous system
SSR	Surgical stress response
TNF	Tumor necrosis factor

CHAPTER I - INTRODUCTION

With the passage of the Affordable Care Act (ACA), healthcare is changing with comprehensive across-the-board reforms. One of the many reforms is a change to a pay for performance model. The hospital value-based purchasing program adjusts hospitals reimbursements based on their performance in three domains. One of these domains is the patient experience of care, which includes the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS). This domain is “weighted” as 30% of Centers for Medicare and Medicaid Services (CMS) calculated total performance score for each hospital (Centers for Medicare & Medicaid Services, 2014). Within the HCAHPS survey, pain management is part of the patients’ evaluation of care. Addressing pain with analgesia management is an important component of anesthesia care, both intraoperatively and postoperatively. A national survey conducted by Apfelbaum et.al (2003) evaluated the severity of pain experienced following surgery. That survey showed 80% of patients experienced acute pain. Eighty-six percent rated their pain as moderate to severe (Apfelbaum, Chen, Mehta, & Gan, 2003), which is an unacceptable outcome

Clinical Question

With the advent of pay for performance measures, nurse anesthetists and hospitals have a financial incentive to manage post-operative pain and provide a better outcome for their patients. This doctoral project investigates how advanced practice nurses provide anesthesia, manage perioperative pain and how their choices influence post-operative pain and length of stay in the post anesthesia care unit (PACU). A retrospective chart review covering a 12 month period was used to accomplish this task. The clinical

question is: In adults undergoing laparoscopic cholecystectomy, does medicating with fentanyl following surgery during emergence versus not medicating during emergence reduce PACU pain scores and shorten length of stay in PACU?

Background and Significance

Managing pain effectively is important to nurse anesthetists because they are among the first to manage and control pain inter-operatively, post-operatively and continuing management until discharge from the post anesthesia care unit (PACU) or transferring over care to the floor or to an intensive care unit (ICU). Hospitals also have an incentive for effective management of pain. A study (Wolosin, Ayala, & Fulton, 2012) showed improvements in nursing care in any of the evaluated HCAHPS domains of just 1 point increases the chance of a top-box score (most positive response to HCAHPS survey question) by 4.9%, which means improving the likelihood of patient satisfaction with care. The HCAHPS survey is designed to standardize and collect patient's perspectives of care by measuring patient's experience in 21 care areas including pain management. The data are then used to objectively compare data between health care institutions, and facilitate accountability to the public through reporting of results.

The CMS publishes a summary of HCAHPS survey results on a periodic basis. The results available include scores from hospitals that are reported on the Hospital Compare web site in December of 2015. The survey data includes patients discharged between April 2014 to March of 2015 (Centers for Medicare & Medicaid Services B. M., 2016). Nationally the pain management median (50th percentile) score was 71, indicating 50% of hospitals scored 71 or higher on the survey. The HCAHPS results are calculated

by individual states. Mississippi's (MS) pain management score ranked 73 (Centers for Medicare & Medicaid Services B. M., 2016). With the use of Hospital Compare web site, HCAHPS surveys for individual facilities can be used to see scores of participating hospitals. In this projects area, hospitals ranked below the state score, indicating a need to find further means to improve pain management for patients.

Pain management can be problematic physiologically in the recovery of patients following surgery and monetarily in longer hospital stays with the potential for patient dissatisfaction with care. Furthermore, research is needed to improve pain management because when mismanaged early on, it can be difficult to control further along in the hospital stay creating a potential of dissatisfaction (Hemangini & Marco, 2014).

Research in this area indicates that appropriate analgesia management has been highly correlated with patient global satisfaction scores and a better relationship between health care workers and patients (Gupta, Daigle, Mojica, & Hurley, 2009). A further review of the problem of pain management includes the negative physiological effects associated with poor pain management.

Inadequate pain management has been implicated in a deleterious physiological derangement defined as the surgical stress response (SSR). The magnitude of the SSR is associated by the severity and duration of the surgery. The systemic pathophysiological alterations include the following systems: cardiovascular system by activation of the sympathetic nervous system (SNS), renal system involvement by altering the hypothalamic/pituitary activity through the renin angiotensin mechanism, and immunological derangement through an exaggerated immune and inflammatory

response. All these are potentially counterproductive to patient recovery (Mertin, Sawatzky, Diehl-Jones, & Lee, 2007).

The population of interest for this project is those patients having laparoscopic cholecystectomy under general anesthesia. The focus is on the anesthesia provider's decision to give fentanyl on emergence from surgery and the effect of that decision on postoperative pain scores and discharge times from PACU. The aim of this doctoral project is to identify best anesthesia pain control practices and if significant results are found, facilitate a practice change. This project specifically investigates whether patients receiving fentanyl during emergence from a laparoscopic cholecystectomy have better PACU pain scores and shorter discharge times than those patients who were not given fentanyl during the emergence time frame.

CHAPTER II – REVIEW OF LITERATURE

The current evidence indicates a need for improvement to manage pain postoperatively (Gan, Habib, Miller, & White, 2014). The data on pain management inadequacies have been strong enough for the United States to adopt a core measurement on the issue and to impart a penalty for those who fail to meet quality standards in an effort to improve care. This section presents the literature in the following topic areas: (a) defining pain, (b) surgical stress response, (c) opioid pharmacology, and (d) current guidelines for acute pain management.

Search Strategy

Utilizing multiple databases to locate published quantitative studies, a search was conducted using Boolean/Phrase in the literature of nursing, biomedical and health sciences over the last 10 years. The literature review included a combined search from the following databases: CINAHL, Academic Search Premier, and MEDLINE. The search applied the following terms: *surgical, surgery, hypothalamic-pituitary, sympathetic nervous system, stress, inflammation, immune* and *opioids*. Initial results produced 20,040 articles, when the search was limited to articles published between 2006-2016 it was further narrowed 13,701 articles. Finally, the search was further restricted to full text and scholarly peer reviewed journals with an end result of 11,560 articles out of which 14 were selected for review because they specifically evaluated surgery on the surgical stress response and the effects of opioids administration. Other inclusion criteria were articles in the English language. Exclusion criteria included duplication, if they were qualitative analysis, or an opinion only, or not peer reviewed.

After reviewing the literature, 11 articles were selection for inclusion. A literature matrix summarizing these articles can be found in appendix A.

Defining Pain

The International Association for the Study of Pain defines pain as an “unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage” (IASP taxonomy, 2016).

Aside from experiencing pain first hand, nurses face the challenge of managing patient pain routinely as care givers. Since management of pain is an everyday task of nursing care we could assume that nurses have an adequate understanding of pain management and sufficient understanding of the connotation of pain. However, the research indicates that nurse’s knowledge and attitudes regarding pain management is inadequate and can improve (Francis & Fitzpatrick, 2013).

Pain is experienced universally among all people. How we experience pain, manage pain, and understand the concept of pain varies greatly among each of us. Our understanding of pain is individual and subjectively unique because our perceptions are formed by afferent signals that travel to the brain where they are interpreted by our past experiences, our present contextual understanding, and what our understanding of the future implications of the pain signal is going to be (Coghill, 2010). Exploring the concept of pain and the physiologic aspects of acute pain, a definition of acute pain is important. It is also important to identify the boundaries that separate acute pain and chronic pain.

Types of Pain

Acute pain and chronic pain by definition are differentiated by the times they occur in the continuum of pain management. Acute pain transpires as a result of abrupt tissue damage such as surgery, trauma, burns, and sport injuries (IASP taxonomy, 2016). These type of injuries lead to a host of physiological processes of sensitizing tissue to initiating inflammatory signals, releasing catecholamine's and stress hormones. Acute pain alerts us to tissue trauma causing immediate behavioral change to guard and protect the injury. Acute pain is transient for about 2 weeks to three months, and resolves because of treatment and healing of the underlying cause. Research has identified a causal link between unrelieved acute pain and progression to chronic pain due to neural plastic changes within the central nervous system (CNS) (Zhuo, 2007).

Surgical Stress Response

It is widely accepted that surgical intervention initiates a release of various cytokines (IL-1, IL-6, TNF) known as the surgical stress response (SSR) (Giannoudis, Dinopoulos, Chalidis, & Hall, 2006). Surgeries that are more invasive and complex in nature tend to produce a greater SSR (Giannoudis, Dinopoulos, Chalidis, & Hall, 2006). The SSR begins with pain stimulus from a wound or surgical intervention. Pain processing takes place by four mechanisms: transduction, transmission, modulation, and perception. Transduction is a chemical or mechanical stimulus translated to an action potential, followed by transmission of the action potential by first, second and third order neurons within the dorsal root ganglia, dorsal horn and thalamus, the signal is then modulated within the dorsal horn and can inhibit or potentiate the signal, finally

perception of the pain signal is processed within the somatosensory and limbic cortices (Barash, et al., 2013).

Physiological effect of the Surgical Stress Response

Tissue trauma created by surgery elicits a heightened sympathetic nervous system, exaggerated innate immune response, and malalignment of hypothalamic-pituitary system which make up the underpinnings of the SSR. Much of the literature agrees with elevation of cytokines due to the SSR while some studies do not. Yitting et.al (2006) noted an 18-fold and 13-fold increase in IL-6 and C-reactive protein (CRP) respectively, while studying the effect of the surgical stress response from open and laparoscopic colectomies on the Mannan-binding lectin pathway. Park et.al (2012) evaluated the surgical stress response between robot assisted gastrectomy verses laparoscopy-assisted distal gastrectomy and noted increases in IL-6, TNF-alpha, CRP within in both groups. Orci et.al (2013) utilized a meta-analysis to determine the effects of cortical steroids on the SSR of patients having a liver resection, noticing a decrease in IL-6, CRP as well as decreases in mortality and hospital length of stay in the treatment group.

Despite the majority of research indicating cytokine release with the SSR, (Chalhoub et al., 2011) evaluated intermediate-risk versus low risk non-vascular open abdominal or urological surgery to determine the SSR on plasma concentrations of cytokines (IL-6, TNF, IL-1, IL-10). Chalhoub, et al., 2011 found no significant increase in plasma cytokine concentration however, did note a significant increase in reactive oxygen species (ROS) in the intermediate-risk group. Reactive oxygen species (ROS)

has been implicated in a host of vascular abnormalities including vasoconstriction and thrombosis (Chalhoub et al., 2011).

Opioids

Opioids can be endogenous peptides produced within the body. The known opioid peptides are endorphins, enkephalins, dynorphins and endomorphins. Opioids are also produced from extracting opium from the poppy plant and then synthetically manufacturing 1 of 20 synthetic alkaloids that can be classified as either a phenanthrene or bensyisoquinoline and then further manufactured to a fully synthetic opioid class known as the phenylpiperidines, which includes fentanyl (Nagelhout & Plaus, 2014).

Opioids are among the most widely used analgesic for pain management in the United States and is currently on the rise (Steinman, Komaiko, Fung, & Ritchie, 2015). The efficacy of opioids has been well researched for providing analgesia in acute pain and chronic pain despite side effects including hyperalgesia, and tolerance over time.

The mechanism by which opioids work begins with binding of an opioid agonist to an opioid receptor, the agonist can be either endogenous or exogenous, for this example, fentanyl is the agonist. The opioid receptor belongs to the G-protein-coupled receptor (GPCRs) class (Barash, et al., 2013). When fentanyl binds GPCR (mu or delta receptor) it initiates a secondary messenger to inhibit G-protein, which then inhibits cyclic adenosine monophosphate (cAMP), potassium and calcium channels inhibited attenuating the pain stimulus through neuronal depression and neuropeptide release (Nagelhout & Plaus, 2014).

Despite opioids' efficacy in treating pain there is the potential for side effects. Common side effects include respiratory depression, sedation, nausea and vomiting

urinary retention, pruritus and skeletal muscle rigidity. Research by Minkowitz et.al (2014) evaluated postsurgical opioid related adverse drug events (ORADE) and identified the following: for those who are >65 years old or had comorbidities including COPD, asthma, cardiac dysrhythmias, enteritis, diverticulitis and ulcerative colitis were at greater risk of an ORADE; increase hospital length of stay, higher readmission rates and greater associated health care costs. Kuo et.al (2013) evaluated 7 common opioids in vivo identifying differences between opioids doses on antinociception, respiratory depression and constipation. The study lends more evidence to ongoing research on opioids regulation by different mechanisms within the body.

Fentanyl, a phenylpiperidine, is a fully synthetic opioid agonist. It is the most commonly administered opioid within anesthesia. Fentanyl onset of Action is 2-5 minutes with peak effect at 20-30 minutes and duration of action of 30-60 minutes (Nagelhout & Plaus, 2014). With rapid onset and short duration, fentanyl is an ideal opioid for anesthesia. Because fentanyl efficacy and potency is well proven at mu and delta receptors, it is an effective analgesic to attenuate the pain propagated by surgical incision and the ensuing SSR. A review of the research agrees that synthetic opioids like fentanyl, and remifentanil attenuate elevations of cortisol, catecholamine's and adrenocorticotrophic hormone (ACTH) promoted by surgical stimulation. Vettorello et al. (2008) evaluated heart rate variability on healthy subjects injected with fentanyl the analysis indicated fentanyl has a sympatholytic effect and reduction within the autonomic nervous system. Bell et al. (2004) showed no difference when using either remifentanil or fentanyl/morphine for perioperative control of surgical stress during pediatric heart surgery on attenuating serum cortisol and mean arterial blood pressure (MAP). Koji et.al

(2013) found similar results on surgical stress with remifentanyl during the pneumoperitoneum phase of a laparoscopic colectomy on mitigating adrenaline, noradrenaline, MAP, HR, and ACTH.

Despite the efficacy of opioids on the treatment of pain, it has historically been ineffective and has prompted a movement to develop guidelines and practices to help healthcare providers to better manage pain.

Current Guidelines for Acute Pain Management

Currently guidelines have been developed by several government and non-government agencies. One of the most well known and most applicable guidelines for perioperative treatment of pain is the Agency for Healthcare Research and Quality (AHRQ) practice guidelines for acute pain management in the perioperative setting developed by the American Society of Anesthesiologist (ASA) task force on acute pain management. The first publication took place in 1995 and was updated in 2004, and again in 2012. The task force defines acute pain as “pain that is present in a surgical patient after a procedure” (Task Force on Acute Pain Management, 2012, p. 248), and perioperative pain management is defined as “actions before, during, and after a procedure that are intended to reduce or eliminate postoperative pain before discharge” (Task Force on Acute Pain Management, 2012, pp. 248-249).

The current practice guidelines for acute pain management in the perioperative setting contain six recommendations derived from a consensus review of literature, and opinion based evidence obtained from a formal survey. Recommendations from the task force on acute pain management (2012) are as follows:

Recommendation I- institutions should establish policies to have a dedicated pain service, established training and educational programs for healthcare providers on pain management including pharmacologic and nonpharmacological interventions. To appropriately document and follow up with pain interventions, and have a 24-hour anesthesia provider accessible for pain management if needed.

Recommendation II- a thorough preoperative evaluation should be complete, an individualized pain management plan developed that considers the surgical intervention, the anticipation of postoperative pain, and a patient's medical history. Risk and benefits of potential pain intervention should be reviewed with the patient and patient preference taken into account when analgesic management is initiated.

Recommendation III- utilizes behavior therapy with education in conjunction with maintaining or augmentation of current analgesic regimen. Manage current pain or anxiety, and utilize multimodal pain management technique prior to surgical incision.

Recommendation IV- Analgesic modalities should include but not limited to intrathecal and neuraxial techniques with opioids, as well as regional blocks, and local injections. Systemic opioids by oral route, patient-controlled analgesia (PCA), intravenous (IV) administration are preferred over intramuscular (IM) injections. Risk benefits should be considered with choice of therapy as well as provider's technical skill level at various techniques.

Recommendation V- Multimodal therapy should be used if not contraindicated. Multimodal therapy includes the use of medications with different mechanisms of actions. For instance, the use of opioids in combination with nonsteroidal anti-inflammatory drugs (NSAIDs). Neuroaxial with opioid improved pain score with some

increase in incidence of pruritus. Other medications mentioned include: ketamine, gabapentin pregabalin and a class of medication known as alpha 2 antagonists have shown effectiveness when given in combination with opioids on the perioperative management of pain.

Recommendation VI- establishes practice guidelines for special populations which include the following: Geriatrics, critically ill, cognitively impaired and pediatrics. An assertive and proactive initiation of therapy is recommended, with the use of cognitively appropriate assessments. Analgesic use should be based on age, weight, metabolism differences, and comorbidities present. The use of behavioral therapy in conjunction with pharmacologic methods is also recommended.

Theoretical Framework

Theories are identified by their degree of abstractness. The more abstract the theory, the more broadly concepts are defined (Moran, Burson, & Conrad, 2014). Theories are ranked by level of abstractness with metatheory as the most abstract then grand theory followed by middle-range theory and ending with least abstract micro-theory (Moran, Burson, & Conrad, 2014). A middle-range theory is abstract enough to generalize yet concrete to be tested (Good & Moore, 1996). The ability of a middle range theory to be tested makes it an ideal theory for research because the concepts are similar to the phenomena of interest or observation from which the hypotheses are shaped and evaluated (Good & Moore, 1996).

The Middle-range theory of Acute Pain by Good and Moore (1996) was developed from the practice guidelines by the Agency for Health Care Policy and Research (AHCPR). Good and Moore (1996) utilized practice guidelines because they

offer a streamlined approach to creating a theory with more prescriptive power in guiding treatment to reduce pain.

Clinical practice guidelines are ideal for middle-range theory because they produce a method of pain management based on a review of literature that is peer appraised and resulting in consensus practice statements. Good and Moore (1996) argue against clinical guidelines as being labeled as theory, rather, theory needs to be applied to practice guidelines to be applicable in research. Good and Moore (1996) developed their theory of acute pain management from the AHCPR guidelines by using statement synthesis and theory synthesis in their construct of this middle-range theory. Theory synthesis and statement synthesis play a specific role in the development of the theory of acute pain management. Statement synthesis finds relationships between concepts and theory synthesis is utilized to combine statements into a complex thoughts or theory (Good & Moore, 1996).

The assumptions of the theory of acute pain management include the following: appropriate collaboration among health care members to manage pain, that pain medication or regional or intrathecal management of pain is indeed needed, that the appropriate antidote is available when indicated for potential side effects, that patients can communicate effectively, and that nurses are knowledgeable about management of pain (Good & Moore, 1996).

Application of Acute Pain Management Theory to Project

The theory of acute pain management is formulated from acute pain guidelines that are developed from a broad review of the literature to identify best practice standards for management of acute pain. The acute pain management theory “provides a

conceptual structure composed of prescription for nursing activity and goals to develop practice knowledge for reducing pain after surgery or trauma” (Good, 1998, p. 120).

One desired outcome of this doctoral project is to determine if timing of fentanyl administration, when given on emergence from anesthesia following laparoscopic cholecystectomy surgery in the perioperative period, will aid in post-operative pain management in the post-anesthesia care unit (PACU). The theory of acute pain management is ideally suited for this project, by attempting to seek better management of acute pain in the post-operative period with the fewest side effects.

Doctor of Nursing Practice Essentials

Doctor of Nursing Practice (DNP) essentials are core elements or competencies required for DNP graduates (American Association of Colleges of Nursing, 2006). This project in partial fulfillment of the requirements for the degree of DNP meets in some fashion all 8 essentials. The main essentials for this project are essentials I and II. These will be discussed here. DNP essential I is the scientific underpinnings for practice. This project utilized a conceptual frame work, a middle range theory to facilitate the integration of theory, and practice guidelines for acute pain management to facilitate the implementation of evidence base research in advance practice nursing.

Essential II is organizational and systems leadership for quality improvement and system thinking (American Association of Colleges of Nursing, 2006). This project evaluates perioperative timing of pain medication and outcomes in the PACU on pain score and discharge times. The ultimate goal is to improve advanced practice nursing in creating best practice standards to promote patient satisfaction and improve healing.

Essentials I and II are the main essentials covered by this project. These and the other DNP essentials related to this project can be viewed in Appendix E.

CHAPTER III - METHODOLOGY

This section outlines the variables of concern and methods used to evaluate the effects of fentanyl when administered on emergence from anesthesia. Emergence is defined as within ten minutes of surgical closure time. The design is a quantitative retrospective comparative study that examines the effects of administration or lack of administration of fentanyl by an anesthesia provider during emergence from surgery. The PICO (population/intervention/comparison/outcome) question configuration was used to form the following research question: ‘In patients undergoing a laparoscopic cholecystectomy, does fentanyl administration on emergence from surgery reduce the amount of opioids administered in PACU and shorten discharge times from PACU?’. This project measures the outcomes of postoperative pain by measuring the amount of morphine equivalents given in PACU and the time to first analgesia given in PACU. The project will review charts retrospectively over a 12 month period. During the data collection process all variables were directly entered into a password protected Microsoft Excel spread sheet. All patient data was de-identified maintaining confidentiality during the entire project.

Setting

A retrospective chart review using a comparative design was conducted utilizing a convenience sample from a local level II 512 bed regional trauma center servicing 19 counties in the Southeast with 17 operating rooms and PACU. The trauma center performs approximately 6998 inpatient surgeries per year including open hearts, vascular, otolaryngology, ophthalmology, plastic, neurology, urology, general, thoracic and laparoscopic procedures.

Population

A retrospective chart review of the anesthesia and PACU electronic medical records of adults (male and female) between 19 years of age to 60 years old who previously had a laparoscopic cholecystectomy surgery are included in the study. Exclusion criteria include: (a) American Society of Anesthesiologist (ASA) score IV-V, (b) patients treated with an opioid other than fentanyl, or a nonsteroidal anti-inflammatory (NSAID) drug during emergence, (c) the surgery is converted to an open cholecystectomy, (d) patient controlled analgesia pump (PCA) is used, (e) if the surgery is combined with another procedure other than cholangiogram, (f) if the patient is pregnant, (g) if the patient requires resuscitation at any point during or after the procedure, (h) if the patient is being treated for chronic pain, (i) and any patients being treated for cancer, arthritis, myalgia, or history of polysubstance abuse.

Sample

A standard power analysis for independent groups t-test, with a power of .80, alpha level of .05 with moderate effect size of .59 was used to determine the appropriate sample size, which was 92 (Faul, Erdfelder, Lang, & Buchner, 2009). The convenience sample included 46 subjects who did not receive fentanyl on emergence and a sample of 46 subjects who did receive fentanyl on emergence, for a total of 92 subjects.

The study meets the ethical codes, regulations set by the institutional review board (IRB) of The University of Southern Mississippi (IRB #16081506), and the health care facility where the study was conducted. (See Appendix F for IRB approval) Further, patient data was protected using privacy rules established by Health Insurance Portability and Accountability Act (HIPAA) of 1996 (PL 104191).

The project evaluated two groups based on the independent variable, fentanyl administration on emergence. Emergence is defined when a provider administered fentanyl within 10 minutes of surgical closure. Group A includes subjects who received fentanyl on emergence, and Group NA, who did not receive fentanyl on emergence from surgery.

The sampling frame was initiated by creating a “ticket” with the Help Desk department of the participating medical facility. The following variables were included in putting together the sample population: (a) all inclusion criteria, (b) surgery date, (c) age, (d) sex, (e) ASA, (f) Anesthesia start time, (g) Anesthesia end time, (h) surgery start time, (i) surgery end time, (j) PACU time in, (k) PACU time out. From the criteria, the sampling frame comprised of 503 patient encounter numbers (PENs) where obtained over a 12-month period from June 1, 2015 to June - 2016.

Applying the exclusion criteria to the sampling frame the following charts were excluded from the study: (a) 9 combined with endoscopic retrograde cholangiopancreatography (ERCP), (b) 7 diagnosis of cancer, (c) 1 re-intubated, (d) 19 diagnosis with arthritis, (e) 14 over 60 years old, (f) 6 with ASA greater than 3, (g) 8 polysubstance abuse, (g) 32 treated for chronic pain, (h) 112 given tordal on emergence, (I) 24 missing PACU discharge times, (j) 6 included ventral hernia repair, (k) 8 converted to open procedure, (l) 7 included a combined umbilical hernia repair, (m) 1 combined with a nephrectomy, (n) 1 combined with hysterectomy, (o) 1 used PCA. As a result, the sampling frame of 247 PENS made it to final analysis.

All chart data were de-identified on location and directly entered into a Microsoft password protected Excel spread sheet. Data hygiene and inspection were completed to

identify errors made during data entry, and to check that data were sensible and possible. From the sampling frame of 247 PENS the independent variables were defined as the following: (Group A) those receiving fentanyl and (group NA) those not receiving fentanyl. Once the sampling frame was divided into Group A and Group NA a systematic random sampling techniques was applied ($k = N/n$). Group A contained 77 PENS and group NA contained 171 PENS. Group A with the 77 PENS was divided by 46, and every second PEN was selected for the study. Group NA with the 171 PENS was divided by 46 and every third PENS was selected for the study.

Methods

Access to the electronic medical records was necessary for evaluating the independent and dependent variables. One dependent variable determined time spent in PACU following administration or non-administration of fentanyl on emergence from surgery. Data included total time in minutes spent from admission to discharge. The two most commonly used criteria for discharge according to Barash et.al (2013) are the modified aldrete scoring system (MASS) and the postanesthesia discharge scoring system (PDSS). Both have shown reliability and validity in evaluation of patient recovery from anesthesia. For this project discharge criteria are determined by PACU staff following facility protocol for discharge out of the unit.

Pain management was another dependent variable evaluated during PACU stay. The most widely employed pain scales according to Hjerstad et al. (2011) are the numerical rating scales (NRS), the verbal rating scales (VRS) and the visual analogue scales (VAS). Each of the scales have overcome scrutiny and are used in the hospital setting to evaluate the patients' perceived pain. This doctoral project will not determine

pain by using a pain scale, rather pain will be evaluated indirectly, by the length of time to first analgesic administration in PACU and the amount of pain medication given during PACU stay. Reasons for not using a pain scale was that an evaluation of pain was not consistently utilized by the medical facilities nursing staff nor was a score reliably charted.

Following IRB approval and gaining access to the facilities protected health information (PHI), the data collection process was initiated. Data collection was performed on location at the facility where the data were directly de-identified and coded then entered into a Microsoft Excel spread sheet during the chart review process. This method minimized the risk to patients' confidentiality in accordance with the requirements of HIPAA and the IRB. The digital content was password protected to maintain confidentiality.

The data collected included the following descriptive data: age, sex, ASA score, anesthesia start, anesthesia stop, surgery start surgery stop, PACU admission time, PACU discharge time, time to first analgesic given in PACU, total dose given in PACU and if fentanyl was give on emergence (see Appendix H).

With the sample population identified, each chart was reviewed for both inclusion and exclusion criteria. The electronic medication administration record (eMAR) was evaluated for the amount of analgesic medication administered in PACU as well as the time to first administration. Next the anesthesia record was reviewed for surgery end time and to determine if fentanyl was or was not administered within 10 minutes of surgical end time. Surgical end time was the marker used to determine emergence from anesthesia. Next opioids administered in PACU needed to be standardized.

The analgesic medications administered in PACU included hydrocodone, morphine, hydromorphone and meperidine hydrochloride. All opioids administered in PACU were converted over to a morphine equivalent to standardize the doses. The guidelines by the Centers for Medicare and Medicaid Services (CMS) for morphine equivalent conversions were used to calculate the opioid morphine equivalents (Opioid Morphine Equivalent Conversion Factors, 2015)

Data Analysis

Descriptive statistics were used to describe the sample and to organize and make meaning of the data as well as to examine for data hygiene and miscoding. The statistical analysis was conducted using independent group t-test. The independent t-test evaluated the fentanyl group (A) and non-fentanyl group (NA) against the following dependent variables: (a) PACU total time in minutes; (b) the time to first analgesic dose in PACU; and (c) the amount of analgesia given in PACU converted over to morphine equivalents.

Following data analysis, a correlations test was done to determine if sex, ASA, and age had a direct effect on the dependent variables: PACU total time, time to first analgesic dose and the amount of morphine equivalents given in PACU.

Conclusion

The previous section outlined the methods used to evaluate the clinical question: In patients undergoing a laparoscopic cholecystectomy does fentanyl given on emergence from anesthesia following surgical closure reduce pain scores and discharge time in the PACU? A qualitative retrospective chart review using a comparative design with a systematic random sample was used to answer the question. The independent variable includes patients receiving or not receiving fentanyl on emergence from anesthesia and

the dependent variables include time to first analgesic administration in PACU, length of stay in PACU, and the amount of pain medication given in PACU.

CHAPTER IV – ANALYSIS OF DATA

This project evaluated 92 charts from the electronic medical record (EMR), 46 in Group A and 46 in Group NA. A standard power analysis for an independent group t-test, with a power .80, alpha level of .05 and a moderate effect size of .59 was used (Faul, Erdfelder, Lang, & Buchner, 2009), indicating that 92 subjects were needed, and so met the power required for the analyses. Group A received fentanyl on emergence from anesthesia following a laparoscopic cholecystectomy with dose selection based on providers' preference and ranged from 25 mcg to 250 mcg. Patients were also administered versed preoperatively ranging from 1-5 mg. Fentanyl was administered on induction to blunt the sympathetic response from direct laryngoscopy and for analgesia, the administered dose varied from 100 mcg to 200 mcg.

The statistical method to determine difference between Group A and Group NA was an independent samples t-test. The sample frame meet the 8 assumptions which included the following: (a) a continuous dependent variable, (b) a categorical independent variable, (c) each chart contained the required data point for both the dependent and independent variables, (d) Each group is without influence of one another and contains independent samples, (e) systematic random sampling was done on the sample frame, (f) the dependent variable was normally distributed in each group, (g) there is homogeneity of variances across groups, (h) the outliers were removed during randomization. A Levene's test for equality of variances was done with the equal variances assumed being reported in the discussion. The statistical analysis was conducted using IBM SPSS version 24). Results were considered significant if they had a p-value less than or equal .05

Discussion of Results

A frequency table was constructed to analyze age, sex, and ASA class. The sample population was mostly female. Of the 92 randomly selected charts 66 (71.7%) were female and 26 (28.3%) male. ASA class was predominately ASA 2 with 64 (69.6%). The age range was 19 years old to 60 years old with a mean of 39.23 and standard deviation of 12.06. See Table 1 for demographics.

Table 1

Patient Demographics

	Group A (n = 46)	Group NA (n = 46)	Total (n = 92)
Gender			
Male	12	14	26 (28.3%)
Female	34	32	66 (71.7%)
ASA			
ASA 1	8	5	13 (14.1%)
ASA 2	32	32	64 (69.6%)
ASA 3	6	9	15 (16.3%)
Age			
Min	19	20	19
Max	55	60	60
Mean	34.48	43.98	39.23
SD	10.43	10.43	12.06

A Pearson correlation analysis was done to determine if the age, gender or sex had an effect on PACU total time, time to first analgesic administered in PACU and the amount of morphine equivalents administered in PACU. It was determined that age sex, or ASA class had no effect on the dependent variables. See Table 2 for Correlations.

Table 2

Pearson Correlation

Demographic	Total length of stay in PACU		Time of first analgesic dose in PACU		Total morphine given in PACU	
	Correlation coefficient	p	Correlation coefficient	p	Correlation coefficient	p
Age	0.033	0.752	0.104	0.325	-0.002	0.996
Sex	-0.010	0.924	-0.190	0.070	-0.003	0.979
ASA	0.168	0.110	0.104	0.324	-0.014	0.898

Correlation is significant at the 0.05 level (2-tailed)

An independent samples group t-test was done to compare total time in PACU between Group A and Group NA. There was no significant difference in scores between Group A (M = 62.30, SD = 29.96) and Group NA (M=52.74, SD=17.75); $t(90) = -1.86$, $p \geq 0.05$, CI.95 -19.77, .636. This analysis suggests fentanyl administration on emergence has no statistically significant effect on the length of stay in PACU. Further, Cohen's effect size value ($d = .38$) suggests a low practical significance.

A second independent samples t-test was done to compare time to first analgesic does in PACU between Group A and Group NA. There was no statistically significant

difference in scores between Group A (M=22.02, SD=13.62) and Group NA (M=26.93, SD 19.99), $t(90) = 1.378$, $p \geq 0.05$, CI.95 -2.17, 11.99. The results indicate no statistically significant effect on the length of time to first dose of pain medication given in PACU. A Cohen's effect size value ($d = .29$) suggests low practical significance.

A third independent samples t-test was done to compare the amount of opioid administered, and measured in morphine equivalents during the PACU stay between Group A and Group NA. There was no significant difference in scores between Group A (M=4.85, SD=2.03) and Group NA (M=3.98, SD=2.61), $t(90) = -1.768$, $p \geq 0.05$, CI.95 -1.83, .107. The results suggest no statistically significant effect on the amount of opioid administered in PACU. Further, Cohen's effect size value ($d = .37$) suggested low practical significance.

Table 3

PACU total time, time to first analgesic, and total Morphine given

	Group A (n= 46)	Group NA (n=46)
Total PACU time (minutes)		
Mean	62.74	52.74
SD	29.96	17.75
t (df)	$t(90) = -1.863$, $p = 0.066$	
Time to first analgesic dose		
Mean	22.02	26.93
SD	13.62	19.99

t (df)	t (90) = 1.378, p = 0.172	
Amount of morphine given		
Mean	4.84	3.98
SD	2.03	2.62
t (df)	t (90) = -1.768, p = 0.080	

Conclusion

The purpose of this retrospective quantitative chart review was to determine if the administration of fentanyl on emergence from a laparoscopic cholecystectomy would reduce the amount of opioid administered in PACU and shorten the length of stay by improving pain management when the patient was first admitted into the PACU. The analysis of Group A and Group NA showed that there was no significant difference between giving or not giving fentanyl on emergence on PACU total length of stay, time to first analgesic administered in PACU, or the amount of opioid given in PACU. Inclusion and exclusion criteria were utilized to try and minimize extraneous influences on opioid requirements in PACU. Evaluating the data, PACU total time in minutes and the total amount of opioid administered in PACU were close to being significant with (p = 0.067 and p = 0.080.) respectively. When looking at PACU total length of stay the fentanyl group was longer (M=62.30) than the non-fentanyl group (M=52.74). when analyzing the amount of opioid administered in PACU the fentanyl group required more (M=4.84) than the non-fentanyl group (M = 3.98). This being opposite than what was hypothesized and appears that those who were administered fentanyl on emergence had inadequate management of post-operative pain. With the exclusion criteria being strictly

followed during the chart review period, it appears that one explanation may be that the fentanyl group may have a potential tolerance to opioids.

Recent research has begun to look at genetic variation among individuals and their effects on opioid consumption. (Chou, et al., 2006) studied polymorphic effects on the Mu-opioid receptor gene OPRM1 and how polymorphism of the nucleotide A118G effected opioid consumption. The results of the study identified three polymorphic variants and those who were identified as a homozygous carrier A118G significantly required more morphine compared to the other variants during the first 24 hours of having knee arthroplasty surgery ($p = 0.033$, $p=0.028$) (Chou, et al., 2006). Another study by (Candiotti, et al., 2011) evaluated polymorphism at the interleukin - 1 receptor antagonist gene (IL1RN) and found similar results as (Chou, et al., 2006). Among the 3 genotypes, those with the homozygote IL1RN 1 allele had a greater 24 hour opioid consumption ($p = 0.003$) than the other genotypes for patients having surgery. The mechanism of action proposed is those with the IL 1RN 1 allele produce less of the receptor antagonist IL-1Ra allowing more interaction of IL-1 alpha and IL 1 beta in producing and maitining incisional pain (Candiotti, et al., 2011).

CHAPTER V – SUMMARY

This doctoral project investigated how advanced practice nurses provide anesthesia, manage perioperative pain and how their timing choices may affect post-operative pain and length of stay in the post anesthesia care unit (PACU). Historically pain has been mismanaged leading to inadequate pain management which has been implicated in a deleterious physiological derangement defined as the surgical stress response (SSR). Recent research has hypothesized a causal link between unrelieved acute pain and progression to chronic pain due to neural plastic changes within the central nervous system. The goal of this project was to determine if IV fentanyl administered on emergence from a laparoscopic cholecystectomy would decrease pain (measured by the amount of morphine given in PACU and the length to first analgesic dose in PACU) and shorten discharge times from PACU. This project indicated that fentanyl administration on emergence did not have a statistically significant effect on reducing PACU pain or discharge times. The results did indicate that those receiving fentanyl on emergence had on average longer PACU length of stay, and required more morphine. Though this finding did not reach statistical significance, it is still worth noting clinically.

Limitations

There were limitations while conducting this project. The retrospective chart review utilized pre-existing convenience data, which can be a potential source of bias. Further, not all charts may have been included due to miscoding of the procedure, and the random sampling from the groups also resulted in some loss of data. The results are based on a convenience sample, with an element of random selection to be in the study, but do not represent the general population. Despite taking measures to reduce outside

influences on the dependent variable with inclusion and exclusion criteria, there may be other factors that were not accounted for that influenced the outcomes of the study, such as gender and genetics. Further, the amount of fentanyl administered during induction could not be controlled and may have influence whether fentanyl was administered on emergence. A retrospective chart review cannot definitively state causation but measures association.

Benefits

There were advantages of doing a retrospective chart review versus other methods. The participating facility maintained electronic medical records that reduced challenges and barriers that can be associated with recruiting and prospective data collection. Specific data points were easily identified for each chart and made available on an overview page. This reduced time going through the entire chart to find data points. There was no additional cost associated with project. No additional resources were required by the medical facility to host the study.

Future Direction

Future studies on this topic could be done. One study could examine patients' weight and first dose of fentanyl on induction and evaluates PACU discharge times and pain scores in PACU. Another potential study is to evaluate why anesthesia providers administer fentanyl on emergence. Another study could evaluate the outcomes PACU pain and discharge times in those who received an opioid and NSAIDS on emergence from surgery. Finally, partnership with a geneticist to perform genetic testing on patients prior to surgery would illuminate whether resistance to fentanyl and other pain medications was a statistically controllable factor when studying pain control.

APPENDIX A – Literature Matrix

Author(s), Date	Purpose or Research Question(s)	Research Design/ Level of Evidence	Sampling Method, Size, & Setting	Results	Strengths	Weaknesses	Implications for Practice
1. (Francis & Fitzpatrick, 2013)	Pilot study to look at nurse's attitudes and knowledge of postoperative pain management	Descriptive exploratory design utilizing the short-form McGill pain questionnaire. Level of Evidence: 4	Convenient sample of 31 nurses from the gastrointestinal and urological units, and 14 first and second day adult post-operative surgical patients	Nurses underrated pain compared with patients on the following: pain intensity. (t= 3.13; p = .002), pain effect (t=4.410; p = .0001), present pain intensity at rest (t=3.498; p< .001), pain intensity on movement (t=6.278; p<.0001), overall pain intensity 9t=2.235; p =.028), and patient suffering due to pain (t=3.774; p= .0001).	The findings were consistent with various other studies regarding the use of nurse's knowledge of pain management. The short-form McGill pain questionnaire has been tested or evidence of validity and reliability	The study was a small sample size, only two patients from the urological unit and could not be compared with those patients. And the study results cannot be generalized.	Identified weakness in nursing knowledge and perceptions of pain management. Will help to improve nursing pain management intervention to improve patient outcomes and satisfaction

Author(s), Date	Purpose or Research Question(s)	Research Design/ Level of Evidence	Sampling Method, Size, & Setting	Results	Strengths	Weaknesses	Implications for Practice
2. (Ytting, et al., 2006)	Evaluated surgical stress on the mannan-binding lectin pathway, while comparing C-reactive protein and IL-6 levels	Randomized cohort study undergoing surgery of colorectal cancer or sigmoid obstruction. Level of Evidence: 3	Cohort 1 made up of 60 patients with primary colon cancer or sigmoid obstruction. Cohort two was made up of 27 patients. Blood samples were drawn just before surgery and at specific periods following the operation.	Cohort 1 decrease in MASP-2 noted at hour 6 (p<.0001) with increase on day 8, MBL decrease during the first 48 hr. (P.0001) increased day 8, IL-6 10-fold mean increase at hour 6 (P<.0001) no difference on day 8. CRP increased 13-fold on day 2 (P<.0001) Cohort 2 MABL decrease up to day 4 (p=.01), MASP-2 decreased noted at 12-hour s (P<.000, IL-6 max at hour 12 18-fold increase (P<.0001) returned normal day 3, CRP increased max at day 2 (P<.0001). No association noted between MBL, MASP-2, IL-6 AND CRP.	The findings were consistent with various other studies that surgical intervention induces changes in serum level of inflammatory markers. Attempt was taken to randomize surgical participants.	MASP- levels have not been studied in acute stress reactions.	The impairment of the MBL pathway may be involved in suppression of the innate immune response to stress. This could have an important role of MBL in the perioperative immune response when the innate immune system is impaired.

Author(s), Date	Purpose or Research Question(s)	Research Design/ Level of Evidence	Sampling Method, Size, & Setting	Results	Strengths	Weaknesses	Implications for Practice
3. (Park, et al., 2012)	Determine the difference between robotic-assisted distal gastrectomy (RADG) and laparoscopy-assisted distal gastrectomy (LADG) on surgical stress response and cost comparison.	Cohort prospective study, single center over 1 year Level of Evidence: 4	convenient sample at a single facility. The patients selected which procedure. 150 total participants. 30 underwent RADG, 120 underwent LADG.	Duration of surgery was longer in the RADG group ($P < .001$), drainage was less ($p = .001$). postoperative performance was better in the LADG group day 1-3 ($p < .001$). Proinflammatory rose after surgery in both groups. CRP was greater in the RADG compared to LADG ($p = .002$; $p = .014$), IL-6 and IL-10 increased in the RADG group over the LADG group ($p < .001$, $p = .012$), TNF less in the RADG than LADG ($p = .001$). RADG group cost more with less patient satisfaction	The study looks at surgical methods and evaluated the surgical stress response as well as pain scores and cost associated with each procedure and measured against patient satisfaction.	The study was a small convenient sample size, not generalizable to the population. The sample is skewed, with lack of randomization.	Comparison of two surgical procedures on stress response indicating no difference, however the cost of RADG was more.

Author(s), Date	Purpose or Research Question(s)	Research Design/ Level of Evidence	Sampling Method, Size, & Setting	Results	Strengths	Weaknesses	Implications for Practice
4. (Orci, Toso, Morel, Mentha, & Majno, 2013)	Evaluate steroid use on perioperative ischemia-reperfusion injury and surgical stress response in patients having liver resection	Comprehensive literature reviews with meta-analysis of randomized controlled trials and non-randomized controlled trials. Meta-analysis according to Preferred reporting items for systematic meta-analysis reviews and Level of Evidence: 2	Multi-data base search from 1966 to current. RCT or non-RCT included articles that compared the effects of perioperative steroid administration. Two authors gathered data independently and disagreement resolved by consensus with third author.	666 articles identified and six studies made the cut. Patients on steroid had lower postoperative morbidity (pooled RR .76, 95% c.i .57 to .99; (P=.047) (Q test: P=.436 I=0 %) Inflammatory response, steroids had lower IL-6 (WMD - 81.76 (-112.01 to - 51.5) pg/ml (P<.001), IL-10 were higher in steroid group.	Independent review of literature with third party review of disputes, primarily randomized control trials, utilized pooled risk ratio and weighted mean differences with SD or 95 CI, statistical heterogeneity assessed with Q test with level set at P=.100	80% of study subjects did not have major hepatectomy so the extent of steroid administration is limited. Some data was extracted from graphs and prone to bias	Indicates a potential benefits for steroid treatment and recovery from ischemia reperfusion injury and SSR in patients having liver resection.

Author(s), Date	Purpose or Research Question(s)	Research Design/ Level of Evidence	Sampling Method, Size, & Setting	Results	Strengths	Weaknesses	Implications for Practice
5. (Chalhoub, et al., 2011)	To determine if low or moderated surgery can produce a release of pro-inflammatory cytokines and reactive oxygen species (ROS).	Non-randomized control study at a single facility Level of Evidence: 3	convenient sample of 32 patients, 16 assigned to intermediate-risk abdominal or urological surgery and 16 patients assigned to low-risk according to cardiac risk classification. All given PCA pump in PACU pain score to be maintained 3/10. Blood samples collected and analysis performed	In both groups no significant released of cytokines in systemic blood. IL-1 in the LPS and SAC analysis showed a decline and returned to normal in 24 hours. IL-10 did not change in the intermediate risk but did peak in the low risk at 24 hrs. ROS was a larger influenced in the intermediate-risk group	Study design isolated the study variable and was able to limit outside influences on the blood samples.	The study was a small sample size, and not standardized in demographics characteristics. IL-6 was not measured; the immunoassay had limited detection of 15-30 pg/ml	ROS production was significantly greater in more intense surgery and maybe useful indicator for severity of the SSR

Author(s), Date	Purpose or Research Question(s)	Research Design/ Level of Evidence	Sampling Method, Size, & Setting	Results	Strengths	Weaknesses	Implications for Practice
6. (Minkowitz, Gruschkus, Shah, & Raju, 2014)	Characterize post-surgical opioid use, estimate rates of ADE and identify risk factors for ADEs and evaluate cost on healthcare systems.	Retrospective cohort study Level of Evidence: 4	Eclipsys sunrise database utilized by Memorial Hermann hospital system includes 11 hospitals 3500 inpatient beds. Patients 18 and older who had an inpatient surgery between jan1 and Dec 31 2010. Opioid utilization was determined and ADE where tracked by ICD-9 codes. Patient where placed into cohorts based on ADE or not. 6285 where included in study	Multivariate logistic regression was used to evaluate odds ratio with 95% CI. 11 % experience a documented opioid ADE. GI ADE were the most common, older are twice as likely to have ADE than younger, men increased risk over women of ADE, comorbidities increased risk of ADE. ADE are significant for higher cost and LOS and increased risk of readmission.	The findings are consistent with various other studies of the adverse effects of opioids, the study utilized a large data base that included data from 11 hospitals.	The data is administrative date ICD codes the true frequency of ADE may be greater, may have overlap of codes, under coding comorbidities, study lacked detailed clinical data	modification of opioid treatment may benefit those with increased risk for opioid ADE.

Author(s), Date	Purpose or Research Question(s)	Research Design/ Level of Evidence	Sampling Method, Size, & Setting	Results	Strengths	Weaknesses	Implications for Practice
7. (Vettorello, Colombo, De Grandis, Costantini, & Raimondi, 2008)	To identify if fentanyl will affect the autonomic nervous system (ANS) by having a sympatholytic effect.	prospective correlational study. Level of Evidence: 4	11 volunteers, age 26-53, six males and 5 females.	ANS analysis has been studies by spectral analysis of heart rate variability (HRV) . 44 total recordings of the 11 subjects, two subjects were excluded. Comparing the SB v FSB showed a sympatholytic effect on HR (P<.05) indicating ANS suppression. PB group also had a sympatholytic effect on HR (P<.003)	The study limited the influence of other anesthetics or pre-medications on the evaluation of spectral analysis separating HF and LF and preventing overlap.	The study was a small sample size, does not address higher doses of fentanyl on ANS, what HRV analysis is actually measuring is unknown.	This study indicates that fentanyl has sympathetic depression and possible vagal activation that could lead to hypotension and impaired cardiac modulation response. However it could attenuate the SSR from.

Author(s), Date	Purpose or Research Question(s)	Research Design/ Level of Evidence	Sampling Method, Size, & Setting	Results	Strengths	Weaknesses	Implications for Practice
8. (Bell, et al., 2004)	Determine how remifentanil vs fentanyl/morphine control SSR in pediatric surgical patients.	Single experiment randomized control study. Level of Evidence: 3	20 patients having open-heart surgery were randomized to one of two treatment groups. Group remifentanil and group fentanyl/morphine at a single facility.	In the post-bypass period the remifentanil group had higher glucose levels than fentanyl/morphine (-2.2, CI (-4.3, -.2). No other differences between the two groups noted both produced perioperative control of the SSR which included change from baseline measurements of HR, MAP, and cortisol level	A direct comparison of two analgesic techniques	The study was a small sample size, not generalizable. The population was pediatric patients only.	The results indicate that remifentanil as well as fentanyl and morphine can provide the same suppression of the SSR during surgery.

Author(s), Date	Purpose or Research Question(s)	Research Design/ Level of Evidence	Sampling Method, Size, & Setting	Results	Strengths	Weaknesses	Implications for Practice
9. (Koji, et al., 2014)	To evaluate thoracic epidural anesthesia, remifentanil low and high dose on the suppression of the hypothalamus-pituitary-adrenocortical axis and sympathoadrenal responses.	20 subjects randomized to 1 of 3 groups. Single experimental study (RCT) Level of Evidence: 3	Randomization by closed envelope, 20 participants, ASA 1-2, age 20-80, at a single facility.	No group difference before anesthesia start. No difference in MAP between all three groups during surgery, however, during pneumoperitoneum HD and LD had significantly lower HR P<.05 HD compared with TEA and LD P<.05 compared with TEA. For adrenocorticotrophic hormone there was a decrease in the HD verses the TEA group P<.05 and P<.01, the LD verses the HD also so significant decrease P<.05 and P<.01. catecholamine concentrations were less during all three groups. Dopamine in LD group higher on induction and pneumoperitoneum	The findings were consistent with various other studies regarding the release of neuroendocrine hormones and catecholamine's.	The study was a small sample size, non-generalizable, single facility.	Indicates that opioids not neuralaxial suppresses neuroendocrine response, and remifentanil at higher does suppress the release of catecholamine's including dopamine, adrenaline and noradrenaline as does neuralaxial techniques.

APPENDIX B – SWOT Analysis

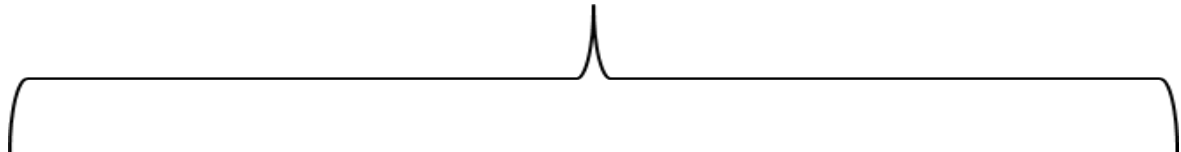
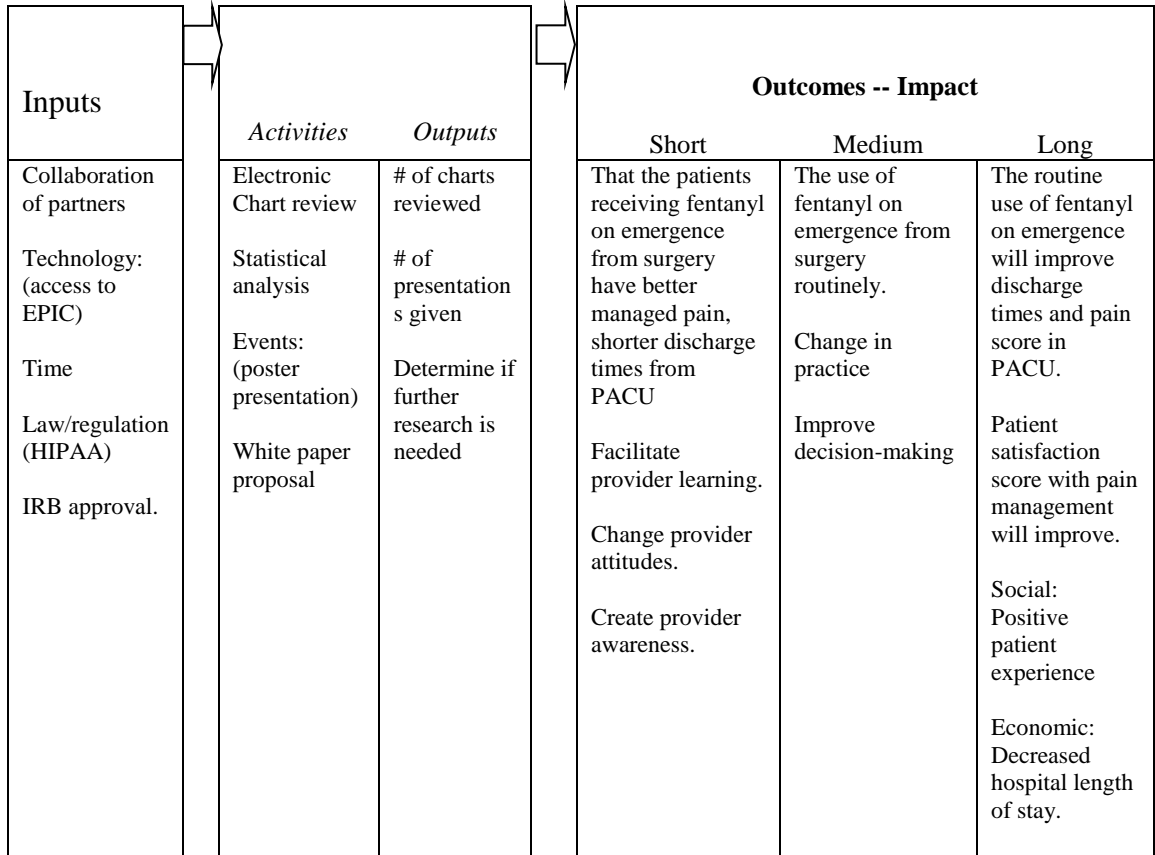
<p>Strengths:</p> <ul style="list-style-type: none"> • retrospective chart review • no cost for clinical site for project implementation. • Access to digital records • Regional trauma center for 19 counties • 6998 inpatient surgeries • 6835 outpatient surgeries 	<p>Weakness:</p> <ul style="list-style-type: none"> • Cannot control variable as with an experimental design • Documentation in records may not be complete
<p>Opportunities:</p> <ul style="list-style-type: none"> • Change in practice in the facility in which project is implemented. • Spur further research in this area. 	<p>Threats:</p> <ul style="list-style-type: none"> • Institutional rejection of project • Unable to obtain key data from chart

APPENDIX C – DNP Essentials

DNP Essentials	Clinical Implications
DNP Essentials I – Scientific underpinnings for practice	The Middle-Range Theory of Acute Pain management utilizes clinical practice guidelines facilitating developing a theoretical model for management of pain.
DNP Essentials II – Organizational and systems leadership for quality improvement and systems thinking	The administration of IV fentanyl may improve postoperative pain management and shorten discharge times from PACU when given on emergence from anesthesia. A practice change will likely be established to improve satisfaction.
DNP Essentials III – Clinical scholarship and analytical methods for evidence-based practice	This project evaluates recommendations currently used to prevent postoperative pain. After the recommendations are reviewed, new guidelines for postoperative pain prevention will be suggested.
DNP Essentials IV – Information systems or technology and patient care technology for the improvement and transformation of health care	With a retrospective chart review, patient data is obtained from their EMR utilizing protection measures to avoid legal ramifications. Electronic databases were also used for the review of literature, dealing with pain management and surgical stress response following surgery.
DNP Essentials V – Healthcare policy for advocacy in healthcare	If an effect is determined following statistical analysis, a practice change will be sought for the reduction in postoperative pain and discharge times with patients undergoing a laparoscopic cholecystectomy. This

DNP Essentials VI – Interprofessional collaboration for improving patient and population health outcomes	change will seek to improve patient pain scores, patient satisfaction and decreased length of stay.
DNP Essentials VII – Clinical prevention and population health for improving the nation’s health	<p>Interdisciplinary collaboration is nurtured by respecting individual expertise while seeking input from team member’s. Sensitivity should be maintained applying cultural, ethnical, and religious consideration.</p> <p>Communication should be open with patients maintaining confidentiality, showing respects and being courteous.</p>
DNP Essentials VIII – Advanced nursing practice	<p>The appropriate management of postoperative pain is important to reduce the effects of the surgical stress response and ensuing neuroendocrine response.</p> <p>Adequate controlled will aid in the recovery of patients by reducing pain scores, length of stay, and return visits as a result of the implications of uncontrolled pain.</p> <p>Postoperative pain management is complex and found to be undermanaged. A research question was created, literature reviewed and evaluation of a potential intervention undertaken. A white paper proposal with suggesting a practice change will occur in collaboration with stake holder for improvement of patient outcomes.</p>

APPENDIX D – Logic Model



Assumption:
 The administration of fentanyl on emergence from surgery will improve pain management and discharge times from PACU.

APPENDIX E – Medical Facility IRB Approval Letter



DATE: August 3, 2016

TO: Andrew Wetzel, BSN
FROM: [REDACTED] General Hospital Institutional Review Board

STUDY TITLE: [028716-1] Does fentanyl administration on emergence from a laparoscopic cholecystectomy surgery positively affect post-anesthesia care unit (PACU) discharge times and amount of analgesia administered in PACU

SUBMISSION TYPE: HIPAA IRB Waiver of Authorization

ACTION: APPROVED
APPROVAL DATE: July 20, 2016
EXPIRATION DATE: July 19, 2017
REVIEW TYPE: Full Committee Review

The [REDACTED] General Hospital Institutional Review Board ([REDACTED] IRB) has reviewed and approved the Waiver of Authorization for use of protected health information (PHI) for this research study as outlined in the approved research protocol.

In approving this Waiver of Authorization, the [REDACTED] IRB has determined the following criteria has been met:

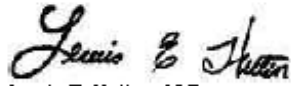
The use or disclosure of the requested information involves no more than a minimal risk to the privacy of individuals based on, at least, the presence of the following elements:

- An adequate plan to protect the identifiers from improper use and disclosure
- An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.
- Adequate written assurances that the requested information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the requested information would be permitted by the Privacy Rule.
- The research could not practicably be conducted without the waiver or alteration
- The research could not practicably be conducted without access to and use of the requested information

In making this determination the FGHI IRB has followed the requirements of the Common Rule using Full Board Review procedures.

If you have any questions, please contact Michele Stanley at 801-288-4324 or mstanley@forredgenet.com. Please include your study title and reference number in all correspondence with this office.

Sincerely,

Handwritten signature of Lewis E. Herten in cursive script.

Lewis E. Herten, M.D.
Chairman, Institutional Review
Board

APPENDIX F – Letter of IRB Approval from USM



INSTITUTIONAL REVIEW BOARD

118 College Drive #5147 | Hattiesburg, MS 39406-0001

Phone: 601.266.5997 | Fax: 601.266.4377 | www.usm.edu/research/institutional.review.board

NOTICE OF COMMITTEE ACTION

The project has been reviewed by The University of Southern Mississippi Institutional Review Board in accordance with Federal Drug Administration regulations (21 CFR 26, 111), Department of Health and Human Services (45 CFR Part 46), and university guidelines to ensure adherence to the following criteria:

- The risks to subjects are minimized.
- The risks to subjects are reasonable in relation to the anticipated benefits.
- The selection of subjects is equitable.
- Informed consent is adequate and appropriately documented.
- Where appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of the subjects.
- Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of all data.
- Appropriate additional safeguards have been included to protect vulnerable subjects.
- Any unanticipated, serious, or continuing problems encountered regarding risks to subjects must be reported immediately, but not later than 10 days following the event. This should be reported to the IRB Office via the "Adverse Effect Report Form".
- If approved, the maximum period of approval is limited to twelve months.
Projects that exceed this period must submit an application for renewal or continuation.

PROTOCOL NUMBER: 16081506

PROJECT TITLE: Fentanyl administration on emergence from surgery and post anesthesia care unit discharge times and pain scores

PROJECT TYPE: New Project

RESEARCHER(S): Andrew Wetzel

COLLEGE/DIVISION: College of Nursing

DEPARTMENT: Advanced Nursing Practice/Nurse Anesthesia Program

FUNDING AGENCY/SPONSOR: N/A

IRB COMMITTEE ACTION: Expedited Review Approval

PERIOD OF APPROVAL: 08/22/2016 to 08/21/2017

Lawrence A. Hosman, Ph.D.

Institutional Review Board

APPENDIX G – Data Collection Tool

Identification # _____

Procedure Date _____ Age _____ Sex _____
 ASA _____

Adverse events in surgery Y / N

Adverse events in PACU Y / N

Current Home Medications:

PMH: _____

Fentanyl given on emergence	Time (24 hr)	Amount (mcg)

Anesthesia Start time	Anesthesia end time	Total Time (minutes)

Surgery Start time:	Surgery stop time:	Total time (minutes)

PACU time in:	PACU time out	Total Time (minutes)

PACU time in:	Time of first analgesic administration (minutes)	Length of time in minutes.	Dose given: Type: _____mg

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