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Preoperative Non-Opioid Medications for the Management of Postoperative Pain: Creation of an Educational Module Based on the Knowledge and Attitudes

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Abstract

Background: Current clinical studies have shown that preoperative non-opioid medications are an effective method to reduce moderate to severe pain in the postoperative settings, but are not commonly utilized in laparoscopic cholecystectomy patients.
Purpose of this study: The purpose of this study was to evaluate the knowledge and attitudes of anesthesia providers about the preoperative use of three different non-opioid medications: clonidine, acetaminophen and gabapentin for the treatment of postoperative pain in laparoscopic cholecystectomy patients.
Design: A descriptive survey research design was used to determine anesthesia providers' knowledge and attitudes regarding preoperative non-opioid medications. A modified evidence based knowledge and attitudes survey was administered to anesthesia providers at the NorthShore University HealthSystem, which included physicians and nurse anesthetists.
Results: This study found that physicians and more experienced anesthesia providers had a more positive attitude towards the use of preoperative non-opioid medications. The findings from this study also suggested that the many anesthesia providers had a lack of knowledge regarding gabapentin and clonidine. Based on the survey results, an educational module was developed focusing on the gap in knowledge and attitude of anesthesia providers towards gabapentin and clonidine as a choice of preoperative medication for postoperative pain control in laparoscopic cholecystectomy patients.
Conclusion: The findings helped identify gaps in knowledge and pervasive attitudes towards preoperative non-opioid medications among anesthesia providers to guide the development of an educational module to address these deficiencies.
Relevance to Nursing Practice: The educational module created in this study will be useful to increase knowledge of the use of preoperative non-opioid medications among anesthesia providers for the management of postoperative pain in patients undergoing laparoscopic cholecystectomy.

Chapter 1 Introduction

Background and Significance

Postoperative pain management is an essential component of care for surgical patients. Inadequately managed postoperative pain results in a wide variety of negative outcomes including a decrease in alveolar ventilation and vital capacity, tachycardia, hypertension, myocardial infarction, insomnia, poor wound healing, and delayed patient discharge from the hospital (Harsoor, 2011). The adequacy of pain control for perioperative analgesia has traditionally been provided by opioid analgesics, but recent studies have confirmed the negative effects of opioid medications and suggested the use of multimodal analgesics as the new "gold standard" to decrease these negative effects in surgical patients (Harsoor, 2011; Jakobsson, 2014). The number of patients that could benefit from non-opioid medications was potentially quite large: For example, a multicenter trial in Canada showed that nearly 30% of patients had moderate to severe pain 24 hours after ambulatory surgery (McGrath et al., 2004).

Minimally invasive surgery is one of the most rapidly expanding fields of surgery. Laparoscopic cholecystectomy (LC) has become the standard of care for the treatment of symptomatic cholelithiasis (Mitra et al., 2012). Pain after LC is common and is generally caused by three main sources: incision sites, pneumoperitoneum resulting in diaphragmatic and peritoneal stretching, and post cholecystectomy wounds within the liver (Mitra et al., 2012). Improper treatment of postoperative pain can lead to complications and poor outcomes, including longer hospital stays, higher rates of medical complications, and decreased patient satisfaction (Morrison et al., 2003). Pain after surgery is distressing to patients, and can cause physiological and psychological harm to them; if left unaddressed for long periods, acute pain can become chronic pain, resulting in a significant decrease in patients' quality of life

(Nishimoto, 2014). Therefore, effective postoperative pain management is vital to optimize patient care.

Pain is the most important independent predictor of recovery time in LC patients, and is the most common postoperative symptom that can delay discharge (Mitra et al., 2012). Yet there is little data on the optimal medications for treatment of moderate to severe pain among LC patients. While there are several methods that can be used for postoperative pain management, opioids are the most common (Harsoor, 2011). Though opioids are effective for rapid pain relief, they are associated with somnolence, postoperative nausea and vomiting, constipation, and respiratory depression, all of which can delay discharge (Mitra et al., 2012).

Clinical studies have found that the use of preoperative non-opioid medications to reduce postoperative pain have several advantages over the use of opioids. Non-opioid medications like acetaminophen, non-steroidal anti-inflammatory drugs (NSAIDs), alpha2 agonists (clonidine), anticonvulsants (gabapentin), and aspirin are some of the most widely used therapeutic agents. It has been postulated that the timing for maximum efficacy of non-opioid medications may be in the preoperative period in order to prevent the large sensory signals that flood the central nervous system (CNS) postoperatively (Romej, Voepel-Lewis, Merkel, & Reynolds, 1996). This excitability may contribute to hyperalgesia postoperatively. Prevention of accumulation of sensory signals should result in more manageable pain postoperatively (Romej et al., 1996).

While NSAIDs and aspirin are excellent in the treatment for pain, their side effect profile, surgical contraindications, and drug interactions limit their use as preoperative medications (Kaufman, 2010). By contrast, acetaminophen is well tolerated, has few side effects, and may represent a better option for most patients in preoperative setting for postoperative pain management (Kaufman, 2010). Many research articles report that oral acetaminophen has been

shown to be safe and effective in a variety of acute pain models (Pergolizzi, Ruffa, Tallarida, Taylor, & Labhsetwar, 2012). An important advantage of acetaminophen over other analgesic agents is its safety and tolerability profile. In contrast to opioids, acetaminophen does not produce sedation, respiratory depression, ileus, constipation, or substance abuse (Ofirmev, 2010).

Clonidine, an alpha-2 agonist, has been found to have potent analgesic properties without respiratory depression, which is particularly helpful for patients who cannot tolerate the respiratory depression caused by opioids. The analgesic effect results from alpha2-adrenoreceptors located in the CNS and spinal cord; in effect, clonidine produces analgesia by preventing pain signal transmission to the brain. In cases where opioids are still being used, alpha2 agonists can also potentiate their analgesic effects, multiplying the impact of a given dosage (Blaudszun, Lysakowki, Elia, & Tramèr, 2012).

Gabapentin, an anticonvulsant with analgesic effects, is another commonly used medication for pain management in LC patients (Mitra et al., 2012). This medication produces an analgesic effect by binding to voltage gated calcium channels and reducing neurotransmitter release. The safety and efficacy of gabapentin has been confirmed in many trials. Other observed benefits include reduction of movement-evoked pain, opioid sparing, and preoperative anxiolysis (Mitra et al., 2012).

While there are several studies that assessed the efficacy of various non-opioid medications, there is limited data on which medication is ideal for a specific surgical procedure. In the absence of procedure specific evidence about non-opioid medications, there are many factors that affect providers' preferences, including institutional preference and availability, surgeon preference, and perceived benefit based on past experience.

Additionally, the providers' knowledge and attitude towards the medications effect the use of the medication. While there is no existing data on the knowledge and attitude of anesthesia providers toward preoperative non-opioid medications in LC patients, the evidence in favor of preoperative non-opioid analgesics raises one singular question: Why are anesthesia providers' at NorthShore University HealthSystem (NSUHS) not utilizing them? According to Mitra, et al (2012), clinicians need information about the choices of preoperative medications and their availability, to then consider these options for each type of surgery.

Problem Statement

After LC, most patients suffer from at least moderate pain (Tiippana, Bachmann, Kalso, & Pere, 2008), which is multifactorial in origin: the incision sites, the pneumoperitoneum resulting in diaphragmatic and peritoneal stretching, and the post cholecystectomy wound within the liver (Mitra et al., 2012). Improved control of postoperative pain is correlated with better patient outcomes, shorter duration of hospital stays, and improved patient satisfaction (Mitra et al., 2012). Achieving proper pain management in these patients requires a multifaceted approach that encompasses non-opioid medications, patient factors, and procedural complexity. As described earlier, there are three different preoperative non-opioid medications that can safely be used for the management of postoperative pain: acetaminophen, clonidine and gabapentin. Anecdotal evidence suggests that anesthesia providers often use opioids postoperatively without considering used of preoperative non-opioid medications. The reason why anesthesia providers do not use preoperative non-opioid medications for pain in LC patients is unknown. Investigating the knowledge and attitude of providers towards the use of non-opioid medications, specifically acetaminophen, clonidine and gabapentin, for LCs would be beneficial.

Purpose of Project

The purpose of this descriptive survey was to evaluate the knowledge and attitude of anesthesia providers at NSUHS about the preoperative use of the three non-opioid medications, acetaminophen, clonidine and gabapentin, for the management of postoperative pain in LC patients. The findings helped identify why many anesthesia providers were not using these medications. Using the survey results, an educational module was created to help close gaps in knowledge, and create awareness of the utility of the use of the preoperative non-opioid medications in LC patients.

Clinical Questions

The following clinical questions were addressed in this study:

- What was the level of knowledge among anesthesia providers regarding the use of preoperative non-opioid medications gabapentin, acetaminophen and clonidine for the treatment of postoperative pain management in patients undergoing laparoscopic cholecystectomy?
- What was the general attitude among anesthesia providers regarding the use of preoperative non-opioid medications gabapentin, acetaminophen and clonidine for the treatment of postoperative pain management in patients undergoing laparoscopic cholecystectomy?

Theoretical Framework

The conceptual framework that guided this study was the needs assessment theory, first modeled by Roger Kaufman, who helped to evaluate the gap between the conditions and the wants of subjects (Wright, Williams, & Wilkinson, 1998). The purpose of a needs assessment is

to gather information about what is required to bring about a beneficial change to the health of a population (Wright, Williams, & Wilkinson, 1998).

Stevens and Gillman (1998) explains various approaches to accomplishing a needs assessment. The "corporate approach" involves the collection of the knowledge and attitudes of participants, such as doctors and nurses, on healthcare services and need. The approach allows for sensitivity to local culture and practices. This DNP project aligns with a corporate approach to the needs assessment. Stevens and Gillman (1998) also assert that a "needs assessment is futile if it does not result in improved services to patients (p.1451)."

Based on the needs assessment theory, a modified survey was used to evaluate the gaps in knowledge and attitude of the anesthesia providers. An educational module was created to meet the needs of the anesthesia providers. The knowledge and awareness provided in the educational module may help influence anesthesia providers' use of preoperative non-opioid medications in LC patients, which may help guide a positive change to the overall patient outcomes.

Chapter 2 Literature Review

The following literature review discusses the three selected non-opioid medications, acetaminophen, clonidine and gabapentin, for the use of postoperative pain management in LC patients. A computerized literature search was completed using the following databases: PubMed, CINAHL complete, ProQuest Nursing & Allied Health Source, and Cochrane Library.

While there was limited data available when searching for use of acetaminophen, clonidine, and gabapentin in pain management of LC patients, the literature review indicates that these the use of these non-opioid medications preoperative helps pain management in a variety of other surgical procedures. Most often, medications used for one type of surgery may also work for another surgical procedure (Toms, McQuay, Derry, & Moore, 2008). Thus, it seems likely

that they can be used preoperatively to help in the management of moderate to severe postoperative pain (Mitra et al., 2012).

Gabapentin

Mechanism of action/side effects. Gabapentin, a gamma-amino butyric acid (GABA) analogue, is a widely used medication for the treatment of seizures and management of neuropathic pain. (Bardal, Waechter & Martin, 2011). Gabapentin is an anticonvulsant that increases the seizure threshold; it exerts its effect through selectively interacting with the α(2)δ subunit of voltage gated calcium channels (Mikkelsen, Hilsted, Anderson, Hjortso, Enggaard, Jorgensen, & Dahl, 2006). The side effects of gabapentin are fatigue, dizziness and ataxia (Bardal, Waechter, & Martin, 2011).

Research. The safety and efficacy of gabapentin for pain management in a variety of surgical procedures, such as LC includes reduction of movement-evoked pain, opioid sparing, and preoperative anxiolysis. Gabapentin can reduce acute postoperative pain and decrease the need for opioids. In a double-blinded randomized trial, 1.2 gm/day dose of gabapentin versus placebo was given before and two days after coronary artery bypass graft (CABG) surgery. The gabapentin group showed significantly lower postoperative pain scores at 1, 2, and 3 days, and decreased consumption of tramadol as a rescue analgesic (Ucak, Onan, Sen, Selcuk, Turan, & Yilmaz, 2012).

In 2007, Kong and Irwin published a review of the strongest available evidence describing the safety and efficacy of gabapentin for the management of postoperative pain. Their review included various RCTs, a systematic review, and a meta analysis. The authors found that gabapentin reduced postoperative opioid requirements, decreased PONV, decreased postoperative delirium and attenuation of hemodynamic response during direct laryngoscopy.

They concluded that a single dose of gabapentin given preoperatively was useful in the management of postoperative surgical pain. Based on their review, they recommended a single dose of 900mg.

Ajori, Nazari, Mazloomfard, and Amiri (2012) conducted a double blind randomized trial to evaluate the preoperative use of gabapentin on postoperative pain management, meperidine consumption and nausea and vomiting in patients undergoing hysterectomy. Ajori et al. (2012) found that 600 mg of gabapentin taken orally versus placebo by patients undergoing abdominal hysterectomy significantly reduced postoperative pain and PONV, and decreased the analgesic and antiemetic drug requirements. Gabapentin has been reported to be a well-tolerated, safe, and effective drug given preoperatively for postoperative analgesia (Chang, Challa, Shah, & Eloy, 2014).

Pandey et al. (2004), conducted a double-blinded randomized trial where subjects were given 300mg gabapentin, 100mg tramadol or placebo two hours before their LC surgery. Patients' pain was evaluated every 2 hours for the first 12 hours and then every 3 hours for the next 12 hours. When gabapentin was compared to the placebo and tramadol group, the pain scores were lower in the gabapentin group all the time intervals except 0-6 hours after surgery, compared to the tramadol group. There was also a decrease in total analgesic consumption (fentanyl) in the gabapentin group (Pandey et al., 2004). This study demonstrated the significance of the analgesic effect of preoperative use of gabapentin (300mg) over tramadol (100mg) or placebo for LC patients.

Amin and Amr (2011) compared the preoperative use of gabapentin and paracetamol (a prodrug of acetaminophen) for pain control in children undergoing tonsil surgery. Tonsillectomy is associated with significant postoperative pain, and, if treated poorly, pain can cause increased

heart rate, blood pressure, respiratory rate, difficulty swallowing, an elevated risk of postoperative bleeding, and prolonged hospital stay (Amin & Amr, 2011). In this double-blinded randomized trial, 70 children underwent adenotonsillectomy and were given either gabapentin (10mg/kg) or paracetamol (20mg/kg) two hours before induction of general anesthesia. Postoperative pain scores were evaluated using the visual analogue scale (VAS) several hours postoperatively. Amin and Amr (2011) concluded that gabapentin significantly decreased postoperative pain scores compared to paracetamol, with no side effects reported.

Acetaminophen

Mechanism of action/side effects. Acetaminophen is an analgesic and antipyretic. Acetaminophen acts on both the peripheral and central pain pathways; while there are a variety of mechanisms of action proposed. (Pergolizzi et al., 2011). Acetaminophen most likely exerts its effects through the inhibition of cyclooxygenase (COX) (Bardal, Waechter, & Martin, 2011). COX helps to catalyze the formation of prostaglandins (PG) and other mediators (which are important part in processing and signaling pain in the brain). An acute overdose (regular doses above 4,000 mg/day) of acetaminophen can be toxic and cause hepatotoxicity. The other associated side effect noted was increased risk for asthma (Bardal, Waechter, & Martin, 2011).

Research. The majority of current research is on the use of paracetamol (prodrug of acetaminophen) and IV acetaminophen. Acetaminophen (paracetamol) is a familiar agent for treating many types of pain, including post-surgical pain. Oral acetaminophen has been proven to be effective and safe in many acute pain models (Pergolizzi, Rafffa, Tallarida, Tayor, & Labhsetwar, 2011). Multimodal medications given with acetaminophen have revealed opioid-sparing effects and therefore decreased the opioid associated side effects (Pergolizzi et al., 2011).

A meta-analysis of seven randomized controlled trials found that acetaminophen (including paracetamol, oral acetaminophen and IV acetaminophen) decreased the consumption of morphine by approximately 20% in the first 24 hours after surgery (Pergolizzi et al., 2011). Another meta-analysis (which was too diverse to perform a formal meta-analysis) of sixteen studies and 1,464 participants found IV acetaminophen was effective across a variety of surgical procedures for acute postsurgical analgesia (Pergolizzi et al., 2011).

In a review article Tom et al. (2008), published a review of the strongest available evidence describing the safety and efficacy of oral paracetamol (prodrug of acetaminophen) for the management of postoperative pain. A prodrug medication is given pharmacologically in the inactive form and becomes active once metabolized. Their review included various RCTs, a systematic review, and a meta analysis. Overall, the authors concluded that a single dose of paracetamol provided effective analgesia for approximately 50% of patients with acute postoperative pain with minimal side effects.

Clonidine

Mechanism of action/side effects. Clonidine is an alpha2 agonist that has sedative, analgesic and anxiolytic properties. The presynaptic activation of alpha2 receptors (that inhibits the release of norepinephrine) is believed to help mediate the analgesia (Barash, Cullen, & Stoelting, 2006). The side effects are bradycardia and hypotension.

Research. In a review article by Lambert, Cyna, Knight, and Middleton (2014), reported a meta-analysis of 11 relevant trials studying 742 children having surgery where premedication with clonidine (4mcg/kg) was compared to placebo or other drug treatment. Premedication with clonidine (4mcg/kg) had beneficial effect on postoperative pain in children. Side effects were

minimal, though in some cases, atropine was given prophylactically with the intention of preventing the side effect of decreased heart rate (Lambert et al., 2014).

Laisalmi, Koivusalo, Valta, Tikkanen, and Lindgren (2001) conducted a prospective randomized controlled trial using clonidine. Preoperatively, 30 patients undergoing LC were given either 4.5mcg/kg of clonidine or the same amount of saline (control group) intramuscularly. Results revealed that LC patients in the clonidine group had opioid sparing effects (50% less alfentanil was needed) along with hemodynamic stability. Postoperatively, rescue opioids were used half as often in the clonidine group compared to the control group. Laisalmi et al. (2001) concluded that preoperative use of clonidine was effective and the concern about hemodynamic instability was unfounded. The results also suggested that clonidine use may protect the kidneys from ischemic injury (Laisalmi et al., 2001).

Singh and Arora (2011) evaluated the preoperative use of clonidine in LC patients. The researchers administered oral clonidine (150 mcg) preoperatively, which resulted in improved perioperative hemodynamic stability, reduced intraoperative anesthetic use, and decreased postoperative analgesic requirements. The randomized single-blinded prospective comparative study had two groups: one was given clonidine (150mcg) and the other was given vitamin C (100mg), both 90 minutes before induction of general anesthesia. Clonidine not only helped blunt the cardiovascular response with insufflation of the carbon dioxide (CO2), but also the body's response to hypercapnia. The overall cumulative analgesic requirement in the first 24 hours was significantly lower for the group that received clonidine, and the patients benefited from improved perioperative hemodynamic stability, reduced intraoperative anesthetic requirements, and decreased postoperative analgesic requirements (Singh & Arora, 2011). The authors concluded that the administration of oral clonidine (150mcg) is a simple, cost effective

form of premedication in LC patients; it not only decreased the postoperative analgesic requirements but also improved intraoperative hemodynamics (Singh & Arora, 2011).

A systematic review and meta-analysis of randomized controlled trials consisted of 30 studies (1,792 patients) were included. 933 of the patients received clonidine in either an IV form or oral dose, preoperative, intraoperative or postoperative. The results concluded that alpha 2 agonist had a positive effect on hemodynamics, reduced incidence of postoperative nausea, moderate opioid sparing postoperatively, with no evidence of lengthening recovery time (Blaudszun et al., 2012).

Existing Knowledge and Attitude

There are several pain medication options that were trialed for LC patients, but there was no study demonstrating the most effective medication. Evidence suggests that different pharmacological agents including acetaminophen, clonidine and gabapentin help reduce postoperative pain scores in patients undergoing surgical procedures, including elective LC. Though the decision of the provider to use a specific medication must weight its benefits against the potential side effects, the literature indicates a trend towards the use of these medications as adjuncts to preoperative pain management in LC patients (Gurusamy, Vaughan, Toon, & Davidson, 2014).

Although there is limited research about the knowledge and attitudes of providers on the use of these medications for LC patients, there is data to suggest that a lack of knowledge is a barrier to use. A study conducted by Temple, Fagerlung, and Saewyc (2005), evaluated the knowledge, belief and assessment of herbal supplements in the anesthesia setting. They concluded that a lack of education and limited familiarity with the supplement resulted in

decreased usage. Following their research, the majority of the of CRNA's requested for more education about herbal supplements (Temple et al., 2005).

Ucuzal and Dogan (2014) performed a survey about the knowledge, attitude and clinical decision making skills regarding pain. The survey concluded that only half the sample of nurses believed that unrelieved pain in the emergency department increased patients' mortality and morbidity. Half the nurses also believed that the patients should be encouraged to withstand the pain as much as possible before using a pain relief method. The implication of this study showed the necessity to create education programs to help understand the attitude and lack of knowledge about pain (Ucuza & Dogan, 2014).

Qadire and Khalaileh (2012) evaluated the knowledge and attitude among nurses regarding pain management in cancer patients. This study stated that 50% of healthcare providers lacked knowledge about pain assessment and management, including information about medications. The overall study found that the nurses did not have enough knowledge to treat patient's pain. This demonstrated the need for continuing pain management education in hospitals (Qadire & Khalaileh, 2012).

Matthews and Malcolm (2007) aimed to evaluate the knowledge and attitude of nurses after a knowledge and competency program about orthopedic pain management. One group of nurses received the training program and the other group did not. The study concluded that the overall score was much better (73.8%) for the nurses that received the program. Matthews and Malcolm (2007) recommended continued mandatory training for nurses in pain management.

A significant body of research supports the use of acetaminophen, clonidine and gabapentin for pain management, even though there is limited research about the use of these specific medications for LC patients. Some studies evaluated the knowledge and attitudes of

healthcare workers about pain management, although there is limited data for these specific non-opioid medications. More specifically, there is even more limited data available about anesthesia providers' knowledge and attitudes about these specific non-opioid analgesics for LC patients. This study aimed to fill the gap in knowledge regarding preoperative use of non-opioid medications in LC patients to anesthesia providers.

Chapter 3 Methods

Research Design

A descriptive survey design was used to gain an understanding of the clinical knowledge and attitude of anesthesia providers at NHUHS with regard to the preoperative use of non-opioid medications for the management of postoperative pain in LC patients. Based on the results, an education module was developed to focus on the gaps identified in the anesthesia providers' knowledge of the medications.

Target Audience

The group of anesthesia providers that were invited to take part in the survey were also the target audience of the educational module.

Sample

The study's sample consisted of a convenience sample of anesthesia providers employed at NSUHS. Inclusion criteria include all anesthesia provider at NorthShore University. Exclusion criteria included nurse anesthesia students (SRNAs), residents and medical students.

Sample size. The Department of Anesthesiology at NSUHS consists of 70 anesthesia providers. A response rate of at least 40% was desired, yielding a proposed target sample size of 28 participants. Though Sivo, Saunders, and Chang (2006) found a response rate of 70% is very good and 60% is good, the authors found that actual response rates of surveys were around 30%.

However, the average response rate was 40% in 4 out 6 journals that were surveyed (Sivo, Saunder, & Chang, 2006).

Setting

The study was conducted among anesthesia providers employed at NSUHS, which is a large health care system consisting of four hospitals and provides a full range of healthcare services in the northern suburbs of Chicago. Among the four facilities, there is a large variety of surgical specialties, ranging from minimally invasive procedures to open heart surgery, including approximately 1,000 laparoscopic cholecystectomies per year.

Instrument

The study survey (Appendix A) consisted of two parts: a demographic and background practice information section and a section assessing the knowledge and attitude associated with the preoperative use of the non-opioid medications. The second section was modeled from a survey conducted by Temple et al. (2005), which assessed the knowledge and beliefs of Certified registered nurse anesthetists regarding herbal supplements.

The knowledge and beliefs survey developed by Temple et al. (2005) was developed alongside two doctorate nursing faculty, a CRNA educator and a nurse researcher. The survey was evaluated for content validity, readability and internal consistency (Cronbach α, 0.82); validity was verified by exploring the positive correlation between the survey and knowledge and beliefs (Temple et al., 2005).

The knowledge and attitude items used in this study were modified from the Temple survey to be more applicable to the non-opioid medications, acetaminophen, clonidine and gabapentin. It was reviewed by 6 anesthesia providers (anesthesiologists and CRNAs) for clarity

and appropriateness. This modified knowledge and attitude survey was formed with a good internal consistency (Cronbach α, 0.79).

The survey consisted of 21 questions. Four demographic questions addressing age, gender, experience and type of anesthesia provider. Three questions were asked to better understand how the anesthesia providers "routinely" practiced. Five knowledge and seven attitude question were asked along with two questions regarding how likely the anesthesia provider felt to recommend non-opioid medications to their patients. For the knowledge and attitude items, responses were rated on either a five-point Likert-type scale, ranging from one to five (1-strongly disagree, 2=disagree, 3=neutral, 4=agree, 5=strongly agree) or a four-point Likert-type scale, ranging from one to four (1=regularly, 2=occasionally, 3=rarely, 4=never). The two recommendation questions were also rated on a four-point Likert-type scale.

The survey was formatted for electronic distribution and collection using the Qualtrics software provided by DePaul University.

Recruitment of Subjects

Before the study was initiated, approval was obtained by the institutional review boards (IRB) from DePaul University and NorthShore University HealthSystem. Copies of IRB approval can be found in Appendix B. A recruitment e-mail (Appendix C) was sent to the anesthesia providers by one of the clinical coordinators, Julia Feczko, CRNA, DNP. The recruitment e-mail contained the purpose of the study and the inclusion/exclusion criteria. An information sheet for participation (Appendix D) was sent to further explain the nature of the study, its anonymous and voluntary nature and the implied consent. By nature of it being a survey, completion of survey implied consent to participant. Those anesthesia providers at NSUHS who met the inclusion criteria were directed to open the Qualtrics link to the online

survey. The survey was distributed via an e-mail link and used the Qualtrics system. Completion of survey was estimated to take no more than 10 minutes.

Data Collection and Analysis

Survey responses were first collected and assessed in Qualtrics for completeness and inclusion/exclusion criteria. Qualtrics allows data to be automatically anonymized and then exported for analysis into Excel spreadsheets and the Statistical Package for the Social Sciences software version 22 (SPSS) program. The SPSS was used to analyze the collected data. Demographic variables and key responses were entered into SPSS descriptive statistics to determine frequencies, mean and standard deviation. Data was further analyzed using the fisher exact test and t-test to determine statistical significance.

Protection of Human Subjects

Collaborative Institutional Training Initiative (CITI) and Financial Conflict of Interest (FCOI) certifications (Appendix E), ensuring the researcher's understanding of what constitutes research and how human subjects must be protected in studies, were completed in December 2014. Upon completion of the modules, the DePaul University IRB and NorthShore University HealthSystem IRB reviewed the study. Once approved, the recruitment e-mail, information sheet for participation, and the link to the survey on Qualtrics was e-mailed to the anesthesia providers via the clinical coordinator at NSUHS, Evanston location. Qualtrics survey link assured no participant identifiers were collected when completing the survey. To ensure anonymity, no links could be tied between the subjects and the researcher.

The participation of the subjects was voluntary and there were no repercussions for deciding not to complete the study. The identity of participants remained anonymous, with supervisors having no access to the information, and participation having no effect on

employment status. There was no direct benefit for the study subjects for their participation in research project. Knowledge gained from this study could be used solely to produce benefits to the anesthesia profession and patient care.

Chapter 4 Results

In this chapter, data results are discussed including the sample and the responsible provider, knowledge of each of the medications, attitudes toward each of the medications, overall association between the knowledge and attitude of acetaminophen, clonidine and gabapentin and the consideration of the use of the medications. The results were used by the study investigator to develop an educational module to provide information to enhance the use of the three indented preoperative non-opioid medications, ultimately to help bridge the gap between the knowledge and attitudes among anesthesia providers (Appendix F).

Description of Sample

The survey was distributed to a total of 70 participants at NSUHS. A total of 33 participants completed the survey for a 47% response rate. The age of the participants ranged from 30 to >59 years. The majority of participants were female (n=23, 70%) CRNAs (n=24, 73%). Most participants had been providing anesthesia for >20 years (n=15, 46%). There were too few participants in each age group to allow for the study to yield statistically significant results at the sub-group level, see Table 1.

Table 1. Description of Sample

VARIABLES (N=33)	FREQUENCY	NUMBER (N)	PERCENT (%)
AGE	20-29	0	0%
	30-39	9	27%
	40-49	9	27%
	50-59	12	36%
	≥59	3	9%
GENDER	Male	10	30%
	Female	23	70%
PRACTIONER TYPE	Anesthesiologist	9	27%
	CRNA	24	73%
YEARS OF PRACTICE	1-3	6	18%
	4-6	3	9%
	7-10	2	6%
	11-15	5	15%
	16-20	2	6%
	>20	15	46%

Background Practice Information on Mangement of Preoperative Pain

The participants were asked which anesthesia providers was usually responsible for obtaining preoperative anesthetic evaluations for patients (survey question 5). The respondents were able to choose multiple answers for this survey question. 52% (n=30) of participants reported it being the anesthesiologist's repsonsibility. 34% (n=20) of participants reported it was the CRNA's responsibilty. 14% (n=8) indicated the "other" option which included the SRNA and anesthesiology resident.

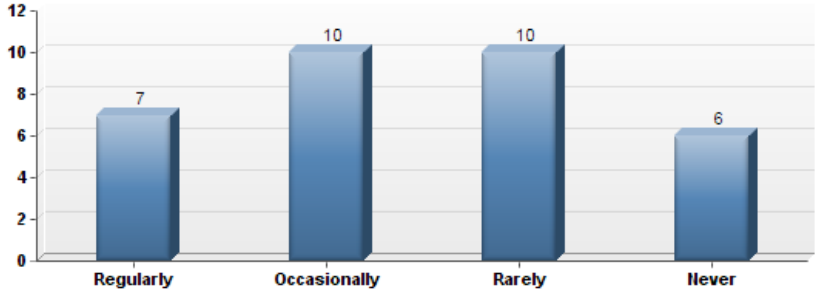
The participants were asked which anesthesia providers were usually responsible for planning/discussing postoperative pain management with the patient (survey question 6). This survey question could be answered with multiple answers. 56% (n=28) of participants reported it being the anesthesiologist's repsonsibility to plan/discuss postopertive pain management with patients. 28% (n=14) of participants reported it was the CRNA's responsibilty. 14% (n=8) indicated the "other" option which included the SRNA, resident, or surgeon, see Table 2.

Table 2. Responsibilty of Preop Evaluation and Planning/Discussing Postoperative Pain

	Responsible for Obtaining Preoperative Evaluations N	(%)	Responsible for Plan/Discus Postoperative Pain with Patient N	(%)
Anesthesiologist	30	52	28	56
CRNA	20	34	14	28
Other	8	14	8	14

The participants were asked how often they ordered non-opioid medications preoperatively for postoperative surgical pain management (survey question 7). The four-point Likert scale was ranging from 1= never, 2=regularly, 3=occasionally, to 4= regularly. 21% (n=7) of the participants answered they regularly ordered non-opioid pain medications preoperatively for management of postoperative surgical postoperative pain. 30% (n=10) indicated they occasionally ordered non-opioid pain medications; these two groups represented 51% of the participants. 30% (n=10) of the participants indicated rarely and 18% (n=6) indicated they never ordered non-opioid pain medications for surgical postoperative pain management; these two groups represented 48% of participants. The mean (out of 5) and standard deviation (2.45 and1.03) implied the average participant reported occasionally or rarely ordering non-opioid medications preoperatively for postoperative surgical pain management, see Figure 1.

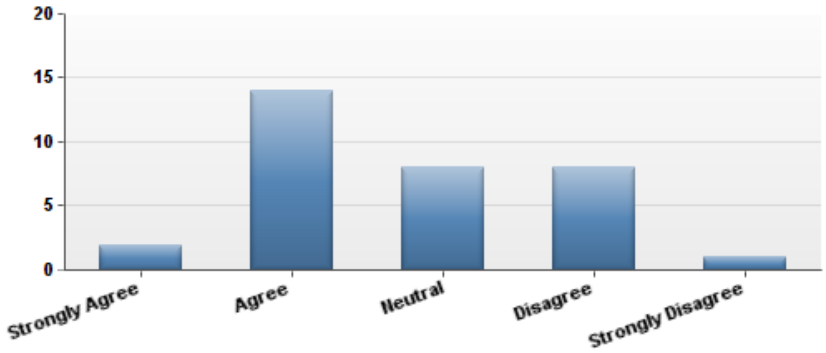
Figure 1. Frequency of anesthesia providers ordering non-opioid medications



Knowledge of Anesthesia Providers

Confidence in knowledge regarding non-opioid preoperative medications. In order to assess the anesthesia providers' knowledge about the preoperative non-opioid medications, the participants were asked about their confidence in their knowledge base regarding the preoperative administration of acetaminophen, clonidine and gabapentin for the management of postoperative pain in patients undergoing LC (survey question 8). The five-point Likert scale ranging from 1= strongly agree to 5 = strongly disagree was used to measure knowledge related questions in this study. 48% (strongly agree, n=2; agree, n=14) expressed that they were confident in their knowledge regarding these non-opioid medications. 24% (n=8) of participants were neutral. 27% (disagree, n=8; strongly disagree, n=1) did not feel confident in their knowledge base. The mean and standard deviation (2.76 and 1.00) indicated that the average anesthesia provider was neutral in his or her knowledge regarding the administration of acetaminophen, clonidine, and gabapentin for the management of postoperative pain in LC patients, see Figure 2

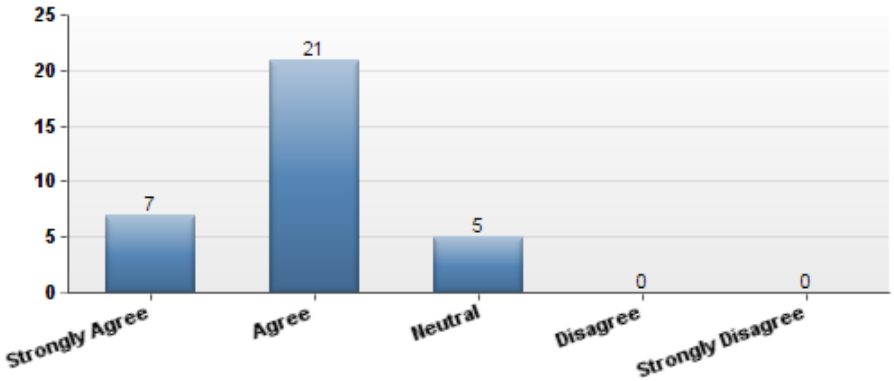
Figure 2. Confidence in Knowledge base:



Desire for educational opportunities. The participants were asked about their desire for more educational opportunities regarding the administration of preoperative non-opioid

medications (acetaminophen, clonidine and gabapentin) for the management of postoperative pain in LC patients (survey question 9). 85% (strongly agree, n=7; agree, n=21) expressed a desire for more education regarding these medications. 15% (n=5) of participants were neutral and none responded disagree or strongly disagree. The mean and standard deviation (1.94 and 0.61) indicated that average participant desired more education regarding the use of acetaminophen, clonidine and gabapentin preoperatively for LC patients, see Figure 3.

Figure 3. Desire for Education:



Specific knowledge about preoperative non-opioid medications. In order to evaluate the participants' knowledge about the individual medications, they were asked about their familiarity with side effects, indications, and possible anesthetic implications (survey questions 14-16), see Figure 4.

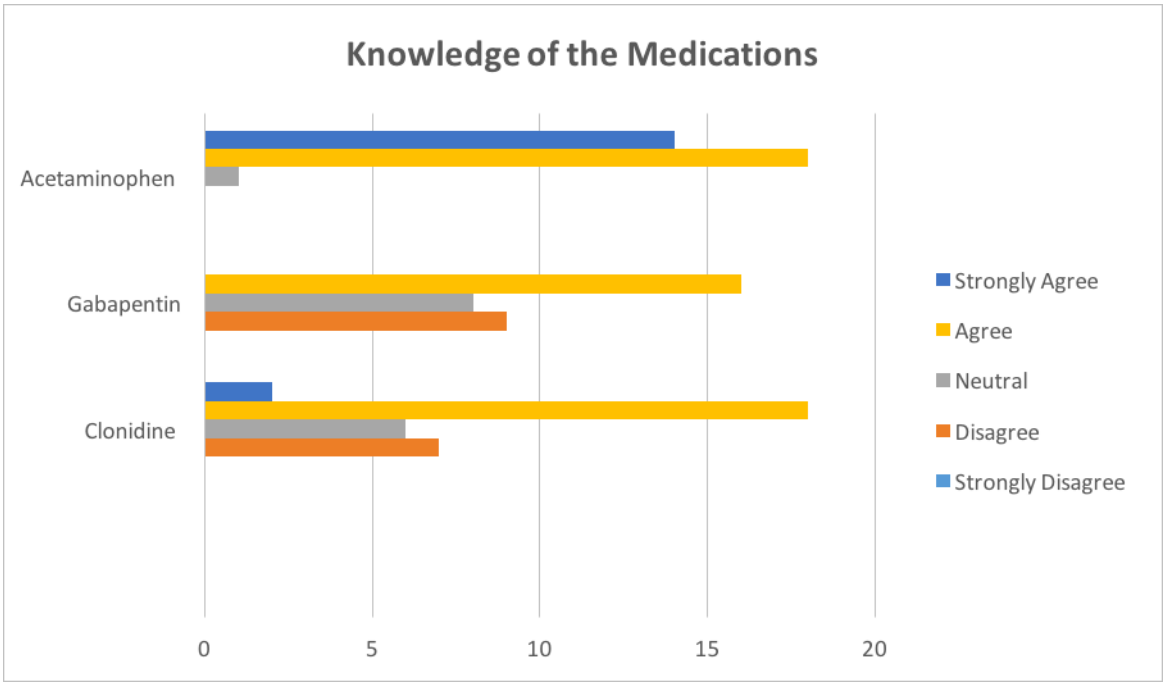
Regarding acetaminophen, 97% (strongly agree, n=14; agree, n=18) of participants indicated familiarity, 3% (n=1) were neutral with the side effects, indications, and possible anesthetic implications. None of the participants indicated unfamiliarity with the medication. The mean value for the knowledge base of acetaminophen was 1.61/5 with a SD of 0.56, which suggested that average anesthesia provider was strongly familiar with this medication.

Regarding clonidine, 61% of participants indicated familiarity (strongly agree, n=2; agree, n=18), 18% were neutral (n=6), and 21% were unfamiliar (disagree, n=7; strongly disagree, n=0) with the side effects, indications and anesthetic implications. The mean value for the knowledge base of clonidine was 2.55/5 with a SD of 0.90, which suggested that average participant felt neutral or familiar with the drug.

Regarding gabapentin, 49% (agree, n=16) of participants indicated familiarity, 24% were neutral (n=8), and 27% were unfamiliar (disagree, n=9; strongly disagree, n=0) with the side effects, indications, and anesthetic implications. The mean value for the knowledge base of gabapentin was 2.79/5 with a SD of 0.86, which suggested that average anesthesia provider felt neutral or familiar with the drug.

From this data, it can be concluded that, while anesthesia providers' level of knowledge regarding acetaminophen was strong, this was not the case for clonidine and gabapentin.

Figure 4. Knowledge of the Medications



Attitude of Anesthesia Providers

In order to assess the participants' attitude about preoperative administration of non-opioid medications for the purpose of postoperative pain management, they were asked to indicate their impression of acetaminophen, clonidine and gabapentin (collectively) in having a positive impact on surgical outcomes, postoperative pain and overall patient outcomes in LC patients (survey questions 10-12). The five-point Likert scale ranging from 1= strongly agree to 5 = strongly disagree was used to measure attitudes, see Figure 5.

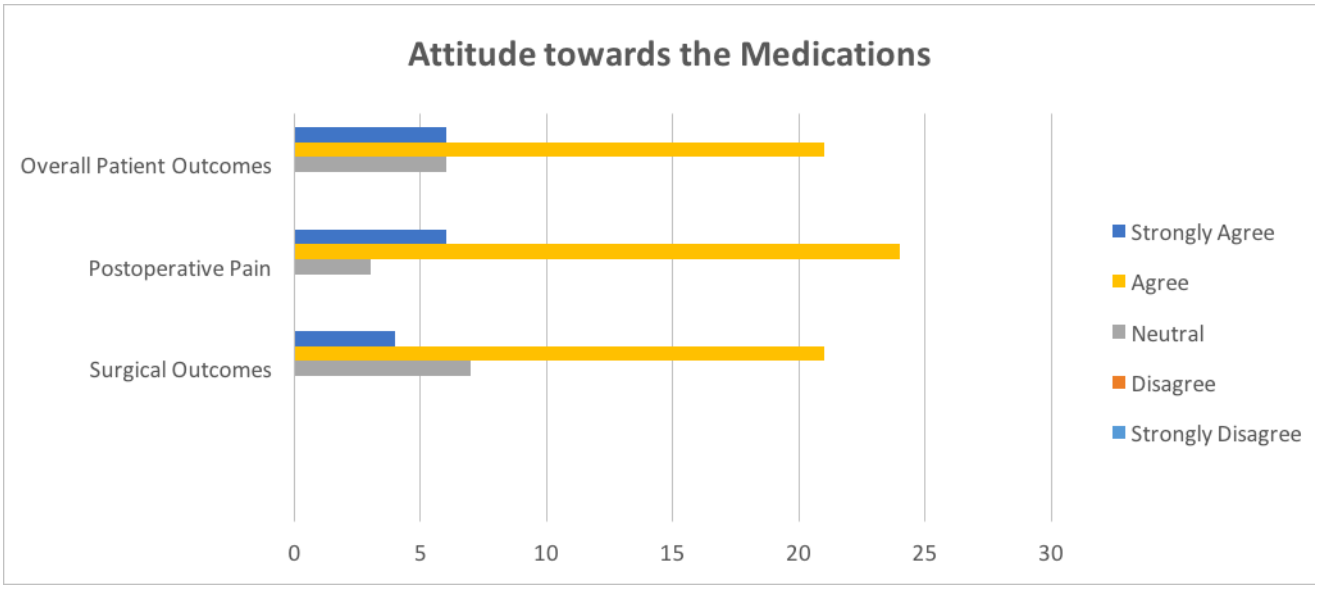
The participants were asked about the use of acetaminophen, clonidine and gabapentin for positive surgical outcomes (survey question 10). 79% of participants (strongly agree, n=4; agree, n=21) expressed that these medications had positive surgical outcomes; 22% (n=7) of participants were neutral. None of the participants expressed a negative attitude. The mean and standard deviation (2.09, 0.59) indicated that on average the participants agreed that the medications had a positive impact on surgical outcomes by helping manage postoperative pain in LC patients.

The participants were asked about the use of acetaminophen, clonidine and gabapentin for postoperative pain management (survey questions 11). 91% (strongly agree, n=6; agree, n=24) of participants indicated the medications had a positive impact on postoperative pain; 9% (n=3) felt neutral. None of the participants expressed a negative attitude. The mean and standard deviation (1.91, 0.52) indicated that on average the participants agreed that the medications had a positive impact on postoperative pain mangment in LC patients.

The participants were asked about the use of acetaminophen, clonidine and gabapentin on overall patients outcomes (survey question 12). 82% (strongly agree, n=6; agree, n=21) of participants indicated the medications had positive overall patient outcomes, and 18% (n=6) felt

neutral. None of the participants expressed a negative attitude. The mean and standard deviation (2.00, 0.61) indicated that the on average the participants agreed that the medications had a positive overall outcome for LC patients.

Figure 5. Attitude towards the Medications



The anesthesia providers were asked whether they would consider using acetaminophen, clonidine and gabapentin (collectively) preoperatively specifically for LC patients (survey question 13). 88% (strongly agree, n=8; agree, n=21) expressed they would consider doing so, and 12% (n=4) participants felt neutral. None of the participants indicated negatively. The mean and standard deviation (1.88, 0.60) indicated that on average the participants agreed to consider the preoperative administration of acetaminophen, clonidine and gabapentin for LC patients.

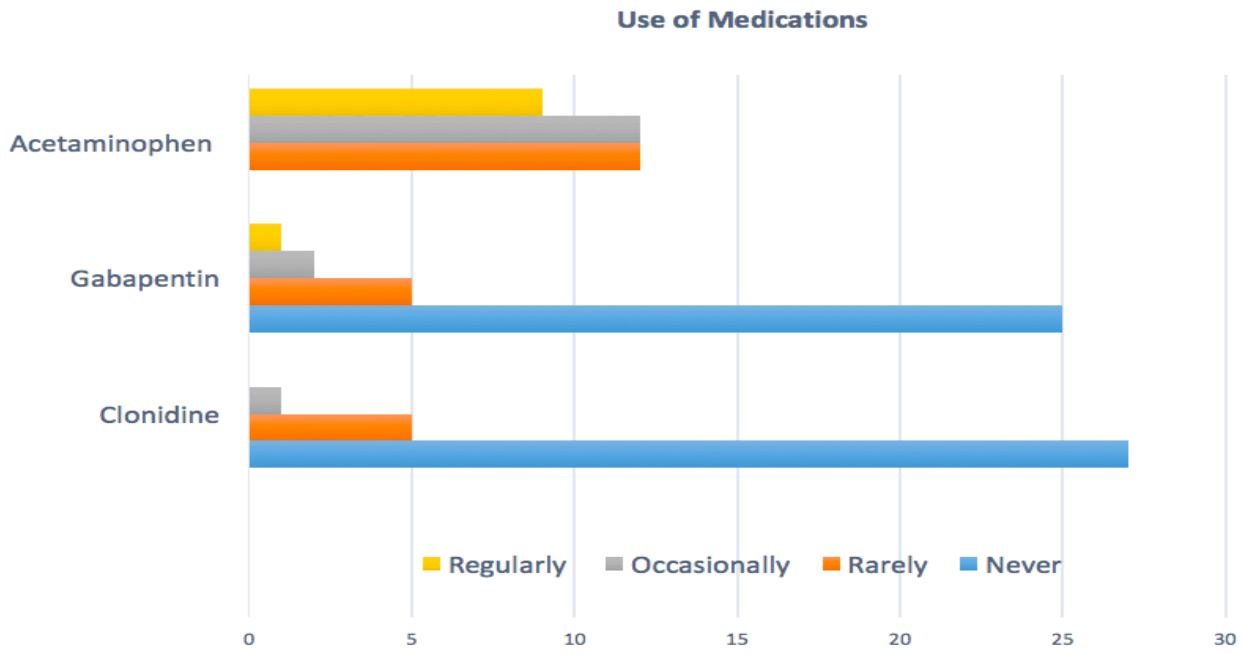
In order to assess the anesthesia providers' attitude about the preoperative use of non-opioid medications, the participants were then asked about the use of each of the specific non-opioid medications, individually (acetaminophen, clonidine and gabapentin) (survey questions 17-19). The four-point Likert scale ranging from 1=regularly, 2=occasionally, 3=rarely, 4= never, was used in this section, see Figure 6.

Regarding acetaminophen, 63% (regularly, n=9; occasionally, n=12) of participants used this medication for postoperative pain management in patients undergoing LC; 36% (n=12) reported rarely doing so. None of the participants reported never using the medication. The mean and standard deviation (2.09, 0.80) suggested that the average participant occasionally used preoperative acetaminophen for postoperative pain management in LC patients.

Regarding clonidine, 3% (n=1) of participants occasionally used this medication for postoperative pain management in patients undergoing LC; 97% (rarely, n=5; never, n=27) of the participants tend not to use the medication. None of the participants indicated they regularly used it. The mean and standard deviation (3.79, 0.48) suggested that the average participant rarely or never used preoperative clonidine for postoperative pain management in LC patients.

Regarding gabapentin, 9% (regularly, n=1; occasionally, n=2) of participants used this medication for postoperative pain management in patients undergoing LC; 91% (rarely, n=5; never, n=25) tended not to use the medication. The mean and standard deviation (3.64, 0.74) suggested that the average participant rarely or never used preoperative gabapentin for postoperative pain management in LC patients.

Figure 6. Use of Medications



Recommendation of Administration

Participants were asked if they recommended or discouraged the administration of acetaminophen, clonidine and gabapentin preoperatively for the management of postoperative pain in LC patients (survey questions 20-21). 48% of participants regularly (n=3) or occasionally (n=13) recommend administration of these non-opioid medications preoperatively, while 52% of participants would rarely (n=10) or never (n=7) do so. The mean and standard deviation (2.64, SD 0.93) suggested that the average participant rarely to occasionally recommended the use of these medications preoperatively.

On the other hand, 97% of participants stated they would never (n=23) or rarely (n=9) discourage the administration of these medications, and only 3% of participants would occasionally (n=1) discourage the administration. The mean and standard deviation (3.67, 0.54) suggested that the average participant rarely to never discouraged the use of these medications.

Association between Knowledge and Use of Acetaminophen, Clonidine & Gabapentin

The mean scores of the knowledge and use of acetaminophen, clonidine and gabapentin are represented in Table 4. Anesthesia providers' indicated a strong knowledge base for the use of acetaminophen and also reported higher use of acetaminophen preoperatively. Conversely, providers felt neutral or agreed to have a familiarity with the side effects, indications, and anesthetic implications of the clonidine and gabapentin, and likewise reported lower use of these medications preoperatively for LC patients.

Table 4. Knowledge and Use of Medications:

N = 33	Knowledge of Medication	Use of Medication
	Mean	*Mean*
Clonidine	2.55	3.79
Gabapentin	2.79	3.64
Acetaminophen	1.61	2.09

Knowledge and Attitude related to Demographics

The fisher exact test was used as an alternative to the chi-square test because of the small sample size. This yielded a more accurate test compared to the chi-square test for the knowledge and attitude survey results. The demographic variables assessed in this section included gender (male, female), provider type (anesthesiologist, CRNA), years of experience (1-15, ≥16), and age (20-49, ≥50). Because of the small sample size, the years of experience and age categories were collated into two sub-sets each.

Knowledge. The age, gender, provider type, and years of experience did not have a statistically significant association with the knowledge of clonidine, gabapentin and acetaminophen.

Attitude. The t-test was used to determine the differences in participants' attitudes based on demographic variables. For age, participants in the ≥50 years age group scored significantly higher than the participants between the ages of 20-49 ($t=2.25$, $df=28$, $P=.032$); however, the

mean difference of 3.1/5 (SD 3.8) for ≥50 age group was similar to the the mean for the ages of 20-49 age group of 3.1/5 (SD 3.75).

Regarding experience, participants with ≥16 years in practice were significantly more likely to have a positive attitude towards using the medications preoperatively than participants with 1-15 years of experience (t=2.65, df=28, P=.013)

With regard to role of the participant, anesthesiologists had a more positive attitude about the use of the medications than CRNAs and this was near statistical significance (t=-1.96, df=28, P=0.06). There was no statistical correlation between demographics and gender.

Chapter 5 Discussion

Pain relief after CL is an issue of great importance, as inadequately managed postoperative pain results in a wide variety of negative outcomes, including impaired ventilation, adverse hemodynamic responses, poor wound healing, and delayed patient discharge from the hospital (Harsoor, 2011). It is the duty of anesthesia providers to care for these patients and attempt to reduce postoperative pain safely and effectively. A multimodal approach, including non-opioid medications started in the preoperative period appears to be a key strategy to decrease postoperative pain and decrease overall opioid consumption (Smith, 2011). Three non-opioid medications have been employed for preoperative use for the management of postoperative pain: acetaminophen, clonidine and gabapentin.

A survey was sent to evaluate NSUHS anesthesia providers' knowledge and attitude regarding the use of these non-opioids in the preoperative setting for the treatment of postoperative pain in LC patients. 73% of the surveys were completed by CRNAs and 26% of the surveys were completed by anesthesiologists. The participants' responses indicated that they lacked knowledge regarding the clonidine and gabapentin; 85% indicated that they desired

educational opportunities on the topic, 15 % were neutral, and no one indicated that they did not desire additional education. Overwhelmingly, the results showed that participants had a positive attitude towards the use of the medications preoperatively, indicating that they understood its usefulness in contributing to positive patient outcomes.

When asked about the three medications, collectively, only 48% of anesthesia providers reported confidence in their knowledge base regarding their use for the management of postoperative pain in LC patients. As noted in the Temple study (2005), lack of education and limited familiarity with the substances resulted in decreased usage. This may explain why only 50% of anesthesia providers routinely ordered non-opioid pain medications preoperatively for postoperative pain management.

When asked about each medication, separately, providers reported strong knowledge regarding acetaminophen and higher use of acetaminophen. They reported lower knowledge of clonidine and gabapentin and, correspondingly, lower use of these medications. The investigator's results mirrored Temple's results, indicating that knowledge of the medication is positively correlated with use, and lends credibility to the idea that an educational module created specifically to improve the knowledge of the anesthesia providers towards the use of clonidine and gabapentin in LC patients would be beneficial in increasing preoperative non-opioid medication use.

The study's small sample size precluded the ability to draw strong conclusions about knowledge base or use for specific sub-populations. Using the fisher exact test given the limited sample size, the study found no correlation between anesthesia providers' gender, age, type of provider (CRNA vs anesthesiologist) and experience on their knowledge of preoperative non-opioid analgesic agents including clonidine, gabapentin and acetaminophen.

A statistically significant relationship was found between the anesthesia providers' age and attitude towards the medications was found: anesthesia providers over 50 years old had a more positive attitude towards the use of the medications in the preoperative setting compared to younger providers (ages 20-49). This relationship can be due to the lack of knowledge and years of experience. The older providers, tended to have more experience and knowledge which could be the reason for the positive attitude. There was also a (highly related) statistical significance between attitude and years of experience: providers with more than 16 years of experience showed a more positive attitude about preoperative medications.

There was near significance when analyzing anesthesia provider type, as anesthesiologists were more likely to have positive attitudes towards the use of the preoperative non-opioid medications than CRNAs. Interesting to note, in evaluating "routine" practices among the group, anesthesiologists were more frequently indicated to be responsible for planning and discussing postoperative pain management with the patients. The difference in attitude towards the use of the medications preoperatively may be explained by the inherent challenges associated with the CRNA/anesthesiologist supervisory nature, including "diffusion of responsibility". Diffusion of responsibility in this case may find the CRNA relinquishing responsibility, expecting the anesthesiologist to take the lead role, (Falke, Lawson, Pandit, & Patrick, 2015).

The findings indicated that an educational module must focus more specifically towards younger anesthesia providers, newer anesthesia providers, and CRNAs to improve their knowledge base and their comfort with the use of the non-opioid medications in the preoperative setting. Additionally, the findings indicated that the module should focus on clonidine and gabapentin, as the providers indicated knowledge and use of acetaminophen.

Educational Module

The educational module was created based on the assessment needs of the participants. The results indicated there was a gap in the knowledge of anesthesia providers about the use of clonidine and gabapentin preoperatively in LC patients; despite the clear potential benefits that are identified in current literature.

While different learning styles of the target audience was considered, the educational module was created in a one-page word document in order to deliver clear and concise information to anesthesia providers. It contains information about clonidine and gabapentin. The information included in the module contains: the mechanism of action, causes of the medications, dose range, most common dose range, the authors recommendation of dose, timing, benefits, side effects and anesthetic considerations. The articles used were by Blaudszun et al., 2012 and Kong et al., 2007. These articles were described above in the literature review and if further information is desired, the reader can refer to PubMed.

The educational module may be distributed to the target audience individually and placed on the intranet for easy access. High level evidence, in the form of systematic review and meta analysis, were chosen as references. The format of the module was a summary of the research articles, highlighting the medications' mechanism of action, dose ranges, usual dose, frequency and timing, side effects and anesthetic considerations. The medications were presented side by side. The module was created to increase awareness of the two medications for the use in LC patients.

Limitations

A limitation of this study was its small sample size. This limited the ability to examine specific relationships amongst sub-groups and resulted in a small power to the study. A larger sample size might have better guaranteed that the educational module was generalizable to the other anesthesia departments. Because the target population only consisted of one employer (NorthShore University HealthSystem), the results may not be generalizable to other organizations.

The anesthesia providers were asked to stratify their knowledge on a Likert scale based survey, which could have created an inherent bias just as any other survey. Anesthesia providers may not have provided accurate answers resulting in an inaccurate educational module. Thus, conducting in-depth interviews with anesthesia providers would be an appropriate method to provide insight into the educational module. However, the data on the educational module would still have a benefit.

Direction for Future Research

Implementation. Implementation of the educational module should begin with a discussion with the Chair of the Anesthesia Department and the Chief CRNA in order to plan for optimal dissemination among the group. Face to face presentations would be scheduled and announced to the group for the purpose of introducing the educational module and allowing for a question and answer session. Following that, the educational module would be placed and posted in strategic places to serve as a reference guide. Suggested places include the break rooms, individual interoffice mailboxes, laminated and secured to each anesthesia Pyxis machine. Ideally, the educational module would be place on EasyCall, the intranet/paging system utilized by NSUHS for easy access).

Evaluation. In order to evaluate if the educational module resulted in a change in practice, various evaluations may be conducted. First, at approximately six months after dissemination of the module, a survey could be distributed to the group asking about their use of gabapentin and clonidine preoperatively for postoperative pain in LC patients. At one-year post dissemination of the module, a retrospective study could be performed to evaluate the use of preoperative gabapentin and clonidine in LC patients. This may pave the way to a randomized control trial to truly evaluate the efficacy of the use of preoperative non-opioid medications directly in LC patients.)

Chapter 6 Conclusion

This study designed to evaluate the knowledge and attitude of anesthesia providers at NSUHS about the preoperative use of the three non-opioid medications, acetaminophen, clonidine and gabapentin, for the management of postoperative pain in LC patients. The results from this study revealed that many anesthesia providers did not routinely use these medications preoperatively for the management of pain after laparoscopic cholecystectomy due to lack of knowledge and negative attitudes. Additionally, younger anesthesia providers and CRNAs had a less favorable attitude towards the use of the medication preoperatively, than their counterparts. Less favorable attitudes may stem from lack of education regarding the use of acetaminophen, clonidine and gabapentin preoperatively. Based on the survey results, an educational module was created to increase the knowledge of the medications, as well as raise awareness for the use of the medications preoperatively for the management of postoperative pain in laparoscopic cholecystectomy patients.

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Appendix A

Survey

Preoperative Non-opioid Medications for the Management of Postoperative Pain: Knowledge and Attitude Survey

Section 1. Demographic Questions

What is your age?

a. 20-29

b. 30-39

c. 40-49

d. 50-59

e. >59

What is your gender?

a. male

b. female

What is your role (job title)?

a. Anesthesiologist

b. CRNA

How many years have you been practicing anesthesia in this role?

a. 1-3

b. 4-6

c. 7-10

d. 11-15

e. 16-20

f. >20

Who is <u>usually</u> responsible for obtaining preoperative anesthetic evaluations at NorthShore University HealthSystem? (Please choose all that apply)

a. Anesthesiologist

b. CRNA

c. Other, please explain_____

Who is <u>usually</u> responsible for for planning/discussing postoperative pain management with the patient? (Please choose all that apply)

a. Anesthesiologist

b. CRNA

c. Other, please explain_____

How often do you order non-opioid medications preoperatively for the management of postoperative surgical pain?

REGULARLY	OCCASIONALLY	RARELY	NEVER

Section 2. Knowledge and Attitudes

Directions: Please answer the following questions designed to assess your knowledge and attitude regarding the use of non-opioid medications preoperatively for the management of postoperative pain in patients undergoing laparoscopic cholecystectomy.
Answer the following questions on a scale of 0 = Strongly Disagree to 5 = Strongly Agree.

I feel confident in my knowledge base regarding the administration of non-opioid medications preoperatively (specifically, clonidine, gabapentin, and acetaminophen) for the management of postoperative pain in patients undergoing laparoscopic cholecystectomy.

Strongly Disagree 1	2	3	4	Strongly Agree 5
○	○	○	○	○

I would like more educational opportunities regarding the administration of non-opioid medications preoperatively (specifically, clonidine, gabapentin, and acetaminophen) for the management of postoperative pain in patients undergoing laparoscopic cholecystectomy.

Strongly Disagree 1	2	3	4	Strongly Agree 5
○	○	○	○	○

Administration of non-opioid medications preoperatively (specifically, clonidine, gabapentin, and acetaminophen) for the management of postoperative pain in patients undergoing laparoscopic cholecystectomy **CAN** have a positive impact on ***surgical outcomes***.

Strongly Disagree 1	2	3	4	Strongly Agree 5
○	○	○	○	○

Administration of non-opioid medications preoperatively (specifically, clonidine, gabapentin, and acetaminophen) for the management of postoperative pain in patients undergoing laparoscopic cholecystectomy **CAN** have a positive impact on ***postoperative pain.***

Strongly Disagree 1	2	3	4	Strongly Agree 5
○	○	○	○	○

Administration of non-opioid medications preoperatively (specifically, clonidine, gabapentin, and acetaminophen) for the management of postoperative pain in patients undergoing laparoscopic cholecystectomy **CAN** have a positive impact on ***overall patient outcomes.***

Strongly Disagree 1	2	3	4	Strongly Agree 5
○	○	○	○	○

Administration of non-opioid medications preoperatively (specifically, clonidine, gabapentin, and acetaminophen) for the management of postoperative pain should be considered for patients undergoing laparoscopic cholecystectomy.

Strongly Disagree 1	2	3	4	Strongly Agree 5
○	○	○	○	○

Please apply the following statement to the next three questions.
I am familiar with the indications, side effects, and possible anesthetic implications of the following non-opioid medications.

Clonidine

Strongly Disagree 1	2	3	4	Strongly Agree 5
○	○	○	○	○

Gabapentin

Strongly Disagree 1	2	3	4	Strongly Agree 5
○	○	○	○	○

Acetaminophen

Strongly Disagree 1	2	3	4	Strongly Agree 5
○	○	○	○	○

Please answer the remaining questions using the scale: Regularly, Occasionally, Rarely & Never.

Apply the following statement to the next three questions:
I personally use the following non-opioid medications preoperatively for the management of postoperative pain in patients undergoing laparoscopic cholecystectomy:

Clonidine

REGULARLY	OCCASIONALLY	RARELY	NEVER

Gabapentin

REGULARLY	OCCASIONALLY	RARELY	NEVER

Acetaminophen

REGULARLY	OCCASIONALLY	RARELY	NEVER

I ***recommend*** the administration of non-opioid medications preoperatively (specifically, clonidine, gabapentin, and acetaminophen) for the management of postoperative pain in patients undergoing laparoscopic cholecystectomy to others.

REGULARLY	OCCASIONALLY	RARELY	NEVER

I ***discourage*** the administration of non-opioid medications preoperatively (specifically, clonidine, gabapentin, and acetaminophen) for the management of postoperative pain in patients undergoing laparoscopic cholecystectomy.

REGULARLY	OCCASIONALLY	RARELY	NEVER

Appendix B

IRB Approvals

NorthShore
University HealthSystem
Research Institute

1001 University Place
Evanston, Illinois 60201
www.northshore.org
Phone (224) 364-7100
Fax (847) 570-8011

November 19, 2015

Pooja Mehta, R.N., B.S.N.
Department of School of Nurse Anesthesia
NorthShore University Health System
2650 Ridge Avenue
Evanston, IL 60201

Re: EH15-384: Mehta, Pooja R.N., B.S.N.: Preoperative non-opioid Medications for the Management of Postoperative Pain: Creation of an Educational Model Based on the Knowledge and Attitudes of Anesthesia Providers

Revision #1 dated October 25, 2015

Dear Ms. Mehta:

The Research Institute received your request for a revision of the above-referenced research protocol on 10/25/2015. The revision has been reviewed in the Research Institute and by a member of the Institutional Review Board (IRB) of NorthShore University HealthSystem. The above referenced revision qualifies for expedited review because the changes to the recruitment and information sheet do not change the risk of the study.

The revision was approved by expedited review in accordance with the Code of Federal Regulations (45 CFR 46 - as revised and 21 CFR 50, 56, as applicable) on the date of this letter. The NorthShore University HealthSystem Institutional Review Board has an approved assurance of compliance with OHRP which covers this activity (Federal Wide Assurance: FWA00003000).

It is noted that this amendment did not require a change in the consent form.

Sincerely yours,

Izabela Wozniak, Pharm.D.
Vice-Chair, Institutional Review Board

/dyc

cc: Mary M. Keegan, R.N.
Robert Stanton, J.D.
Susan Krawczyk, CRNA, DNP

DEPAUL
UNIVERSITY

Office of Research Services
Institutional Review Board
1 East Jackson Boulevard
Chicago, Illinois 60604-2201
312-362-7593
Fax: 312-362-7574

Research Involving Human Subjects

NOTICE OF INSTITUTIONAL REVIEW BOARD ACTION

To: Pooja Mehta, RN, BSN, Graduate Student, School of Nursing

Date: October 20, 2015

Re: Research Protocol # PM092115NUR
"Preoperative Non-opioid Medications for the Management of Postoperative Pain: Creation of an Educational Module based on the Knowledge and Attitudes of Anesthesia Providers"

Please review the following important information about the review of your proposed research activity.

Review Details
This submission is an initial submission.

Your research project meets the criteria for Exempt review under 45 CFR 46.101 under the following category:

> *(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:*
> *(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.*

Approval Details
Your research was originally reviewed on October 2, 2015 and revisions were requested. The revisions you submitted on October 19, 2015 were reviewed and approved on October 20, 2015.

Number of approved participants: 117 Total
You should not exceed this total number of subjects without prospectively submitting an amendment to the IRB requesting an increase in subject number.

Funding Source: 1) None.

Approved Performance sites: 1) DePaul University; 2) NorthShore University Health System.

Reminders
- Under DePaul's current institutional policy governing human research, research projects that meet the criteria for an exemption determination may receive administrative review by the Office of Research

Services Research Protections staff. Once projects are determined to be exempt, the researcher is free to begin the work and is not required to submit an annual update (continuing review). As your project has been determined to be exempt, your primary obligation moving forward is to resubmit your research materials for review and classification/approval when making changes to the research, but before the changes are implemented in the research. **All changes to the research must be reviewed and approved by the IRB or Office of Research Services staff.** Changes requiring approval include, but are not limited to, changes in the design or focus of the research project, revisions to the information sheet for participants, addition of new measures or instruments, increasing the subject number, and any change to the research that might alter the exemption status (either add additional exemption categories or make the research no longer eligible for an exemption determination).

- **Once the project is complete, you should submit a final closure report to the IRB.**

The Office of Research Services would like to thank you for your efforts and cooperation and wishes you the best of luck on your research. If you have any questions, please contact me by telephone at (312) 362-6168 or via email at jbloom8@depaul.edu.

For the Board,

Jessica Bloom

Jessica Bloom, MPH
Research Protections Coordinator
Office of Research Services

Cc: Susan Krawczyk, CRNA, DNP, Faculty, School of Nursing

Appendix C

Recruitment email

Dear anesthesia providers.

My name is Pooja Mehta, RN, BSN. I am a doctoral student at DePaul University and the NorthShore University HealthSystem School of Nurse Anesthesia. You are receiving this email to ask for your participation in my doctoral project. Participation in this survey includes the following criteria: licensed and employed anesthesia providers at NorthShore University HealthSystem who are providing anesthesia to laparoscopic cholecystectomy patients. The study will include attending physicians, both MD and DO, that have anywhere from 1-30 years of post-residency training. Certified Registered Certified Nurse Anesthetists (CRNA) will also be present with anywhere from 1-30 years of postgraduate experience.

The goal of this survey is to determine your knowledge and attitude about the use of preoperative, non-opioid analgesics in laparoscopic cholecystectomy patients. Your time is valuable, and this survey will take less than 10 minutes to complete. Attached is an information sheet describing the voluntary and anonymous nature of this survey. Completion of the survey implies voluntary agreement to participate in the survey. Your input is greatly appreciated and I thank you in advance for your participation.

If you have questions about this study please contact Pooja Mehta at pnmehta1128@gmail.com or 562-818-7484.

Again thank you in advance for your time and participation.

Survey Website: https://depaul.qualtrics.com/ControlPanel/

Pooja Mehta, RN BSN
NorthShore University HealthSystem
School of Nurse Anesthesia

Appendix D

Information Sheet for Participation

INFORMATION SHEET FOR PARTICIPATION IN RESEARCH STUDY

THE ATTITUDE AND KNOWLEDGE OF ANESTHESIA PROVIDERS ABOUT NON-OPIOID PREOPERATIVE PAIN MEDICATIONS FOR LAPAROSCOPIC CHOLECYSTECOMY PATIENTS

Principal Investigator: Pooja N Mehta, RN BSN

Institution: DePaul University, USA

Faculty Advisor: Susan Krawczyk, CRNA, DNP. Faculty NorthShore University HealthSystem

Collaborators: Julia Feczko, DNP, CRNA. Staff NorthShore University HealthSystem
Young-Me Lee, PhD, RN. Assistant Professor DePaul University

I am conducting a research study, because I am trying to learn more about the knowledge and attitude of anesthesia providers about the preoperative use of the three different non-opioid medications: clonidine, gabapentin, and acetaminophen for the management of postoperative pain in laparoscopic cholecystectomy patients. I am asking you to participate in the research because you are a licensed and employed anesthesia provider, working at NorthShore University HealthSystem, and provide anesthesia to laparoscopic cholecystectomy patients. You are included if you are an attending physicians, both MD and DO, that have anywhere from 1-30 years of post-residency training. Certified Registered Certified Nurse Anesthetists (CRNA) will also be present with anywhere from 1-30 years of postgraduate experience.

If you agree to be in this study, you will be asked to complete a 10 minute anonymous survey. The survey will include demographic questions along with questions about preoperative pain management in laparoscopic cholecystectomy patients. The survey includes questions about clonidine, gabapentin, and acetaminophen. I will also collect some personal information about you such as your title, gender, age group, and number of years practicing anesthesia. If there is a question you do not want to answer, you may skip it.

This study will take about 10 minutes of your time. Research data collected from you will be anonymous.

Your participation is voluntary, which means you can choose not to participate. There will be no negative consequences if you decide not to participate or change your mind later after you begin the study. You can withdraw your participation at any time prior to submitting your survey. If you change your mind later while answering the survey, you may simply exit the survey. Once you submit your responses, I will be unable to remove your data later from the study because all data is anonymous and I will not know which data belongs to you. Your decision whether or not to be in the research will not affect your employment at NorthShore University HealthSystem

You must be age 18 or older to be in this study. This study is not approved for the enrollment of people under the age of 18

If you have questions, concerns, or complaints about this study or you want to get additional information or provide input about this research, please contact Pooja N Mehta, RN BSN at 562-818-7484 or email at pnmehta1128@gmail.com

If you have questions about your rights as a research subject you may contact Susan Loess-Perez, DePaul University's Director of Research Compliance, in the Office of Research Services at 312-362-7593 or by email at sloesspe@depaul.edu. You may also contact DePaul's Office of Research Services if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.

Appendix E

CITI & FCOI certifications

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COURSEWORK REQUIREMENTS REPORT*

* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- **Name:** Pooja Mehta (ID: 4560032)
- **Email:** pnmehta1128@gmail.com
- **Institution Affiliation:** DePaul University (ID: 1435)
- **Phone:** 847-570-1958

- **Curriculum Group:** Students
- **Course Learner Group:** Students - Class projects
- **Stage:** Stage 1 - Basic Course

- **Report ID:** 14806156
- **Completion Date:** 12/18/2014
- **Expiration Date:** 12/17/2017
- **Minimum Passing:** 80
- **Reported Score*:** 93

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
Students in Research	12/18/14	9/10 (90%)
History and Ethical Principles - SBE	12/18/14	5/5 (100%)
Defining Research with Human Subjects - SBE	12/18/14	5/5 (100%)
The Federal Regulations - SBE	12/18/14	5/5 (100%)
Assessing Risk - SBE	12/18/14	4/5 (80%)
Informed Consent - SBE	12/18/14	4/5 (80%)
Privacy and Confidentiality - SBE	12/18/14	5/5 (100%)
Conflicts of Interest in Research Involving Human Subjects	12/18/14	5/5 (100%)
DePaul University	12/18/14	No Quiz

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

CITI Program
Email: citisupport@miami.edu
Phone: 305-243-7970
Web: https://www.citiprogram.org

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COURSEWORK TRANSCRIPT REPORT**

** NOTE: Scores on this Transcript Report reflect the most current quiz completions, including quizzes on optional (supplemental) elements of the course. See list below for details. See separate Requirements Report for the reported scores at the time all requirements for the course were met.

- **Name:** Pooja Mehta (ID: 4560032)
- **Email:** pnmehta1128@gmail.com
- **Institution Affiliation:** DePaul University (ID: 1435)
- **Phone:** 847-570-1958

- **Curriculum Group:** Students
- **Course Learner Group:** Students - Class projects
- **Stage:** Stage 1 - Basic Course

- **Report ID:** 14806156
- **Report Date:** 12/18/2014
- **Current Score**:** 93

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
Students in Research	12/18/14	9/10 (90%)
History and Ethical Principles - SBE	12/18/14	5/5 (100%)
Defining Research with Human Subjects - SBE	12/18/14	5/5 (100%)
The Federal Regulations - SBE	12/18/14	5/5 (100%)
Assessing Risk - SBE	12/18/14	4/5 (80%)
Informed Consent - SBE	12/18/14	4/5 (80%)
Privacy and Confidentiality - SBE	12/18/14	5/5 (100%)
Conflicts of Interest in Research Involving Human Subjects	12/18/14	5/5 (100%)
DePaul University	12/18/14	No Quiz

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

CITI Program
Email: citisupport@miami.edu
Phone: 305-243-7970
Web: https://www.citiprogram.org

DevelopU

NorthShore University HealthSystem Learning Portal

This certificate is awarded to

Pooja Mehta

for the successful completion of the course

Financial Conflicts of Interest in Research - 528016

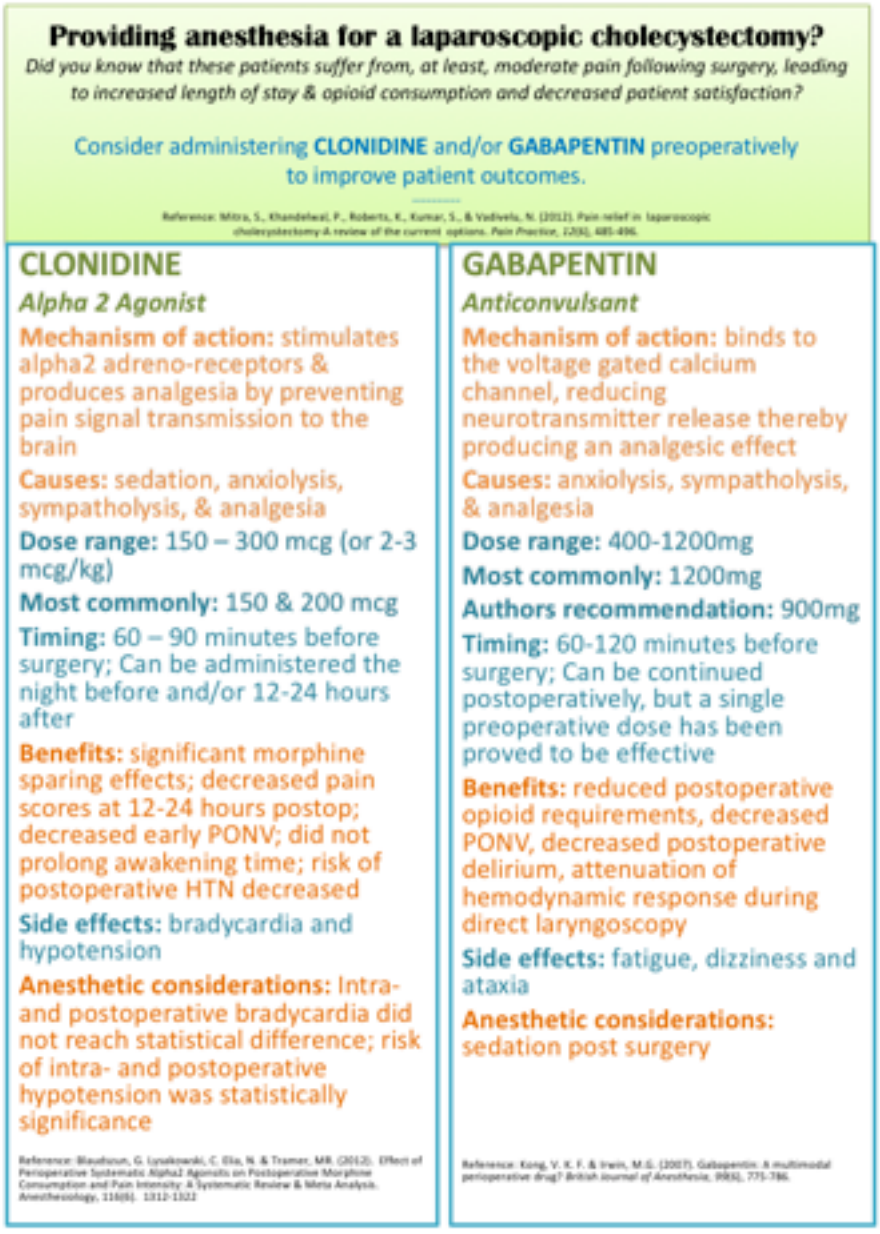
By NorthShore

Date: 12/18/2014

Congratulations from Learning & Development and Epic Training

Appendix F

Educational module



Providing anesthesia for a laparoscopic cholecystectomy?

Did you know that these patients suffer from, at least, moderate pain following surgery, leading to increased length of stay & opioid consumption and decreased patient satisfaction?

Consider administering **CLONIDINE** and/or **GABAPENTIN** preoperatively to improve patient outcomes.

Reference: Mitra, S., Khandelwal, P., Roberts, K., Kumar, S., & Vadivelu, N. (2012). Pain relief in laparoscopic cholecystectomy-A review of the current options. *Pain Practice, 12*(6), 485-496.

CLONIDINE

Alpha 2 Agonist

Mechanism of action: stimulates alpha2 adreno-receptors & produces analgesia by preventing pain signal transmission to the brain

Causes: sedation, anxiolysis, sympatholysis, & analgesia

Dose range: 150 – 300 mcg (or 2-3 mcg/kg)

Most commonly: 150 & 200 mcg

Timing: 60 – 90 minutes before surgery; Can be administered the night before and/or 12-24 hours after

Benefits: significant morphine sparing effects; decreased pain scores at 12-24 hours postop; decreased early PONV; did not prolong awakening time; risk of postoperative HTN decreased

Side effects: bradycardia and hypotension

Anesthetic considerations: Intra- and postoperative bradycardia did not reach statistical difference; risk of intra- and postoperative hypotension was statistically significance

Reference: Blaudoun, G. Lysakowski, C. Elia, N. & Tramer, MR. (2012). Effect of Perioperative Systematic Alpha2 Agonists on Postoperative Morphine Consumption and Pain Intensity: A Systematic Review & Meta Analysis. Anesthesiology, 116(6). 1312-1322

GABAPENTIN

Anticonvulsant

Mechanism of action: binds to the voltage gated calcium channel, reducing neurotransmitter release thereby producing an analgesic effect

Causes: anxiolysis, sympatholysis, & analgesia

Dose range: 400-1200mg

Most commonly: 1200mg

Authors recommendation: 900mg

Timing: 60-120 minutes before surgery; Can be continued postoperatively, but a single preoperative dose has been proved to be effective

Benefits: reduced postoperative opioid requirements, decreased PONV, decreased postoperative delirium, attenuation of hemodynamic response during direct laryngoscopy

Side effects: fatigue, dizziness and ataxia

Anesthetic considerations: sedation post surgery

Reference: Kong, V. K. F. & Irwin, M.G. (2007). Gabapentin: A multimodal perioperative drug? *British Journal of Anesthesia, 99*(6), 775-786.