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Prevention of Postoperative Nausea

Susie Chuites
THE FLORIDA STATE UNIVERSITY

SCHOOL OF NURSING

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SUSIE CHUITES, BSN, RN

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The members of the Committee approve the thesis of Susie Chuites defended on November 3, 2004.

______________________________
Jeanne Flannery
Professor Directing Thesis

______________________________
Denise Tucker
Committee Member

______________________________
Mary Beth Schall
Committee Member

Approved:

______________________________________
Linda Sullivan, Director of Graduate Program

______________________________________
Katherine Mason, Dean, School of Nursing

The Office of Graduate Studies has verified and approved the above named committee members.
This manuscript is dedicated to those who championed and loved me through it all:

To my parents, Kenneth and Charlotte Chuites, whose unconditional love and strength, and eternal belief in me has provided me with the confirmation and determination to pursue my dreams. You have instilled in me the endurance to see life’s opportunities, and the perseverance to reach what, at times, appeared to be unattainable goals.
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ABSTRACT

Nausea and vomiting are common complications of surgery, which are not only unpleasant for the patient, but also increase cost through prolonged hospital stays and additional interventions. Specific risk factors for postoperative nausea and vomiting (PONV) have been identified in the literature. Utilizing the combination of Betty Neuman’s Systems Model (1995) and the physiology of nausea, the nurse is able to identify risk factors and promote primary prevention. One primary intervention for prevention of PONV is administration of a 5-HT3 serotonin receptor antagonist IV intraoperatively. Examination of current use of 5-HT3 blocking agents, particularly, granisetron hydrochloride (Kytril), to prevent PONV in laparoscopic cholecystectomy patients provides a means for evaluation of current practices.

Employing a retrospective, comparative design, a random matched sample was selected from a population of approximately 600 laparoscopic cholecystectomy patients who met inclusionary criteria. The medical records of 46 patients who received a 5-HT3 blocking agent IV intraoperatively and 51 patients who did not, were audited for variables believed to influence the risk and occurrence of PONV. This study revealed that those patients included in the group that received a 5-HT3 blocking agent IV intraoperatively had a lower incidence of PONV than those who did not. However, this difference was so small that the findings are not of statistical significance nor are they of clinical importance.
CHAPTER 1
INTRODUCTION

There is always the assumed risk that complications may arise after surgical procedures. Nausea and vomiting are two common complications reported after surgery. The prevention of postoperative nausea and vomiting (PONV) is believed not only to increase patient satisfaction, but also to provide cost-effective care (Watcha, Bras, Cieslak, & Pennett, 1995). While caring for patients, nurses are responsible for assuring that the needs of patients are recognized and addressed. This is achieved through coordination with other health team members within the health care system (The American Society of Post Anesthesia Nurses, 1992). The interdisciplinary collaboration between the nurse and other health care team members is paramount, as the nurse takes on the role of patient advocate. The nurse has an important role in the assessment of risk factors for PONV, preoperatively. As risk factors are identified, the nurse must communicate findings to the appropriate members of the health care team. Assessing for the presence of nausea and vomiting, postoperatively, provides the nurse with key information. If PONV is reported, rescue antiemetics are administered; the effectiveness of antiemetics are evaluated; and the need for further intervention, if nausea and vomiting are unrelieved, are communicated to the other health care team members (Seidel, Ball, Dains & Benedict, 1999).

Nausea is described as the unpleasant sensation associated with the urge to vomit or awareness of the potential to vomit. When describing nausea, the following terms are commonly used: queasiness, heaviness, pressure, uneasiness, or a sinking feeling in the back of the throat, esophagus, and epigastrium (Kapit, Macey & Meisami, 2000). Diminished gastric tone, reduced peristalsis, duodenal contractions, and reflux of intestinal contents into the stomach are the physiologic changes associated with nausea.
The sensation of nausea is often accompanied by vasomotor changes such as diaphoresis, increased salivation, rhythmic contraction of abdominal muscles, and retching (Jenns, 1994). The occurrence of nausea is often accompanied with, or followed by, vomiting. Retching, labored rhythmic respiratory effort, sometimes, but not always, precedes vomiting. Vomiting is the forceful ejection of liquid or semisolid stomach contents through the mouth (Norris, 1982). This occurs as a result of overdistention, irritation, or overexcitation of the upper gastrointestinal tract (Jenns, 1994).

A variety of factors can lead to the occurrence of nausea and vomiting. For example, surgical patients, having received anesthesia, are at risk for developing PONV, and some surgical procedures have greater risk for PONV than others. Cholecystectomy is an example of a procedure with a high risk. A cholecystectomy is the surgical removal of the gallbladder and is the primary treatment of both acute and chronic cholecystitis. This surgical procedure provides relief from the symptoms associated with this diagnosis, which includes abdominal pain and nausea. There are two approaches to this surgery; they are open cholecystectomy or a laparoscopic cholecystectomy. Approximately 80% of cholecystectomy cases involve using the laparoscopic approach (Wright, 1999). This approach was developed partly to reduce the incidence of PONV, yet it is still one of the most common side effects associated with this surgical procedure, with an occurrence rate of 28 to 83% (Smith, 2000). Approximately 60% of the laparoscopic cholecystectomy surgical procedures performed at the selected hospital are performed on an outpatient basis.

The laparoscopic cholecystectomy, which was developed in 1989, involves the insertion of a long narrow cylinder tube with a camera on the end, through an approximately 1 centimeter incision in the abdomen, which allows visualization of the internal organs and projection of this image onto a video monitor. Three smaller incisions allow for insertion of other instruments to perform the surgical procedure. A laser may be used for the incision and cauterization of any unwanted tissue or to stop bleeding. The laparoscopic approach to this surgery was developed with the intent to reduce postoperative complaints, such as pain, nausea, vomiting, and length of stay (Wright, 1999). The occurrence of PONV increases length of stay, which increases cost and decreases patient satisfaction.
The care received after a laparoscopic cholecystectomy is similar to that of any patient undergoing surgery with general anesthesia. Patients may experience a unique postoperative pain in the right shoulder, which is related to pressure caused by the carbon dioxide used during the procedure through the laparoscopic tubes. Lying on the left side with the right knee and thigh drawn up to the chest may relieve this pain. Also, walking will increase the body’s reabsorption of this gas. Patients who undergo this procedure usually are discharged within the first 24 hours postoperatively (Wright, 1999).

The overall aim for healthcare providers for a surgical patient is to eliminate postoperative complications such as nausea. The prevention and elimination of postoperative nausea reduces the patient’s length of hospital stay, as well as reduces the impact that nausea may have on the patient’s ability to participate in therapy or convert to oral medications (Kovac, 2000). For patients that may already have a long hospital length of stay, at the time of surgery, it is paramount for healthcare providers to prevent nausea and eliminate the need for rescue antiemetics.

In the past, the effective prevention of PONV was not possible. The approval of blocking agents of the serotonin 5-HT3 receptor has produced new approaches to accomplish this objective. Granisetron hydrochloride (Kytril), approved in 1993 by the FDA, is a selective blocking agent of the serotonin 5-HT3 receptor. Studies have indicated that this serotonin receptor is an important link in nausea and vomiting associated with chemotherapy, radiation, and surgical procedures. Serotonin is believed to act on the vagus nerve to trigger nausea and vomiting. Granisetron hydrochloride (Kytril) blocks receptors on the vagus nerve, thereby reducing the occurrence of nausea and vomiting. This medication can be administered either orally or intravenously. Granisetron hydrochloride (Kytril) can cause headache, constipation, weakness, drowsiness, and/or diarrhea. These side effects are manageable and reversible with dose modification or interruption (Nutley, 2002).

Of surgical patients, 30 to 50% experience postoperative nausea and vomiting postoperatively. The actual risk of postoperative nausea and vomiting can depend on various factors, including gender, age, previous history of postoperative nausea and vomiting, motion sickness, smoking status, other medical conditions, length of surgery, surgical site, degree and extent of surgical pain, and opioid and anesthesia use.
Antiemetics used to treat postoperative nausea and vomiting are given after surgery when the patient begins to experience nausea and/or vomiting. These medications are considered “rescue” anitemetetics and provide varying degrees of relief. However, there have been recent studies examining the use and administration of antiemetics while the patient is in the operating room in order to prevent postoperative nausea and vomiting (Nutley, 2002). In a local regional medical center, the use of granisetron hydrochloride (Kytril) IV has been being used to evaluate its effectiveness in eliminating the occurrence of postoperative nausea and vomiting. The medical staff evaluated the effects of administering 0.1mg of granisetron hydrochloride (Kytril) IV as a prophylactic antiemetic (D. Dusenbury, personal communication, September 2003).

Data, provided by this local regional medical center, showed that 44% of all patients who had laparoscopic cholecystectomy reported nausea in the post anesthesia care unit (PACU) requiring additional, or rescue, antiemetic medications. The data also showed that 33% of all patients were nauseated at 2 hours postoperatively, and that 39% of all patients were nauseated at 4 hours postoperatively. Twenty-five percent of patients were given a prophylactic antiemetic intraoperatively, anzemet (another 5-HT3 receptor blocking agent), phenergan (an anhistimine, which blocks naturally occurring histamine chemically), or reglan (which increases the rate at which the stomach empties into the intestines and increases the strength of the lower esophageal sphincter), with half of these patients still requiring additional antiemetics in the PACU (D. Dusenbury, personal communication, September 2003).

Granisetron hydrochloride (Kytril) IV, when given introperatively, offers protection against nausea and vomiting for 24 hours. Past studies have also shown that giving 2 mg of granisetron hydrochloride (Kytril) orally preoperatively, reduces postoperative nausea and vomiting of laparoscopic cholecystectomy patients by 83% (Nutley, 2002).

Problem Statement

Patients frequently list pain, nausea, and vomiting as their most important perioperative concerns. Currently, the overall incidence of PONV is estimated to be 28 to 80%, with severe, intractable PONV estimated to occur in approximately 18% of all
patients undergoing surgery (Nutley, 2002). The risk of PONV, in laparoscopic cholecystectomy patients, can actually be increased by various factors, such as gender, age, and a previous history of PONV. PONV can lead to delayed postanaesthesia care unit (PACU) discharge and unanticipated increased hospital stay, thereby increasing medical costs, not only for the patient, but also for the hospital (Kovac, 2000).

Significance of the Problem

Nausea is an unpleasant sensation associated with the urge to vomit, which is the forceful ejection of liquid or semisolid stomach contents. PONV is dissatisfying for patients and is among the top concerns of anesthesiologists. PONV is experienced, on average, by nearly 50% of all surgical patients. The occurrence of PONV prevents patients from resuming oral intake, increases pain, delays healing, increases hospital length of stay, and increases cost. Today’s limited financial resources for health care make cost a greater issue in the clinical decision making of healthcare providers. The accurate assessment of patient risk factors for PONV is necessary in developing an effective plan of care for this patient population. In order to provide economical and effective care for surgical patients, interventions must be geared towards reducing the occurrence of postoperative complications (Watcha, Bras, Cieslak & Pennett, 1995).

Nurses have the opportunity, performing research, to improve the care patients receive when they undergo surgical procedures. The identification of factors that have the potential to benefit surgical patients, as a result of research, allows nurses to deliver best practice nursing care. Patients who do not receive best practice nursing care run the risk of experiencing adverse events, nausea for example, following surgical procedures (Siedel, Ball, Dains & Benedict, 1999).

The role of the nurse in both preoperative and postoperative assessment for nausea and vomiting is particularly crucial today. Typically, medications used to treat PONV are given after surgery when the patient begins to experience nausea and/or vomiting. Granisetron hydrochloride (Kytril), which is an effective antiemetic, is available for intraoperative use in surgical patients, in order to prevent PONV. The use of this serotonin receptor antagonist has been shown to improve antiemetic effectiveness. However, granisetron hydrochloride (Kytril) is not so completely effective in preventing PONV as it is for chemotherapy-induced nausea and vomiting (Kovac, 2000). Thus, the
indiscriminant use of granisetron hydrochloride (Kytril) in all acute care surgical patients is unnecessary.

Cost of granisetron hydrochloride (Kytril) also prohibits indiscriminant use, making the careful selection of appropriate candidates essential. The prevention of PONV assists in the reduction of a patient’s length of stay in an acute care setting. A shortened hospital stay is financially beneficial for both surgical patients and acute care settings. Patients are able to return to their daily activities, while acute care settings are able to utilize vacant hospital beds for other patients. Thus, when these aspects of savings are considered, one can argue for the use of more expensive antiemetics (Johnstone & Martinec, 1993). When compared to the cost of dolasetron myelate (Anzemet), another 5-HT3 blocking agent, which is $10.47 per dose (12.5 mg IV), granisetron hydrochloride (Kytril) is nine times more expensive, with a cost of $93.50 per dose (1.0 mg IV); (M. McQuone, personal communication, November, 2004). The evaluation of granisetron hydrochloride (Kytril) use and effectiveness is needed in order to justify its cost. Only then, when all aspects of savings have been considered, can one argue for the use of this more expensive medication.

Advanced practice nurses (APN) play an integral role in prevention and treatment of PONV. The APN provides the advanced clinical knowledge necessary for the treatment of surgical patients and postoperative complications. The APN facilitates the appropriate identification of patients at risk for operative complications. They monitor patient dissatisfaction, increased lengths of stay, and high cost of interventions. Patient plans of care are designed by the APN to direct the delivery of patient care with the goal of preventing postoperative complications (Pasero, Gordon & McCaffery, 1999). The APN is compelled to evaluate the effectiveness of all antiemetics in order to provide the most effective care for surgical patients. This is particularly true for antiemetics that have the capacity to prevent such a prevalent postoperative problem. The APN has the responsibility to evaluate the effectiveness of the antiemetics that have the ability to prevent such a prevalent postoperative problem as nausea and vomiting.

Purpose

The purpose of this study is to determine the effectiveness of an intraoperatively administered 5-HT3 serotonin receptor antagonist, particularly, granisetron hydrochloride
(Kytril) IV, on PONV for patients receiving a laparoscopic cholecystectomy. As a consequence of this study, it is the researcher’s hope that acute care facilities will realize the potential postoperative benefits and cost effectiveness of using this medication for laparoscopic cholecystectomy surgical procedures.

Research Questions
To accomplish the purpose of this study, the following questions were asked:

1. What are the demographic characteristics of the patients used for this study?
2. What is the nature of the association between patient demographic variables/risk factors and the onset of PONV?
3. What is the effectiveness of an intraoperatively administered 5-HT3 serotonin receptor antagonist, particularly, granisetron hydrochloride (Kytril), on PONV for patients receiving a laparoscopic cholecystectomy?

Hypothesis
There is only one inferential question in this analysis. It is hypothesized that granisetron hydrochloride (Kytril) IV administered intraoperatively will, in fact, be effective in decreasing the frequency of PONV postoperatively.

Operational Definitions
Operational definitions explain how the variables under investigation are observed and measured within a study (Polit & Hungler, 1999). For the purpose of this study, the following operational definitions were utilized.

Postoperative nausea and vomiting (PONV) Documentation by the nurse in the medical record, in either the Post Anesthesia Care Unit (PACU) Flow Sheet or the Nurses Notes, that the patient experienced nausea and/or vomiting postoperatively.

Risk factors for PONV Those variables documented in the medical record, which, based on previous research, are hypothesized to place the patient at risk for PONV. The following will be collected from the preoperative assessment form:

Age (adults age 18 and older). The patient’s age at the time of surgery will be entered on the Demographic and Postoperative Data Form (DPDF) and this variable will be treated as continuous and interval in scale.
**Body Mass Index (BMI).** A calculation of the patient’s height and weight at the time of surgery. These data will be collected and entered on the DPDF and will be treated as continuous and interval in scale.

**Rescue Antiemetics.** Defined as antiemetics administered to the patient postoperatively for the treatment of nausea and vomiting as documented in the medical record by the nurse on the PACU Flow Sheet or the Nurses Notes. These medications include hydroxyzine (Vistaril), promethazine (Phenergan), prochlorperazine (Compazine), and dolasetron mesylate (Anzemet).

*Granisetron hydrochloride* (Kytril) is a selective 5-Hydroxytryptamine₃ (5-HT₃) receptor antagonist believed to prevent nausea and vomiting by blocking serotonin-induced depolarization of vagal afferent nerves, and possibly binding sites at the chemoreceptor trigger zones (Cerenex pharmaceuticals, 1995). Granisetron hydrochloride (Kytril) is operationally defined as the documentation on the operating room report in the medical record that a patient received granisetron 0.1mg. intravenously.

*Dolasetron mesylate* (Anzemet) is a selective 5-Hydroxytryptamine₃ (5-HT₃) receptor antagonist believed to prevent nausea and vomiting by blocking 5-HT₃ receptors (Cerenex pharmaceuticals, 1995) Dolasetron mesylate (Anzemet) is operationally defined as the documentation on the operating room report in the medical record that a patient received dolasetron 12.5 mg intravenously. For the purpose of this study, patients who received dolasetron mesylate included those who received this medication prophylactically intraoperatively. This researcher also identified patients who received this medication postoperatively as a rescue antiemetic, and this aspect of the management of nausea, using rescue antiemetics, is not part of this study.

**Effect of Intraoperatively administered Granisetron hydrochloride (Kytril)** Defined as the difference in relative frequencies of PONV for the two different groups of patients (those who received granisetron hydrochloride (Kytril) intraoperatively and those who did not).

**Demographic Variables** Demographic variables obtained via medical record review and recorded on the Demographic and Postoperative Data Form (DPDF), which included age, gender, height, and weight.
Theoretical Framework

In order to guide the research process, Betty Neuman’s Systems Model (1995) and the physiology of nausea were selected as the theoretical framework for this study. The effectiveness of a 5-HT3 serotonin receptor antagonist, particularly granisetron hydrochloride (Kytril) IV intraoperatively, was investigated in relation to Neuman’s Systems Model and the physiology of nausea.

The Neuman Systems Model

Betty Neuman’s Systems Model (1995) provides a theoretical framework for this study. This holistic systems model addresses physiological, psychological, sociocultural, developmental, and spiritual aspects of the person as he/she interacts with internal and external environmental stressors (Neuman, 1995). The individual is viewed as an open system composed of a core and surrounding protective rings. The core is the person’s basic survival factors. Examples of these core factors include the ability to regulate body temperature, genetic structure, and organ strength or weakness. According to Neuman, an adaptational level of health for a person is developed over time. She refers to this as the normal line of defense (Sohier, 1997). Factors that may impact the outcomes of laparoscopic cholecystectomy patients, following surgery, include response pattern and organ strength or weakness.

Neuman’s model described mechanisms that protect the individual’s stability when faced with a stressor. The flexible line of defense, a cushioning mechanism, protects the normal line of defense from penetration by stressors. Lines of resistance are internal factors that protect the core from stressors that penetrate the normal line of defense. The lines of resistance ideally decrease stressor reaction, increase client resistance, and allow the client to reconstitute or return to some level of wellness and stability (Sohier, 1997). As Neuman (1995) implied, it is essential to strengthen the flexible line of defense through primary prevention strategies, to promote client wellness by stress prevention through health promotion strategies (Fawcett & Neuman, 2002). Thus, the prophylactic administration of 5-HT3 serotonin receptor antagonists for surgical patients strengthens the flexible line of defense, thereby protecting the normal line of defense from the stressor PONV.
The model is concerned with stressors, which may disrupt stability of the system. The stressor is identified as a possible risk to the body’s flexible and normal lines of defense (Fawcett & Neuman, 2002). The individual’s degree of reaction to the stressor is dependent upon the time of occurrence of the stressor, the present and past condition of the individual, the nature and intensity of the stressor, and the amount of energy required by the individual to adapt to the stressor. Stressors may be intra-, inter-, and extrapersonal (Sohier, 1997). These stressors, in regards to this study, are discussed in the following paragraphs.

Neuman (1995) defined intrapersonal stressors as internal environmental forces occurring within the boundary of the client. Examples of intrapersonal stressors are conditioned responses and autoimmune responses. Examples of intrapersonal factors, which influence the response of PONV, include age, gender, and obesity. PONV may be viewed as an intrapersonal stressor and also as a conditioned response. Data will be collected on age, gender, and obesity for the purpose of this study.

Interpersonal stressors are external environmental interaction forces occurring outside the boundaries of the client at proximal range (Fawcett & Neuman, 2002). An example of this is conflict of role expectations. When patients assume the sick role of the surgical patient and temporarily cannot perform their usual roles of provider, homemaker, etc., they often become anxious as a result of this role conflict. Anxiety, therefore, is a factor, which could potentially increase the risk of PONV (Sohier, 1997). However, the effect anxiety has on PONV will not be addressed in this study.

Extrapersonal factors are external environmental interaction forces occurring outside the boundaries of the client at distal range. Financial concerns are an example of an extrapersonal stressor (Sohier, 1997). However, the effect financial concerns have on PONV will not be addressed in this study.

The goal of nursing, in this model, is the promotion of optimal wellness of the individual through maintenance or attainment of system stability. This goal is accomplished through intervention at three prevention levels (Sohier, 1997).

Neuman (1995) described primary prevention as an intervention before a reaction occurs. This type of intervention may begin when a risk factor or potential stressor is suspected or identified. Primary prevention promotes wellness by protecting the normal
lines of defense. This is done by reducing the likelihood of an individual’s encounter with stressors and by strengthening flexible lines of defense (Sohier, 1997). In the acute care surgical setting, when a member of the health care team identifies a risk factor for the stressor of PONV, primary prevention interventions may be initiated. Primary prevention, such as the prophylactic administration of 5-HT3 serotonin receptor antagonist, particularly, granisetron hydrochloride (Kytril), during a surgical procedure, may allow the person to avoid nausea and vomiting, maintaining system stability.

Secondary prevention is aimed at the treatment of existing symptoms. Its focus is on the strengthening of internal lines of defense to reduce the degree of reaction, promote reconstitution, and prevent death (Sohier, 1997). An example of a secondary prevention intervention, in the acute care surgical setting, is the administration of a rescue antiemetic following the occurrence of PONV in order to assist the individual’s return to stability.

Tertiary prevention focuses on readjustment toward optimal system stability. The primary goal is to strengthen resistance by reducing the exposure to stressors in order to prevent recurrence of a reaction (Neuman, 1995). An example of a tertiary prevention is the normal recovery or healing of patients following surgery without postoperative complications, such as nausea and vomiting, causing delay. This outcome is the effect measured by length of stay in this study.

**Physiology of Nausea**

The terms nausea, vomiting, and retching are not synonymous. Nausea is an unpleasant sensation in the throat and epigastrum associated with the urge to vomit. Vomiting is the forceful expulsion of gastric contents, whereas retching is the rhythmic contraction of respiratory muscles including the diaphragm and abdominal muscles without the expulsion of gastric contents (Flake, Scalley & Bailey, 2004).

The neurologic structures involved in the emetic reflex include the vomiting center, or emetic center, in the lateral reticular formation of the medulla; the chemoreceptor trigger zone (CTZ) in the area postrema of the medulla; the cerebral cortex; and the vagal and splanchnic afferents from the gut to the vomiting center and CTZ. The vomiting center is the final common pathway for vomiting stimuli and coordinates the act of vomiting. This reflex center receives stimuli from the vestibular areas, the pathway involved in motion sickness; from the cerebral cortex, the pathway
believed to be involved in anticipatory vomiting; from the CTZ; and from the gut through the vagal and greater splanchnic afferents (Crow & Ghaddar, 1997). The vomiting center in the medulla oblongata is in close proximity to other visceral centers like the respiratory and vasomotor centers. There are four types of receptors involved; they are cholinergic, dopaminergic, histaminic, and serotonergic (Islam & Jain, 2004).

The vomiting reflex is triggered by the stimulation of the CTZ, which includes serotonin receptors, in the upper gastrointestinal (GI) tract and mechanoreceptors in the wall of the GI tract, which is activated by both contraction and distention of the gut as well as by physical damage (Islam & Jain, 2004). A coordinating center, in the CNS, controls the emetic response. Afferent nerves to the vomiting center arise from the abdominal vagal nerves, vestibule-labyrinthine receptors, the cerebral cortex and the CTZ. The CTZ contains chemoreceptors that sample both blood and cerebrospinal fluid. There are direct links that exist between the emetic center and the CTZ. The CTZ is exposed to emetic stimuli of endogenous origin such as hormones associated with pregnancy and to stimuli of exogenous origin such as drugs (i.e. anesthetics). The vagus nerve produces the complex coordinated set of muscular contractions, cardiovascular responses and reverse peristalsis that characterizes vomiting (Bellville, 1959; Gerlach et al., 1992; Kapit, Macey, & Meisami, 1987; McCarthy, 1964; Norris, 1982; Watcha & White, 1998).

The response of nausea postoperatively is based on the brain’s response to the messages it receives, as well as how those messages are processed by the brain. Since the CTZ is in the area postrema, an area of the medulla characterized by the absence of an effective blood-brain barrier, this center may be directly stimulated by anesthetic agents or their metabolites (Crow & Ghaddar, 2002). Patients’ experiencing nausea postoperatively requires immediate therapeutic intervention, especially those experiencing vomiting with intravascular volume depletion. Vomiting postoperatively may also cause other postoperative complications, such as mucosal injury, bleeding, aspiration, and esophageal rupture. The administration of 5-HT3 antiemetics blocks the stimulation of the serotonin receptors involved in the activation of the emetic center.
When 5-HT3 receptors are blocked effectively, the emetic reflex is prevented. Therefore, patients’ undergoing operative procedures should be evaluated preoperatively to identify any conditions which may increase the risk of developing PONV (Kuver, Sheffield & MacDonald, 2001).

As previously stated, Neuman (1995) described prevention as intervention before a reaction occurs. This type of intervention begins when a risk factor, or potential stressor, such as PONV, is identified. Thus, the assessment of risk factors promote wellness. The administration of granisetron hydrochloride (Kytril) IV intraoperatively protects the normal line of defense by reducing the likelihood of PONV and by strengthening the flexible line of defense. If PONV occurs, then the normal and flexible lines of defense are penetrated and the patient must rely on lines of resistance to protect the core. Unless rescue antiemetics are given as a secondary intervention to support the lines of resistance, a patient’s recovery will be compromised and PONV (degree of reaction) will be increased. At best, reconstitution is delayed. Nausea and vomiting is the degree of reaction from the stressor of surgery. In regards to the physiology of nausea, when 5-HT3 serotonin receptor antagonists are administered the 5-HT3 receptors are blocked and the emetic response is prevented, as primary prevention.

Assumptions

Assumptions are the basic principles that are believed to be true by the researcher. During the course of this study, the researcher made assumptions in regards to the data collected and analyzed (Polit & Hungler, 1999).

1. The researcher assumes that the sample will adequately represent the targeted population.
2. The researcher assumes that the nurse will accurately administer and document the use of granisetron hydrochloride (Kytril) IV during the surgical procedure.
3. The researcher assumes that the nurse accurately assesses and documents the patient’s report of postoperative nausea.
4. The researcher assumes that the patient will report an occurrence of postoperative nausea to the nursing staff.
Limitations

The following limitations influenced this study:

1. Only one setting was examined, making it difficult to be able to apply the findings to other settings.
2. Nausea is a subjective experience.
3. The operative patients may have a history of health conditions that may predispose them to developing nausea in spite of granisetron hydrochloride (Kytril) IV use intraoperatively.
4. Postoperative complications, if they occur, may result in the patient’s developing nausea in spite of granisetron hydrochloride (Kytril) IV use intraoperatively.
5. Patients selected for granisetron hydrochloride (Kytril) use were included for another study and, as retrospective data, may not be representative of the population of patients undergoing laparoscopic cholecystectomy.

Summary

Cholecystitis, an acute or chronic inflammatory process of the gallbladder, is treated with a cholecystectomy, the surgical removal of the gallbladder. The laparoscopic approach has become the most common technique (Wright, 1999). Nausea is still one of the most common postoperative complaints patients report following a cholecystectomy, even with the laparoscopic approach (Jones & Jones, 2001). The overall aim for healthcare providers for this type of patients is to eliminate postoperative nausea (Watcha, 1995). The prevention and elimination of postoperative nausea, not only improves patient comfort and satisfaction, it reduces the impact the nausea may have on the patient’s ability to convert to oral medications, and reduces the patient’s length of hospital stay and overall costs of hospitalization (Kovac, 2000).

In order to determine whether the administration of a 5-HT3 serotonin receptor antagonist reduced or eliminated the occurrence of postoperative nausea, the medical records for postoperative cholecystectomy patients, both who received, and did not receive granisetron hydrochloride (Kytril) IV, will be reviewed. This will be done through guidance by the conceptual framework created through the combination of Betty Neuman’s Systems Model and the physiology theory of nausea. Results of this study may provide a raised awareness of best practice nursing care and the need for quality
improvement for postoperative patients. Chapter 2 provides support from the literature for the implementation of the described study.
CHAPTER 2
REVIEW OF LITERATURE

This chapter will examine the Neuman Systems Model, the theoretical basis for this study, as well as review the literature supporting the purpose of this research study. A theoretical description and empirical review of the literature relating to Betty Neuman’s Systems Model, the physiology theory of nausea, postoperative nausea and vomiting, the factors contributing to the incidence of PONV, and Granisetron will be presented.

Theoretical Review

The Neuman Systems Model

The Neuman Systems Model (1995) has been widely used in nursing education, practice, and research since its creation in the 1970’s by Betty Neuman. The dynamic model is based on the patient’s relationship to environmental stress, which has the potential to cause a reaction, or could affect the patient’s reconstitution following treatment of a stress reaction. The goal of the nurse is to facilitate an environment of optimal wellness through retention, attainment, or maintenance of patient system stability (Fawcett & Neuman, 2002).

Neuman’s model (1995) describes mechanisms that protect the individual’s stability when faced with a stressor. The flexible line of defense, a cushioning mechanism, protects the normal line of defense from penetration by stressors. Lines of resistance are internal factors that protect the core from stressors that penetrate the normal line of defense. The lines of resistance ideally decrease stressor reaction, increase client resistance, and allow the client to reconstitute or return to some level of wellness and stability (Sohier, 1997).
The model is concerned with stressors which may disrupt stability of the system. The stressor is identified as a possible risk to the body’s flexible and normal lines of defense. The individual’s degree of reaction to the stressor is dependent upon the time of occurrence of the stressor, the present and past condition of the individual, the nature and intensity of the stressor, and the amount of energy required by the individual to adapt to the stressor. Past coping patterns and behaviors are helpful in predicting an individual’s response to a new stressor. Stressors may be intra-, inter-, and extrapersonal (Sohier, 1997).

Neuman (1995) defined intrapersonal stressors as internal environmental forces occurring within the boundary of the client. Examples of intrapersonal stressors are conditioned responses and autoimmune responses. Examples of intrapersonal factors which influence the response of PONV include age, gender, and obesity. PONV may be viewed as an intrapersonal stressor and also as a conditioned response (Fawcett & Neuman, 2002).

Interpersonal stressors are external environmental interaction forces occurring outside the boundaries of the client at proximal range. An example of this is conflict of role expectations. When patients assume the sick role of the surgical patient and temporarily cannot perform their usual roles of provider, homemaker, etc., they often become anxious as a result of this role conflict. Anxiety, therefore, is a factor which could potentially increase the risk of PONV (Sohier, 1997).

Extrapersonal factors are external environmental interaction forces occurring outside the boundaries of the client at distal range. Financial concerns are an example of an extrapersonal stressor (Sohier, 1997).

The use of Neuman’s Systems Model (1995) fits well with the current research project. Neuman’s model explores a system’s, or person’s, reaction to stress and reconstitution following stress. A person may react quite differently to stress while being a patient in a hospital versus home. The reality of an illness may cause a patient to be overwhelmed more easily when compared to another point in time. As a result of stress placed on a hospitalized patient, an individual may have a weakened flexible line of defense, normal line of defense, and/or lines of resistance. The stress may ultimately affect the client’s basic structure leading to a reaction within the system (Fawcett &
Neuman, 2002). This reaction, such as occurrence of PONV following laparoscopic surgery, may affect the future treatments and length of time for recovery.

The goal of nursing, in this model, is the promotion of optimal wellness of the individual through maintenance or attainment of system stability. This goal is accomplished through intervention at three prevention levels (Sohier, 1997).

Primary prevention is described as an intervention before a reaction occurs. This type of intervention may begin when a risk factor or potential stressor is suspected or identified. Primary prevention promotes wellness by protecting the normal lines of defense. This is done by reducing the likelihood of an individual’s encounter with stressors and by strengthening flexible lines of defense (Sohier, 1997).

In the acute care surgical setting, when a member of the health care team identifies a risk factor for the stressor of PONV, primary prevention interventions may be initiated. Primary prevention, such as administration of granisetron hydrochloride (Kytril), during a surgical procedure, may allow the person to avoid nausea and vomiting, maintaining system stability.

Secondary prevention is aimed at the treatment of existing symptoms (Fawcett & Neuman, 2002). Its focus is on the strengthening of internal lines of defense to reduce the degree of reaction, promote reconstitution, and prevent death (Sohier, 1997). An example of a secondary prevention intervention, in the acute care surgical setting, is the administration of a rescue antiemetic following the occurrence of PONV in order to assist the individual’s return to stability. In order to promote reconstitution, the administration of granisetron hydrochloride (Kytril) IV intraoperatively has the potential to prevent PONV, thus decreasing length of stay in the hospital and improving patient satisfaction.

Tertiary prevention is aimed at the readjustment toward optimal system stability. The primary goal is to strengthen resistance by reducing the exposure to stressors in order to prevent recurrence of a reaction (Fawcett & Neuman, 2002). Tertiary prevention, for example is the normal recovery or healing of patients following surgery without postoperative complications, such as nausea and vomiting, causing delay.

*The Physiology of Nausea*

Nausea and vomiting are controlled and coordinated by the vomiting center in the dorso-lateral reticular formation of the medulla oblongata. This center may be stimulated
to initiate the vomiting reflex by (a) afferent stimulation of the vagus nerve and the sympathetic nervous system in response to distention, irritation, or inflammation of the stomach, or myocardial ischemia; (b) visceral receptors in the gastrointestinal tract, heart kidneys, pharynx, or uterus in response to spasm, inflammation, or obstruction of one of these organs; (c) the chemoreceptive trigger zone (CTZ) on the floor of the fourth ventricle of the brain stimulated by motion sickness or drugs; and (d) the cerebral cortex, in response to psychological stress or visual, auditory, olfactory, tactile, gustatory, or painful stimuli (Crow & Ghaddar, 1997).

Chemoreceptors are located in the mucosa of the upper gut and are sensitive to noxious chemical stimuli. The CTZ lies within the brain stem. The area postrema is able to detect circulating toxins in the CSF and to activate the vomiting center. Four types of receptors are involved in the stimulation of the vomiting center, they are cholinergic, dopaminergic, histaminic, and serotonergic. The stimulation of these receptors activate the vomiting center and emetic response (Islam & Jain, 2004).

The vomiting reflex includes a sequential pattern of responses. First, the glottis closes. Then the cardiac sphincter opens. Next, contraction of the abdominal and respiratory muscles exerts pressure on the stomach. Finally contents of the stomach are expelled (Kuver, Sheffield & McDonald, 2001).

Neuman’s theory (1995) described prevention as intervention before a reaction occurs. This type of intervention begins when a stressor is identified, such as nausea and vomiting. In order to promote wellness, the assessments of such stressors are done. After a stressor (nausea and vomiting) is identified, the intervention of administering of granisetron hydrochloride (Kytril) IV intraoperatively protects the normal lines of defense by reducing the likelihood of nausea and vomiting and by strengthening flexible lines of defense.

Postoperative Nausea and Vomiting

Cholecystitis is an inflammatory process of the gallbladder that may be either acute or chronic. Acute cholecystitis has associated stone formation in 90% of all cases, causing obstruction and inflammation. Acute cholecystitis without stones results from any condition that affects the regular emptying and filling of the gallbladder. Such conditions include physical immobilization and sudden starvation. The primary symptom
of acute cholecystitis is pain in the right upper quadrant, which radiates around to the midtorso region and to the right scapular region. The pain experienced is abrupt and severe and may last up to 2 to 4 hours. Chronic cholecystitis refers to repeated attacks of acute cholecystitis in a gallbladder that is scarred and contracted. Patients with chronic cholecystitis exhibit fat intolerance, flatulence, nausea, anorexia, and nonspecific abdominal pain and tenderness of the right hypochondriac region (Seidel et al.; 1999).

The laparoscopic cholecystectomy was introduced in 1987, the beginning of explosive growth in minimally invasive surgery. Surgical procedures that historically required days of postoperative hospitalization are now being performed on an ambulatory basis. New procedures are constantly being introduced, spurred by technologic innovations and advanced instrumentation. Patients have grown to expect minimal postoperative complication (i.e. pain, nausea, and vomiting) and rapid hospital discharge, regardless of their underlying medical condition. Older, sicker patients who might have been deemed high risk for the morbidity of an open incision are routinely scheduled for laparoscopic procedures. Still, these patients are at risk for developing postoperative complications, such as PONV. It is the healthcare provider’s responsibility to assess for, and prophylactically, treat patients in order to minimize postoperative complications (Jones & Jones, 2001).

Pain, nausea, and vomiting are frequently listed by patients as their most important perioperative concerns. Currently, the overall incidence of PONV is estimated to be 30 to 50%, with severe, intractable PONV estimated to occur in approximately 18% of all patients undergoing surgery. The actual risk of PONV, in laparoscopic cholecystectomy patients, can depend on various factors including gender, age, and a previous history of PONV. PONV can lead to delayed postanaesthesia care unit (PACU) discharge and unanticipated increased hospital stay, thereby increasing medical costs (Kovac, 2000).

Postoperative nausea and vomiting is a common disorder at the forefront of laparoscopic cholecystectomy surgical procedures. New antiemetic drugs, such as granisetron hydrochloride (Kytril), and improved anesthetic techniques have decreased the incidence of anesthetic-induced PONV. Anesthesia, as well as patient characteristics and surgical factors, are largely responsible for PONV. Healthcare providers should
consider both prophylactic drug intervention and direct treatment of PONV for these types of surgical patients (Haynes & Bailey, 1996).

Nausea and vomiting following surgery are common complications of anesthesia. Avoiding PONV is one of the highest priority for most patients, especially those receiving volatile anesthetics and opioids. If volatile anesthetics and opioids are given to susceptible patients such as female, those with previous history of PONV or motion sickness and non-smoker, this is likely to result in PONV. PONV occurrence, for those having received anesthesia, has been reported to range from 27% to 80% (Pierre & Corno, 2003).

Watcha and White (1998) summarized literature related to postoperative nausea and vomiting including an overview of physiology of vomiting, nonanesthetic and anesthetic-related factors associated with postoperative vomiting, and prevention and treatment of PONV. They reported an incidence of postoperative vomiting between 20-30%.

The incidence of PONV varies significantly according to the operative procedure (Bellville, 1959; Bellville, Bross, & Howland, 1960; Larson, Halliburton, & Julio, 1993; Smessaert, Schelr, & Artusio, 1959; Watcha & White, 1998). Surgical procedures involving middle ear manipulation, gastrointestinal trauma, peritoneal irritation, or increased gastric pressure from swallowed blood or secretions were identified by Larson et al. as procedures with the highest risk of PONV.

Bellville (1959); Smessaert et al. (1959); and Watcha and White (1998) identified a history of motion sickness and/or previous postoperative nausea as factors which increase the risk of PONV. According to Watcha and White these individuals may have a more well-developed reflex arc for vomiting.

Numerous pathophysiological mechanisms are known to cause nausea or vomiting, however their role for PONV is not quite clear. Volatile anesthetics, nitrous oxide, and opioids appear to be the most important causes of PONV. A history of motion sickness and PONV has been listed as one of the most important patient specific risk factors for PONV. An objective risks assessment, when performed preoperatively, provides a rational basis for prophylactically treating PONV prior to surgical procedures.
Whether the risk of PONV is low, moderate, or high, the use of none, a single or a combination of prophylactic antiemetic interventions appears to be justified (Apfel & Roewer, 2004).

Factors contributing to the incidence of PONV

Age. In a descriptive study, Smessaert, Schehr, and Artusio (1959) observed 1602 postoperative patients for PONV in the recovery room. Variables recorded included age, gender, anesthetic agents, premedication, duration of anesthesia, presence of gastric tube, endotrachial intubation, use of muscle relaxants, and body structural type. Results showed that 24.3% of postoperative patients experienced vomiting and 29.5% experienced nausea. Differences in incidence of PONV are correlated with age, gender, anesthetic agents, and site of operation.

Children experience a higher rate of PONV than adults. The pediatric incidence of nausea and vomiting following surgery increases with age peaking in the 11-14 year age group. In adults, the relation between PONV and age is not so clear (Smessaert et al., 1959; and Watcha & White, 1998).

In regards to age, identifying risk factors and predictive models for PONV and developing antiemetic guidelines for its prevention and treatment is paramount. Avoiding PONV seems to be one of the highest priorities of adult operative patients. For patients receiving volatile anesthesia, simplified risk scores are available to estimate the individual risk of PONV. A strategy to prevent and treat PONV should depend on the individual’s risk (Corno, 2003).

Gender. Narcotic-induced nausea and vomiting is thought to be a common occurrence, but the gender incidence and associations are not well defined. Pain management is an important part of a surgical patient’s care, however it can be complicated by nausea and vomiting as a result of the opiates used during this period. Not only does the type of opiate used influence the degree of nausea and vomiting, but gender also seems to be a factor. If has been documented that female postoperative patients have an increased risk of nausea and vomiting (60% of women and 35% of men; Zun & Downey, 2002).

PONV is one of the most common side effects associated with surgical procedures. This complication not only can be distressing to patients but can lead to
other medical conditions. Smith (2000) stated that after receiving general anesthesia, 37% of patients reported nausea and 20% reported vomiting postoperatively. Certain patient groups are at a higher risk of PONV than others. The prevalence of PONV is three times higher in women than in men. This gender difference is not evident in prepubertal children or in the elderly, which indicates that there may be hormonal involvement causing this gender variation (Smith, 2000).

In a descriptive retrospective study of 3794 randomly selected surgical patients, variables which influenced PONV were identified (Bellville, Bross, & Howland, 1960). They found that women had three times the risk of postoperative vomiting as men. However, in preadolescent patients and adults over 70 years old, there was no significant gender-related difference in PONV (Watcha & White, 1998).

**Obesity.** A positive correlation between body weight and postoperative emesis has been reported by Smessaert, Schehr, and Artusio (1959). Since adipose tissue retains inhaled anesthetic agents, obese patients can be expected to have a larger reservoir of inhaled anesthetics and, therefore, experience more postoperative side effects. Furthermore, the larger residual gastric volume, higher incidence of esophageal reflux, and more gastric inflation during attempts to maintain an adequate airway may be contributing factors (Watcha & White, 1998).

Laparoscopic procedures are becoming more popular in the treatment of patients with morbid obesity. Obesity was initially regarded as a contraindication to laparoscopy because of technical considerations. The use of longer instruments now allows surgeons to perform laparoscopic procedures along with avoiding the problem of needing to retract thick layers of adipose tissue in order to reach a surgical site. Laparoscopic procedures not only require smaller incisions, they also reduce the patients risk of pulmonary complications and wound healing. Also, with these types of procedures, patients have decreased blood loss, decreased narcotic use, and a quicker return of bowel function (Jones & Jones, 2001)

*Granisetron hydrochloride as a 5-HT3 Antagonist*

Granisetron hydrochloride (Kytril) is a selective 5-hydroxytryptamine₃ receptor antagonist. Five-hydroxytryptamine (serotonin) is an endogenously produced amine which is believed to be a central neurotransmitter. These neurotransmitters fall into three
main categories: 5-HT₁, 5-HT₂, and 5-HT₃. Serotonin acts on smooth muscle and afferent nerve endings. Granisetron is believed to prevent nausea and vomiting by blocking serotonin-induced depolarization of vagal afferent nerves, and possibly binding sites at the chemoreceptive trigger zone. Five-HT₃ receptor-binding sites have been radiolabeled in the central nervous system. Radioligand-binding studies, in which a molecule such as an antigen or antibody has a radioactive tracer attached to it, found a high density of 5-HT₃ recognition sites in the area postrema which contains the vomiting centers of the central nervous system and subpostrema (Crow & Ghaddar, 1997). The area postrema is located in the medulla oblongata on the floor of the fourth ventricle. Its capillaries monitor blood borne and cerebral spinal fluid-borne information. The area postrema’s main function is mediation of emesis. This area is also believed to have a role in general regulation of ingestive functions. The area postrema contains subtypes of serotonergic receptors (Adipudi & Simansky, 1995).

Nausea and vomiting can cause considerable distress and discomfort to patients undergoing surgery. Several classes of antiemetic agents exist to combat these side effects, though the 5-HT₃ receptor antagonists have become the first line of treatment choice for many patients and are considered the “gold standard” in antiemetic therapy. There are three 5-HT₃ receptor antagonists utilized for the prevention or treatment of nausea; they are granisetron (Kytril), odansetron (Zofran), and dolasetron (Anzemet); (Goodin & Cunningham, 2002).

Research

*The Neuman’s Systems Model*

The application of a conceptual model in nursing research provides a mechanism for contribution to nursing knowledge. Betty Neuman’s systems model has been applied as a conceptual framework for numerous research studies. The situations in which the model has been applied provides support for adaptation of the model in the prevention of postoperative nausea and vomiting (Chinn & Kramer, 1991; Meleis, 1991; Neuman, 1995).

The application of Neuman’s model in research and practice has been described in the literature, and demonstrated both clinical and educational settings. In 1991, Lindel and Olsson utilized Neuman’s model by integrating sociological, psychological,
physiological, philosophical, developmental, and interpersonal stressors to facilitate contraceptive counseling as primary prevention against the stressor of undesired pregnancy. In 1988, the application of the model to promote health through nutrition was discussed by Gavan, Hastings-Tolsma, and Troyan. Neuman’s systems model was applied to 111 patients randomly assigned into three groups, giving various amounts of information regarding the procedure, expected sensations, and coping strategies to each group (Ziemer, 1982). The findings did not demonstrate any significant difference in postoperative coping related to the information received by different groups. In 1989, Smith applied the model in the assessment, planning, intervention, and evaluation of the care of a post myocardial infarction patient in a cardiac rehabilitation program.

The versatility of Neuman’s model is demonstrated by the diverse application in which it has been used. The continued use of the model in new applications of nursing research will add to its validity and utility for future use in nursing practice.

Postoperative Nausea and Vomiting

Quaynor and Raeder (2002) examined the effectiveness of administering 20 mg of metoclopramide (Reglan) at the end of surgery by using granisetron hydrochloride (Kytril) 2 mg as a reference. A randomized, double-blinded study design was used in order to evaluate 122 patients scheduled for elective laparoscopic cholecystectomy under general anesthesia. Patients received either metoclopramide (Reglan) 20 mg or granisetron hydrochloride (Kytril) 2 mg IV at the end of the operative procedure. The patients were observed for 24 hours for PONV, pain, side effects, and need for rescue antiemetic medication. Findings identified that there was no significant difference in the incidence of PONV or need for rescue antiemetic treatment during the 0-24 hour postoperative study period. The overall incidence of PONV was 43% in the granisetron hydrochloride (Kytril) group and 47% in the metoclopramide (Reglan) group. It was found that the granisetron hydrochloride (Kytril) patients had a significantly higher incidence of moderate or strong pain during the postoperative observation period (61% vs 35% in the metoclopramide group) ($p < 0.05$). The patients receiving metoclopramide had less pain than the patients receiving granisetron hydrochloride (Kytril).

Stadler and Bardiau (2003) examined the difference in risk factors for PONV. The authors designed a prospective study to identify and differentiate the risk factors for
PONV in various surgical populations in a clinical audit setting. The study included 671 consecutive surgical inpatients, aged 15 years or older, undergoing various procedures. The study focused on postoperative nausea visual analog scale scores every 4 hours and vomiting episodes within 72 hours. Both vomiting and retching were considered as emetic events. Surgery-related variables that were considered to have a possible effect on the proportion of patients experiencing PONV were examined. The bivariate Dale model for binary correlated outcomes was used to identify the potential risk factors of PONV. Postoperative incidence rates of nausea and vomiting were estimated from the data. Statistical calculations were conducted using all data available. Results were considered to be significant at the 5% critical level ($p < 0.05$). Among the 671 patients in the study, 126 (19%) reported one or more episodes of nausea, and 66 patients (10%) suffered one or more emetic episodes during the study period. There was a highly significant association between the two outcomes. Some risk factors were predictive of both nausea and vomiting (age, gender, obesity, and previous history of PONV). History of migraine was almost significantly related to nausea ($p = 0.052$) but not to vomiting ($p = 0.63$). Duration of surgery was unrelated to outcomes. However, the type of surgery was significantly associated with nausea but not with vomiting, except for urological procedures ($p = 0.037$). Patients undergoing gynecological ($p = 0.0082$), urological ($p = 0.022$), and abdominal ($p = 0.028$) surgery had an increased risk of developing nausea and vomiting.

Factors contributing to incidence of PONV

Age. Papdimitriou and Livanios (2001) evaluated the occurrence of PONV in female surgical patients, aged 20 to 43 years of age. One hundred and twenty female patients scheduled for minor gynecological laparoscopy were randomly allocated to receive pretreatment with tropisetron 5mg ($n = 57$) or granisetron hydrochloride (Kytril) 1 mg in combination with metoclopramide (Reglan) 5mg ($n = 63$). The authors found that fewer patients in the combined treatment group experienced PONV (14% vs. 37%, $p = 0.008$) or needed rescue antiemetic treatment (3% vs. 16%, $p = 0.038$). The combination of the antiemetics used were found to be superior, which can be explained by the fact that the two drugs have different mechanisms of action, thus preventing emesis by blocking different pathways.
The authors also found that patients younger than 30 years of age complained most often of PONV (20%), while only 4% of patients older than 30 years of age did so. Eberhart and Morin (2004) evaluated the applicability of risk scores developed and tested in adult patients were applied to 983 pediatric patients (1-12yr) undergoing various surgical procedures. The predictive properties of five models were compared with respect to their ability to predict PONV in children. Predictive incidences of PONV were correlated with actual incidences of PONV. To allow comparison of the different scores, the predicted risk of PONV was clustered into five groups. This approach resulted in unequal numbers of patients in each group. Therefore, weighted linear regression analysis was used to compare the predicted and actual incidences of PONV. The cumulative incidence of PONV was 33.2% within 24 hours. The discriminating power was found to be low and insufficient in all models tested ($p = 0.56 - p = 0.65$). It was discovered that the predictive incidences of the scores correlated only vaguely with the actual incidences observed. The authors stated that specialized scores for children are required in order to assess risk for PONV. They suggested the assessment of a patient’s history of PONV, type of surgery, duration of anesthesia (>45 minutes), age (> 5 years), and the administration of postoperative opioids as independent risk factors. Also, the authors discussed how the prediction of PONV is now widely accepted to be useful in clinical practice. The identification of patients with a high baseline risk allows for the goal-related use of antiemetic measures that may not be indicated for routine practice. Due to the unnecessary risk from potential side effects of antiemetics, prophylaxis should be reserved for patients at moderate to high risk of PONV.

**Gender.**

Gossman and Rosenbaum (2002) examined the gender-related complication of nausea and vomiting after opiate administration. The study hypothesis stated that men and women have the same rate of narcotic-induced emesis postoperatively. A prospective-convenience study of the use of narcotic analgesic followed by PONV in surgical patients was performed. A total of 325 consenting patients were studied over a 2-year period. The patients consisted of 174 men and 151 women, with an average of 35.8 years of age. Of the total of 325 patients, 20.3% (74) required an antiemetic because of nausea and/or vomiting postoperatively. The authors found that women had nausea
and vomiting postoperatively more often than men. It was found that women described more PONV ($t = 2.85, p < .05$) and that women received more rescue antiemetics ($t = 2.26, p = <.01$) than men.

**Obesity.** Kranke and Apfel (2001) compared the correlation of obesity, or increased Body Mass Index (BMI), and the occurrence of postoperative nausea (PN) and postoperative vomiting (PV) among surgical patients. In this study, 587 adult patients from a randomized controlled antiemetic trial who underwent general anesthesia were allocated to four weight groups: underweight (BMI < 20), normal weight (BMI 20-25), overweight (BMI 25-30), and obesity (BMI > 30). Through Chi Square analysis, the following incidences of PONV were found to be: 45.8% for underweight, 41.7% for normal weight, 47.8% for overweight, and 44.1% for overweight and obesity, respectively ($p = 0.69$). The incidence of PN ($p = 0.76$) and PV ($p = 0.36$) did not differ. The researchers stated that the systematic search of the literature provided no evidence for a positive relationship of increased BMI and PONV. The data collected for this study confirmed that an increased BMI is not a risk factor for PONV. This negative finding identifies the need to focus on the relevant risk factors, prior to surgical procedures, to allow for an objective risk assessment of PONV (Kranke & Apfel, 2001).

**Granisetron**

In a double blind, randomized study of 51 female patients, aged 20-40 years undergoing gynecological diagnostic laparoscopy were examined. The purpose of the study was to compare the efficacy of granisetron hydrochloride (Kytril)-dexamethasone (Decadron) combination with granisetron hydrochloride (Kytril) alone for prevention of PONV. Group 1 ($n = 26$) received 1 mg granisetron hydrochloride (Kytril) IV and group 2 ($n = 25$) received a combination of 1 mg granisetron hydrochloride (Kytril) and 8 mg of dexamethasone (Decadron) IV soon after induction of anesthesia. It was found that group 1 had a greater incidence of vomiting (35%) than in group 2 (8%) ($t = 2.77; p < 0.05$). The combination group showed better control of delayed vomiting when compared with the granisetron hydrochloride (Kytril) group (4% vs 35%) ($t = 2.20; p < 0.01$). The combination of granisetron hydrochloride (Kytril) and dexamethasone (Decadron) provided adequate control of PONV, with delayed PONV being better controlled than early PONV (Rajeeva, Bhardwaj, Batra & Dhaliwal, 1999).
Saitoh and Tanaka (2000) examined the efficacy of granisetron hydrochloride (Kytril) in the prevention of PONV in patients undergoing general anesthesia for major gynecological surgery. In a randomized, double-blind study, 90 female patients received 2.5mg granisetron hydrochloride (Kytril) IV immediately before the induction of anesthesia. Nausea and vomiting assessments were performed continuously during the first 24 hours after anesthesia. The incidence of PONV was found to be 20% with granisetron hydrochloride (Kytril) using a Fisher’s exact probability test ($t = 2.57; p < 0.05$). Granisetron hydrochloride (Kytril) was found to be effective in preventing PONV in female patients with a history of postoperative emesis.

Naguib et al. (1996) showed the effectiveness of granisetron hydrochloride (Kytril) in the prevention of PONV when given prophylactically in patients undergoing laparoscopic cholecystectomy. This study’s aim was to compare the antiemetic activity of different 5-HCT3 receptor antagonists with that of granisetron hydrochloride (Kytril) and placebo. A prospective, randomized, double-blind method was utilized in order to compare the antiemetic activity of the prophylactic administration of granisetron hydrochloride (Kytril) 3 mg and ondansetron (Zofran) 4 mg with that of metoclopramide (Reglan) 10 mg and placebo in 132 patients undergoing laparoscopic cholecystectomy. All study drugs and placebo were given as a short IV infusion 10 minutes before the induction of anesthesia. Nausea and vomiting were assessed by direct questioning of the patient at 1, 9, 12, and 24 hours after recovery from anesthesia. Prophylactic antiemetic treatment with granisetron hydrochloride (Kytril) and ondansetron (Zofran) resulted in a lower incidence of PONV ($t = 2.11, p < 0.02$) than with metoclopramide (Reglan) and placebo ($t = 2.89; p = 0.07$). Granisetron hydrochloride (Kytril) and ondansetron (Zofran), when given in combination prophylactically, resulted in significantly lower incidence of PONV than when metoclopramide (Reglan) and placebo were given in combination prophylactically.

Summary

This chapter provided a review of the literature that supports this study. Nausea and vomiting are two common complications reported following surgical procedures (Kovac, 2000). The prevention of PONV is believed, not only to increase patient satisfaction, but also to provide cost-effective care (Watcha, Bras, Cieslak & Pennett,
Assessing for the presence of PONV provides key information during postoperative care (Jones & Jones, 2001). When PONV is reported, rescue antiemetics are administered; the effectiveness of antiemetics are evaluated; and the need for further intervention, if nausea and vomiting are unrelieved, are communicated to health care team members (Seidel, Ball, Dains & Benedict, 1999).

An overview of the incidence of PONV in correlation with age, gender, anesthetic agents, and site of operation has been provided (Corno, 2003; Jones & Jones, 2001; Smessaert et al., 1959; Smith, 2000; Watcha & White, 1998; Zun & Downey, 2003).

Children experience a higher rate of PONV than adults. The pediatric incidence of nausea and vomiting following surgery increases with age peaking in the 11-14 year age group. In adults, the relation between PONV and age is not so clear (Smessaert et al., 1959; Watcha & White, 1998). In regards to age, identifying risk factors and predictive models for PONV and developing antiemetic guidelines for its prevention and treatment is paramount. Avoiding PONV seems to be one of the highest priorities of adult operative patients. A strategy to prevent and treat PONV should depend on the individual’s risk. In this chapter, the risk factors discussed included age, gender, and obesity (Corno, 2003).

The control, coordination, and steps of the vomiting reflex are described in the literature (Watcha & White, 1995). The existence of PONV and associated risk factors (i.e. age, gender, obesity) have been well documented (Corno, 2003; Jones & Jones, 2001; Smessaert et al., 1959; Smith, 2000; Watcha & White, 1995; Zun & Downey, 2002). Also, the efficacy of granisetron hydrochloride (Kytril) in preventing PONV has been demonstrated (Adipudi & Simansky, 1995; Crow & Ghaddar, 1997; Goodin & Cunningham, 2002; Naguib et al., 1996; Rajeeva et al., 1999; Saitoh & Tanaka, 2000).

The administration of 5-HT3 antiemetics block the stimulation of the neurologic structures involved in the emetic center. When 5-HT3 receptors are blocked effectively, the emetic reflex is prevented (Crow & Ghaddar, 1997). Therefore, patients’ undergoing operative procedures should be evaluated preoperatively to identify any conditions which may increase the risk of developing PONV (Kuver, Sheffield & MacDonald, 2001).
The implications of PONV for the laparoscopic cholecystectomy surgical patient population have been discussed in this chapter. The accurate assessment and effective prophylactic treatment of PONV not only has the potential to reduce cost and postoperative complications, but also to increase patient satisfaction.

The Neuman Systems Model (2002), a portion of the theoretical basis for the current study, has been widely used in nursing education, practice, and research since its creation in the 1970’s by Betty Neuman. This dynamic model is based on the patient’s relationship to environmental stress (cholecystectomy), which has the potential to cause a reaction (PONV) or could affect the patient’s reconstitution (LOS) following treatment of the stress reaction (PONV). The goal of the nurse is to facilitate an environment of optimal wellness through retention, attainment, or maintenance of patient system stability (Neuman, 2002). Several studies demonstrating the use of Neuman’s Systems Model in nursing research and practice were discussed (Chinn & Kramer, 1991; Meleis, 1991; Neuman, 2002; Sohier, 1997). Additionally, studies on PONV were presented that manipulated a variable (i.e. administration of granisetron hydrochloride IV intraoperatively) with the goal of decreasing the reported level of PONV (Naguib et al., 1996; Rajeeva, Bhardwaj, Batra & Dhaliwal, 1999; Saitoh and Tanaka, 2000).

Chapter 3 will provide discussions on the methodology of investigating the prevention of PONV in laparoscopic cholecystectomy patients. The research questions, statistical analysis, design, procedure, protection of human subjects, and instruments for the study will likewise be discussed.
CHAPTER 3
METHODOLOGY

This chapter will explore the methodology that was used to collect and analyze data relating to prevention of postoperative nausea and vomiting (PONV) using a 5-HT3 antagonist in patients who were at risk for PONV because of the surgical procedure they received. The research design, setting, population and sampling plan, protection of human subjects, instrument, procedure, and data analysis will be discussed.

Research Design

The reader is reminded that the purpose of this study was to investigate the effectiveness of intraoperatively administered 5-HT3 serotonin receptor antagonists, particularly, granisetron hydrochloride (Kytril), on PONV for patients receiving a laparoscopic cholecystectomy, a surgical procedure known to have a high risk for it. In order to accomplish this objective, a non-experimental, comparative design was selected, utilizing retrospective data. Data were collected using a Demographic and Postoperative Data Form (DPDF; Appendix A). No interventions were performed.

Setting

The data for this study were collected within a private, not-for-profit, full-service, urban, regional medical center in north Florida. This integrated health care system located in north Florida includes 770 licensed beds (a 597 bed tertiary hospital, a 60 bed psychiatric hospital, a 53 bed subacute facility, and a 60 rehabilitation facility), two home health care agencies, nine family medicine practices in seven surrounding counties, and a medical staff of 435 physicians (Strategic Plan, 2003). The selected hospital has more than 24,000 in-patient admissions per year and offers a comprehensive system of healthcare services, including surgical procedures, such as laparoscopic
cholecystectomies. Approximately 300 laparoscopic cholecystectomies are performed each year at the selected hospital (personal communication Dusenbury, 2003).

A few areas of excellence and expertise, at the selected hospital, include a Behavioral Health Center, the longest continually-accredited Cancer Program in the state of Florida, a comprehensive Diabetes Center, which provides acute inpatient care, dietary consultation, educational programs, and medical research, a Heart and Vascular Institute, a Home Health Care Center, a NeuroScience Center, which is a clearinghouse of information and a referral source for injuries and conditions affecting the brain and nervous system, and a Women’s Pavilion, which encompasses health education, support groups, resources, counseling, mammography suite, breast cancer support services, maternal support services, and a perinatal bereavement program (Strategic Plan, 2003).

This north Florida hospital derives 80.8% of its admissions from its primary service area, and commands a 76% market share. The medical center serves a population base of approximately 600,000 in 16 counties of north Florida, southwest Georgia, and southeast Alabama (Strategic Plan, 2003). The primary service area has a population of 322,000, which has grown 28%, and is 63% White, 34% African American, 4% Hispanic, 2.4% Asian, and < 0.5% American Indian. Ninety-one percent of people 25 years and older have graduated from high school and 38% have a bachelor’s degree or higher. There is a 10% dropout rate for people 16 to 19 years of age. The median income for households is $37,110, with 84% of the households receiving earnings. Retirement income is received by 12% of the households and 19% of the households receive Social Security. The average income from Social Security received is $10,908. Eighteen percent of the households in this population receive some level of public assistance or non-cash benefits, with 15% of the population in poverty. Also, 20.5% of adults are obese, with a BMI > 30 (Census Bureau, 2000).

Population and Sampling Plan

There were two target populations, both of which are theoretical and infinitely large. One was composed of cholecystectomy patients who received a prophylactic antiemetic in the classification of 5-HT3 blocking agents, particularly, granisetron hydrochloride (Kytril) IV intraoperatively, and met inclusionary criteria during the specified time frame; these included the accessible population of patients whose charts
were available for sampling. The second was composed of cholecystectomy patients who did not receive an IV intraoperative prophylactic antiemetic and met inclusionary criteria and were available for sampling.

Inclusionary criteria for this study were patients who had undergone an inpatient or outpatient laparoscopic cholecystectomy at the selected hospital during the specified time frame. Patients selected were 18 years of age or older, oriented to person, place, time, and situation, and able to report the occurrence of PONV. Exclusionary criteria were patients with postoperative complications, patients with cognitive impairments, and any patient given a secondary diagnosis following hospital admission.

Koussi’s (2001) study used 120 laparoscopic surgery patients and allowed for an 80% or more chance of detecting a 45% change in PONV due to the administration of granisetron hydrochloride (Kytril) IV (alpha = 0.05). The plan for this current study was to have an alpha of 0.10, Power of 0.80, and Effect Size of $w = .349$ (Cohen, 1990) rendering a minimal sample size of 90. This researcher chose an alpha of .10 in order to accommodate the size of the accessible population.

Due to the limited number of laparoscopic cholecystectomy patients that received an intraoperative prophylactic antiemetic in the classification of 5-HT3 blocking agents, particularly, granisetron hydrochloride (Kytril) IV intraoperatively, the total population of patients that received this intervention was examined. A non-experimental, comparative design was used to analyze the retrospective data for patients who did not receive an intraoperative IV prophylactic antiemetic for the same surgical procedure.

Procedure

Following approval of the Institutional Review Board at Florida State University, and the Institutional Review Board of the selected hospital, the following procedures were employed.

A granisetron hydrochloride (Kytril) utilization report and a list of the adult patients who had a laparoscopic cholecystectomy was obtained from the Pharmacy department. A computer-generated sample was then obtained for patients who had a laparoscopic cholecystectomy, as an outpatient or inpatient, and either did, or did not, receive granisetron hydrochloride (Kytril) IV intraoperatively, with January, 2002, as the start date. A list of approximately 600 cholecystectomy patients was generated through
this process. Then, a matched sampling of these patients, was obtained for review. Next, every seventh patient was selected from this listing starting with the first name on the list. This resulted in a list of 86 laparoscopic cholecystectomy patients, excluding those who had received granisetron hydrochloride (Kytril), who had this surgical procedure during the specified time frame. There were a total of 30 laparoscopic cholecystectomy patients that received granisetron hydrochloride (Kytril) IV intraoperatively during the specified time frame. This resulted in a list of 116 charts. There were a total of 19 patients that met exclusionary criteria and, therefore, were removed from the medical review listing, resulting in a total of 97 charts reviewed by this researcher. Those patients who met exclusionary criteria included five patients who developed a postoperative infection; seven were identified as having dementia; two were diagnosed with aspiration pneumonia postoperatively; four were diagnosed with a comorbidity postoperatively; and one was under the age of 18 years.

The medical record for each subject was audited using the DPDF. The data that were collected included demographic information, preoperative, intraoperative, and postoperative factors influencing a subject’s risk of nausea and vomiting. Demographic data included patient age, gender, height, and weight. Also, each medical record review assessed postanesthesia care unit (PACU) length of stay, hospital length of stay, the occurrence of nausea and/or vomiting during the first 24 hours postoperatively, and any postoperative complications.

Instrument

A Demographic and Postoperative Data Form (DPDF) was utilized for data collection in this study (Appendix A). This form, created by the investigator, was used to collect demographic and postoperative assessment data on laparoscopic cholecystectomy patients. Since it served only to organize extracted data for eight variables and was used for a small scale study, no validity or reliability studies were required. If this had been a large scale study, then establishing a congruency statistic or inter-rater reliability measure would have been justified. Due to the brevity of the instrument, it is reasonable to assume that the instrument is valid.
Protection of Human Subjects

Before any data were collected, the researcher sought approval from the Institutional Review Boards at both Florida State University and the selected hospital. The researcher obtained, from the selected hospital, an a priori waiver from HIPAA regulations. Once approved, the researcher looked at the medical records of patients meeting the inclusionary criteria for this study. All data collected from the medical records will be kept confidential, to the extent allowed by law. All confidential information will be treated and respected according to the guidelines of Florida State University and the selected hospital. The subjects’ names were not recorded by the nurse researcher. Subjects were assigned a code number by the researcher, in lieu of their name, on the DPDF. There was no contact with any subject included in this study. The original records did not leave the medical records department of the selected hospital. The completed data forms will be secured in a locked file cabinet in the investigator’s home following data collection until January, 2010, at which time the data forms will be destroyed through a shredding process. Data will not be viewed by anyone except the investigator and the statistical consultant. Also, any information which may reveal the identity of the subjects has been excluded from reports, presentations, or publications that may result from the data collected for this study.

Data Analysis

The analyses utilized for this study are presented according to the research questions.

Research Question One

Research question one inquired of the demographic characteristics of the patients used for this study. Descriptive statistics were used to summarize the demographic factors. The description used measures of central location, dispersion, association, and skew that are appropriate, given the nature of the variables and data to be analyzed. For the demographic variables that are continuous and interval in scale, the mean and median were used for central location and the standard deviation and range were used for spread. Frequencies, cumulative frequencies, and skew were used for the distributional properties of data. Discrete variables were analyzed using frequencies and percentages.
Research Question Two

Research question two examined the nature of the association between patient risk factors and the onset of PONV. To answer this question a Pearson Product Moment Correlation Coefficient (PPM) was used for variables that are continuous and interval in scale and for which linearity can be reasonably assumed. The Point-Biserial correlation coefficient was used to estimate the degree of relationship between two variables, one of which is continuous and interval in scale and the other, discrete and dichotomous. Finally, associations between variables, both of which are discrete, were estimated with contingency coefficients.

Research Question Three

Research question three examined the effectiveness of 5-HT3 serotonin receptor antagonists, particularly, granisetron hydrochloride (Kytril), given IV intraoperatively, on PONV for patients receiving laparoscopic cholecystectomy. To answer this question the difference in the frequencies of PONV for the two groups, those who received a 5-HT3 serotonin receptor antagonist intraoperatively and those who did not, were compared inferentially utilizing a Fisher Exact Test (Chi Square analysis with one degree of freedom). The Chi Square statistic is a nonparametric procedure used to test if the differences between the observed and expected frequencies are large enough to warrant rejection of the Null Hypothesis.

H₀: A 5-HT3 serotonin receptor antagonist, particularly, granisetron hydrochloride (Kytril), is ineffective in decreasing the frequency of PONV for patients receiving granisetron hydrochloride (Kytril) intraoperatively. The analytical interpretation of this null is that: the two samples of PONV frequencies are selected from the same population.

Hₐ: A 5-HT3 serotonin receptor antagonist, particularly, granisetron hydrochloride (Kytril), is effective in decreasing the frequency of PONV in all patients receiving a laparoscopic cholecystectomy who received this medication intraoperatively. The analytical interpretation of this alternate hypothesis is that: the two samples of PONV frequencies are selected from different populations.
**Statistical assumptions**

To test the null hypothesis that two samples were selected from identically distributed populations of frequencies of success (prevention of PONV) with a 2x2 Contingency Table, the assumptions were:

1. The observations are independent (Intra-sample Independence).
2. The categories/classifications into which the data were placed are mutually exclusive and exhaustive.
3. The scale of measurement for the data is at least nominal (Brewer & Workman, 2003).

This researcher can provide some comfort to the reader with the first assumption, that the two target populations were independent of one another in the sense that they were both of an infinitely large population, but were selected from two distinctly different accessible populations, those who did, and those who did not, receive an intraoperative prophylactic 5-HT3 blocking agent. This selection process also provides comfort that each classification for data was exclusive and that the measurement of data was nominal in scale. In other words, data examined had one of two possible scores when measured.

**Summary**

This chapter discussed the research design, setting, population, instrument used, procedure, protection of human subjects, and data analysis. A retrospective, non-experimental, comparative design was used to investigate whether the administration of granisetron hydrochloride (Kytril) IV intraoperatively was effective in preventing PONV. Data consisted of information obtained from a medical record review of two distinct groups of patients, during the specified time frame, at the selected hospital. Both patient groups included patients who had a laparoscopic cholecystectomy, were 18 years of age or older, oriented to person, place, time, and situation, and had the ability to report the occurrence of PONV. The total population of patients receiving an intraoperative IV prophylactic antiemetic in the classification of 5-HT3 blocking agents, particularly, granisetron hydrochloride (Kytril) IV was reviewed. Also, a matched random selection of medical records was reviewed for cholecystectomy patients who did not receive an IV intraoperative 5-HT3 blocking agent. The association between patient risk factors and the onset of PONV was examined. A comparison was made between the two populations.
on the incidence of PONV in order to assess the effectiveness of a 5-HT3 serotonin receptor antagonist, particularly, granisetron hydrochloride (Kytril), in preventing PONV. Additionally, the demographic characteristics of the patients were examined.

Chapter 4 will present the results of the data analyses. Tables will be provided for comparisons between the two data groups and the findings will be interpreted.
CHAPTER 4
RESULTS

Introduction

This non-experimental, comparative study utilized retrospective data to investigate the effectiveness of an intraoperatively administered 5-HT3 serotonin receptor antagonist, particularly granisetron hydrochloride (Kytril), on postoperative nausea and vomiting (PONV) for patients who had received a laparoscopic cholecystectomy. Demographic characteristics and the association between patient risk factors and the onset of PONV were also of interest to the researcher. Betty Neuman’s Systems Model (1995) and the Physiology of nausea (Islam & Jain, 2004) guided the investigation. The purpose of this chapter is to present and interpret the statistical findings with respect to each research question.

Patient Characteristics

Research Question One

The first research question inquired of the demographic and other descriptive characteristics of the patients whose charts were sampled for this study. The descriptive data obtained from the patient charts included age, gender, height, weight, post anesthesia unit (PACU) length of stay, hospital length of stay, and whether the individual was admitted as an inpatient or an outpatient. The height and weight were used to calculate a Body Mass Index (BMI) for each patient. A total of 116 patient charts, in the designated time frame, who had laparoscopic cholecystectomies during the specified time frame were reviewed for this study. Following elimination of charts that did not meet inclusionary criteria, 97 patient charts were selected and compiled the total number of cholecystectomy patients who received the 5-HT3 serotonin receptor antagonist, granisetron hydrochloride (Kytril) as well as a matched random selection of cholecystectomy patients who did not, from a total of 86, during the specified time frame.
Patients were predominantly female ($n = 73, 75.3\%$) and had a median age of 53.6 years ($\text{Mean} = 50, \text{SD} = 16.05$). The patients ranged in age from 19 to 86 with 75% being 40 years of age or older and 25%, 60 years of age or older. Table 4.1 provides descriptive statistics for the continuous variables selected to describe the patient characteristics.

<table>
<thead>
<tr>
<th>Table 4.1</th>
<th>Descriptive Statistics for Patient Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>Weight</td>
</tr>
<tr>
<td>Mean</td>
<td>50</td>
</tr>
<tr>
<td>Median</td>
<td>49.0</td>
</tr>
<tr>
<td>Standard Dev.</td>
<td>16.05</td>
</tr>
<tr>
<td>Skew</td>
<td>.239</td>
</tr>
<tr>
<td>Minimum</td>
<td>19</td>
</tr>
<tr>
<td>Maximum</td>
<td>86</td>
</tr>
<tr>
<td>Range</td>
<td>67</td>
</tr>
</tbody>
</table>

With regards to age, 3.1% of the total sample had an age of 21 years or younger, with one patient being 19 years of age. Also, 24.7% of the total sample were 60 years of age or older. With regards to BMI, 39.6% of the total sample had a BMI of 30 or greater, with one patient with a weight of 324. PACU LOS revealed one patient with a LOS of 7.08 hours, this was due to the patient’s remaining in the PACU until he was discharged from the hospital as an outpatient. Hospital length of stay revealed one patient with a LOS of 225.83 hours; this was due to treatment of comorbidities of this patient during hospitalization.

This study consisted of two samples. One included patients that received prophylactic 5-HT3 serotonin receptor antagonist antiemetic therapy intraoperatively and the second included those patients who did not. During the collection of these data, it was found that the patients who received a 5-HT3 serotonin receptor antagonist not only received granisetron hydrochloride (Kytril) ($n = 26, 26.8\%$), but some received dolasetron myselate (Anzemet), ($n = 20, 20.6\%$) which is one of three medications in the same classification and used for the same purpose as granisetron hydrochloride (Kytril). Those who received granisetron hydrochloride (Kytril) were administered 0.1 mg IV (one-tenth of the recommended dose on the scale of recommended dosage) intraoperatively, whereas those who received dolasetron myselate (Anzement) were administered 12.5 mg IV (the initial dose on the scale of recommended dosage).
intraoperatively. Dolasetron myselate (Anzemet) is a 5-HT3 serotonin receptor blocking agent, which matches granisetron hyrdochloride (Kytril), therefore, when given for the same purpose, the group of patients who received dolasetron myselate (Anzemet) were considered in the same way as the granisetron hydrochloride (Kytril) group. Thus, the evaluation of the statistical findings for those who received a 5-HT3 serotonin receptor antagonist included those patients who received granisetron hydrochloride (Kytril), as well as those who received dolasetron myselate (Anzemet). Table 4.2 provides descriptive statistics for the comparative groups examined.

A total of 46 patients received a prophylactic antiemetic intraoperatively. They were predominantly female \( (n = 37, 50.7\%) \), and had a median age of 47 \( (\text{Mean} = 49, SD = 15.98) \). The patients ranged in age from 21 to 85 years and had a median BMI of 28.66 \( (\text{Mean} = 30.25, SD = 7.18) \). They had a median PACU LOS of 1.41 hours \( (\text{Mean} = 1.71, SD = 1.31) \) and a median hospital LOS of 28.17 hours \( (\text{Mean} = 42.93, SD = 36.66) \).

A total of 51 patients did not receive a prophylactic antiemetic intraoperatively. They were predominantly female \( (n = 36, 49.3\%) \), and had a median age of 50 \( (\text{Mean} = 50, SD = 15.97) \). The patients ranged in age from 19 to 86 years and had a median BMI of 29.22 \( (\text{Mean} = 31.07, SD = 6.27) \). They had a median PACU LOS of 1.20 hours \( (\text{Mean} = 1.29, SD = 0.45) \) and a median hospital LOS of 12.08 hours \( (\text{Mean} = 34.69, SD = 35.65) \).

There were a total of 44 inpatient medical records reviewed. They were predominantly female \( (n = 26, 59.1\%) \) and had a median age of 53.5 \( (\text{Mean} = 53.27, SD = 18.31) \). Inpatients ranged in age from 19 to 86 and had a median BMI of 27.53 \( (\text{Mean} = 29.42, SD = 5.84) \). They had a median PACU length of stay (LOS) of 1.25 hours \( (\text{Mean} = 96.62, SD = 49.19) \) and a median hospital LOS of 66.75 hours \( (\text{Mean} = 70.41, SD = 33.27) \).

A total of 53 outpatient medical records were reviewed. Patients in this group were also predominantly female also \( (n = 47, 88.7\%) \) and had a median age of 46.0 \( (\text{Mean} = 47.23, SD = 13.30) \). Outpatients ranged in age from 21 to 76 and had a median BMI of 29.69 \( (\text{Mean} = 31.65, SD = 7.20) \). They had a median PACU LOS of 1.16 hours \( (\text{Mean} = 1.41, SD = 1.10) \) and a median hospital LOS of 10.58 hours \( (\text{Mean} = 13.78, SD = 7.39) \).
Table 4.2 Descriptives by Comparison Group

<table>
<thead>
<tr>
<th></th>
<th>Prophylactic Antiemetic given</th>
<th>No Prophylactic Antiemetic given</th>
<th>Total Sample n = 97</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yrs)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median</td>
<td>47</td>
<td>50</td>
<td>49.00</td>
</tr>
<tr>
<td>Mean</td>
<td>49</td>
<td>50</td>
<td>50</td>
</tr>
<tr>
<td>Standard Dev.</td>
<td>15.98</td>
<td>15.97</td>
<td>16.05</td>
</tr>
<tr>
<td>Minimum</td>
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</tr>
<tr>
<td>Maximum</td>
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</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Males</td>
<td>37.5</td>
<td>62.5</td>
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</tr>
<tr>
<td>Females</td>
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<td>BMI</td>
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<tr>
<td>Median</td>
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<tr>
<td>Mean</td>
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</tr>
<tr>
<td>Standard Dev.</td>
<td>7.18</td>
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<tr>
<td>Minimum</td>
<td>17.36</td>
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<td>Maximum</td>
<td>55.61</td>
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</tr>
<tr>
<td>PACU Length of Stay (hrs)</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Median</td>
<td>1.41</td>
<td>1.20</td>
<td>1.25</td>
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<tr>
<td>Mean</td>
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<tr>
<td>Standard Dev.</td>
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<tr>
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<td>0.33</td>
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<tr>
<td>Maximum</td>
<td>7.08</td>
<td>2.50</td>
<td>7.08</td>
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<tr>
<td>Hospital Length of Stay (hrs)</td>
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<tr>
<td>Median</td>
<td>28.17</td>
<td>12.08</td>
<td>25.58</td>
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<td>42.93</td>
<td>34.69</td>
<td>41.32</td>
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<tr>
<td>Standard Dev.</td>
<td>36.66</td>
<td>35.65</td>
<td>41.03</td>
</tr>
<tr>
<td>Minimum</td>
<td>6.33</td>
<td>5.55</td>
<td>5.55</td>
</tr>
<tr>
<td>Maximum</td>
<td>152.00</td>
<td>125.65</td>
<td>225.83</td>
</tr>
</tbody>
</table>

Research Question Two

Research question two examined the association between patient risk factors and the onset of PONV. Point-Biserial correlation coefficients were used to calculate the degree of relationship between two variables, one being continuous and interval in scale (age & BMI), while the other was discrete and dichotomous (PONV). Also, contingency coefficients were used to estimate the associations between discrete variables (gender, patient type, & PONV). Table 4.3 provides Point Biserial correlations for PONV and various risk factors.
Table 4.3 displays whether or not continuous variables had a positive or negative correlation with one another. Also, contingency coefficients are provided for gender and patient type (inpatient/outpatient). The samples were virtually identical with regard to the risk factors, on which the samples were matched. The samples were tested for significant differences with regards to risk factors and none of them tested significantly, with the exception of the correlation between PONV and PACU LOS (Point Bi-serial correlation = .640, \( p = .213 \)). There was one patient that was a potential outlier, whose extreme results may have skewed the relationship Pearson correlation between these two variables.

**Table 4.3 Associations between Patient Characteristics and PONV w/in 24 hrs.**

<table>
<thead>
<tr>
<th></th>
<th>PONV w/in 24hr</th>
<th>Age</th>
<th>BMI</th>
<th>PACU LOS (hrs)</th>
<th>Hospital LOS (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PONV w/in 24hr</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Point Bi-serial Correlation</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sig. (2-tailed)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>97</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Point Bi-serial Correlation</td>
<td>.759</td>
<td>.1</td>
<td>.388</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sig. (2-tailed)</td>
<td></td>
<td>.844</td>
<td>.025</td>
<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>97</td>
<td>97</td>
<td>91</td>
<td></td>
<td>97</td>
</tr>
<tr>
<td>BMI</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Point Bi-serial Correlation</td>
<td>.988</td>
<td>-.235</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sig. (2-tailed)</td>
<td></td>
<td>.071</td>
<td>.025</td>
<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>91</td>
<td>91</td>
<td>91</td>
<td></td>
<td>97</td>
</tr>
<tr>
<td>PACU LOS (hrs)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Point Bi-serial Correlation</td>
<td>.640</td>
<td>-.020</td>
<td>.388</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Sig. (2-tailed)</td>
<td></td>
<td>.213</td>
<td>.849</td>
<td>.000</td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>97</td>
<td>97</td>
<td>97</td>
<td></td>
<td>97</td>
</tr>
<tr>
<td>Hospital LOS (hrs)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Point Bi-serial Correlation</td>
<td>.978</td>
<td>.269</td>
<td>-.113</td>
<td>.112</td>
<td>1</td>
</tr>
<tr>
<td>Sig. (2-tailed)</td>
<td></td>
<td>.148</td>
<td>.008</td>
<td>.286</td>
<td>.275</td>
</tr>
<tr>
<td>n</td>
<td>97</td>
<td>97</td>
<td>91</td>
<td>97</td>
<td>97</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pt. Type</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>In/Out Patient</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contingency Coefficient</td>
<td>.036</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contingency Coefficient</td>
<td>.092</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
The total sample \((n = 97)\) consisted of 24 males and 73 females. The sample included patients from inpatient \((n = 44)\) and outpatient \((n = 53)\) settings. Patients were matched on risk factors, including age, BMI, and patient type (inpatient or outpatient). Confounding variables were analyzed to assess their relationship to the occurrence of PONV. All patient characteristics were found not to have significance for confounding effects. Neither of the two groups, those who received a 5-HT3 serotonin receptor antagonist intraoperatively and those who did not, differed significantly with respect to any of the patient characteristics other than PACU LOS \((p = .047)\).

In relation to the difference between those who received a 5-HT3 serotonin receptor antagonist intraoperatively and those that did not with respect to patient type (inpatient or outpatient), there was no difference observed (contingency coefficient = .006, \(p = .956)\). Likewise, despite the fact that there are differences between patient type with respect to PONV, the difference was virtually uncorrelated with the dependent variable (contingency coefficient = .036, \(p = .726)\).

For ease of discussion, the data were sorted by those patients who had PONV and those who did not. A total of 57 patients reported PONV and included 15 (26.3%) patients that received granisetron hydrochloride (Kytril), 11 (19.3%) that received dolasetron myselate (Anzemet), and 31 (54.4%) that received no intraoperative prophylactic. These patients were predominantly female \((n = 41, 71.9\%)\) and had a median age of 48 years \((\text{Mean} = 50, SD=15.07)\). Patients with PONV ranged in age from 20 to 86 and had a median BMI of 28.36 \((\text{Mean} = 29.65, SD = 5.39)\). They had a median PACU LOS of 1.33 hours \((\text{Mean} = 1.38, SD = .50)\) and a median hospital LOS of 25.58 hours \((\text{Mean} = 36.26, SD = 33.30)\).

A total of 40 patients did not report the occurrence of PONV and included 11 (27.5%) patients that received granisetron hydrochloride (Kytril), 9 (22.5%) that received dolasetron myselate (Anzemet), and 20 (50%) that received no intraoperative prophylactic intervention. These patients were predominantly female \((n = 32, 80.0\%)\) and had a median age of 53 years \((\text{Mean} = 51.02, SD=17.53)\). Patients without PONV ranged in age from 19 to 85 and had a median BMI of 31.94 \((\text{Mean} = 32.24, SD = 8.15)\). They had a median PACU LOS of 1.16 hours \((\text{Mean} = 1.63, SD = 1.36)\) and a median hospital LOS of 27.12 hours \((\text{Mean} = 48.54, SD = 49.61)\).
These two groups, those who had PONV and those who did not, were found to be virtually identical in regard to age, gender, BMI, PACU LOS, and hospital LOS. There was a 58.8% overall occurrence of PONV for the total sample.

Of the patients who received a 5-HT3 blocking agent ($n = 46$) intraoperatively, a total of 26 (45.6%) experienced PONV. These patients were predominantly female ($n = 19$) with a mean BMI of 30.69, with 44% of these patients having a BMI greater than 30. These patients ranged in age from 21 to 76 years.

Of the patients who did not receive a 5-HT3 blocking agent ($n = 51$) intraoperatively, a total of 31 (60.8%) experienced PONV. These patients were predominantly female ($n = 23$). Patients had a mean BMI of 29.72, with 31% of these patients having a BMI greater than 30. These patients ranged in age from 21 to 86 years.

Research Question Three

Research question three examined the effectiveness of a 5-HT3 serotonin receptor antagonist, particularly, granisetron hydrochloride (Kytril), given IV intraoperatively, on PONV for patients who received laparoscopic cholecystectomies. This is an inferential question and, due to the discrete nature of the dependent variable, a Fisher’s Exact test was conducted on the frequencies of those patients in each of the two groups who experienced PONV within 24 hours postoperatively. A Chi Square statistic, using a 2 x 2 contingency table, was used to test if the difference between the observed and expected frequencies was large enough to warrant rejection of the null hypothesis.

Of the total sample of 97 patients, 57 reported the occurrence of PONV ($n_A = 26$, $n_{NA} = 31$). The percentage of patients with PONV by medication group (antiemetic, no antiemetic) was calculated. This researcher found that of those patients who received a intraoperative IV 5-HT3 blocking agent, 60.8% experienced PONV. Whereas, 56.5% of the patients, who did not receive a 5-HT3 blocking agent IV intraoperatively, experienced PONV. Table 4.4 displays the cross-tabulation of PONV for those patients who did and did not receive a 5-HT3 serotonin receptor antagonist intraoperatively.

The null hypothesis for the Fisher’s Exact test of the frequencies in Table 4.5 is: $H_0$: 5-HT3 serotonin receptor antagonists given IV intraoperatively, particularly granisetron hydrochloride (Kytril) are ineffective in decreasing the frequency of PONV
for patients receiving a laparoscopic cholecystectomy. The alternate hypothesis, is by necessity, non-directional and states that granisetron hydrochloride (Kytril) is, in fact,

Table 4.4 Cross-tabulation of PONV and Comparison Groups

<table>
<thead>
<tr>
<th>P/O NV w/in 24hr</th>
<th>No Antiemetic</th>
<th>Antiemetic</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Count</td>
<td>20</td>
<td>20</td>
<td>40</td>
</tr>
<tr>
<td>% with PONV</td>
<td>50.0%</td>
<td>50.0%</td>
<td>100.0%</td>
</tr>
<tr>
<td>% within Group</td>
<td>39.2%</td>
<td>43.5%</td>
<td>41.2%</td>
</tr>
<tr>
<td>Yes</td>
<td>31</td>
<td>26</td>
<td>57</td>
</tr>
<tr>
<td>Count</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>% with PONV</td>
<td>54.4%</td>
<td>45.6%</td>
<td>100.0%</td>
</tr>
<tr>
<td>% within Group</td>
<td>60.8%</td>
<td>56.5%</td>
<td>58.8%</td>
</tr>
<tr>
<td>Total</td>
<td>51</td>
<td>46</td>
<td>97</td>
</tr>
</tbody>
</table>

Table 4.5 Fisher’s Exact Test of the Frequency of PONV

<table>
<thead>
<tr>
<th>Fisher's Exact Test</th>
<th>Value</th>
<th>df</th>
<th>Exact Significance (2-sided)</th>
<th>Exact Significance (1-sided)</th>
</tr>
</thead>
<tbody>
<tr>
<td>df</td>
<td>1</td>
<td></td>
<td>.685</td>
<td>.413</td>
</tr>
<tr>
<td>Contingency Coefficient</td>
<td>.043</td>
<td></td>
<td></td>
<td>.670</td>
</tr>
<tr>
<td>n of Valid Cases</td>
<td>97</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Conclusions

The following conclusion was drawn from the analysis of data:

1. Due to the hospital’s policy to administer the minimal dosage (0.1 mg) of granisetron hydrochloride (Kytril) IV intraoperatively, its effectiveness was destined to be less than comparable in regards to dolasetron myselate (Anzemet) and the non-medication group of patients. And yet, as demonstrated by the data, the evidence suggests that the granisetron hydrochloride (Kytril) group did as well as the dolasetron myselate (Anzemet) group with one-tenth of the recommended dose.

Summary

This study provided statistical findings to describe demographic information related to the samples of cholecystectomy patients studied. Differences regarding PONV were assessed for those patients, who either received a 5-HT3 serotonin receptor antagonist, particularly granisetron hydrochloride (Kytril), and those who did not. Risk factors and their influence on PONV were evaluated for the samples studied. Also, the relationship between PONV and various variables were examined. As a result of these findings, the typical laparoscopic cholecystectomy patient experiencing PONV was identified as mostly females with a mean age of 50 years and a mean BMI of 29.65. A discussion of factors that could have had an effect on the outcomes of this study will be discussed in Chapter 5.
CHAPTER 5
DISCUSSION

The purpose of this study was to determine the effectiveness of an intraoperatively administered 5-HT3 serotonin receptor antagonist, particularly, granisetron hydrochloride (Kytril), on PONV for patients who received a laparoscopic cholecystectomy. The actual risk of PONV depends on various factors, including age, gender, and BMI (Nutley, 2000). Medications used to treat PONV, called rescue antiemetics, are typically given after surgery when a patient begins to experience nausea and/or vomiting. There have been recent studies examining the use and administration of antiemetics while patients are undergoing surgical procedures in order to prevent the occurrence of PONV (Shaitoh & Tanaka, 2000; Quaynor & Raeder, 2002; Stadler & Bardiau, 2003; and Rajeeva, Bhardwaj, Batra & Dhaliwal, 1999).

Cost prohibits the indiscriminant use of such antiemetics, making the careful selection of appropriate candidates who receive this intervention essential. The prevention of PONV assists in the reduction of a patient’s length of stay in an acute care setting. A shortened hospital stay is financially beneficial for both surgical patients and acute care settings. Patients are able to return to their daily activities, while acute care settings are able to utilize vacant hospital beds for other patients.

This chapter includes discussion related to the findings in this study and comparison to the literature. The theoretical framework utilized for this study is discussed along with examining whether or not it did or did not work in the context of this study. Limitations of the study are discussed, as well as implications and recommendations for nursing practice, nursing education, nursing administration, and recommendations for future nursing research.
Findings Related to the Literature

The literature reviewed and presented for this study included findings and recommendations related to prevention and treatment of PONV. Based on the literature, 28 to 83% of laparoscopic cholecystectomy patients experience PONV (Smith, 2000). This researcher found a 58.5% overall occurrence of PONV for the total sample in this study.

The total sample consisted of 97 laparoscopic cholecystectomy patients which were predominantly female (73). Based on the literature review, 20% of surgical patients under the age of 30 complain of PONV while 4% over the age of 30 complain of PONV (Papdimitriou & Livanios, 2001). This was not evident in this study. The mean age for the two surgical samples was found to be 50, with 75% of those who experienced PONV being over age 40. However, the literature included for review examined only those 43 years of age or younger. Thus, only 25% of this sample matches that which was found in the literature; therefore, age cannot be compared.

The literature reviewed also revealed, in a study of 3794 surgical patients, that women are at three times the risk of PONV than men (Watcha & White, 1998). Based on the review of 97 total medical records, 41 females had the occurrence of PONV, while 16 males had the occurrence of PONV, which demonstrates a similar ratio.

Smessaert, Schehr, and Artusio (1959) identified a positive correlation between body weight and PONV. Based on the findings of this study, patients’ BMIs ranged from 17.36 to 55.61. Of those patients who reported PONV, the mean BMI was 28.36, while those who did not experience PONV had a mean BMI of 31.94. The mean BMI for those patients who received a 5-HT3 blocking agent IV intraoperatively, and experienced PONV in spite of this, was 30.25, with the maximum BMI in this group being 55.61.

Upon analyzing the effectiveness of a 5-HT3 serotonin blocking agent, those with PONV had a mean BMI of 30.69, with 44% of these patients having a BMI greater than 30. Patients who did not receive a 5-HT3 blocking agent IV intraoperatively and experienced PONV, had a mean BMI of 29.72, with 31% of these patients having a BMI greater than 30. These BMIs were found to be larger than the average BMI for the population served by the selected hospital. The selected hospital serves a population that includes adults; of which, 20.5% are obese, with a BMI greater than 30. This difference
is likely due to the type of patient that requires cholecystectomy. The larger BMI of the sample used in this study may have confounded the effect of the 5-HT3 blocking agents. The reader is reminded that, in this study, there was a strong positive correlation found between BMI and PONV. Even though this correlation was not of statistical significance in this study, it assists in explaining that as BMI increases, so does PONV.

The results of this study correlate with the studies that have been cited, specifically related to gender and BMI. The benefits of preventing PONV is clearly apparent. Even though the administration of a 5-HT3 blocking agent, particularly, granisetron hydrochloride (Kytril), intraoperatively was not effective in the prevention of PONV for this surgical population, the study found that granisetron hydrochloride (Kytril) was effective in preventing PONV in patients more than when no prophylactic interventions were used. However, the difference was so small it was not of statistical significance, nor was it of clinical importance. Patients who received a 5-HT3 serotonin receptor antagonist, either granisetron hydrochloride (Kytril) or dolasetron myselate (Anzemet), had a lower incidence of PONV, when compared to patients who received no prophylactic intervention. The group of patients that received dolasetron myselate (Anzemet) were found to have a lower incidence of PONV than the granisetron hydrochloride (Kytril) group and the group that received no prophylactic intervention. However, the patients that received dolaseton myselate (Anzemet), were administered 12.5 mg IV intraoperatively, which is the recommended dose. Whereas, the patients that received granisetron hydrochloride (Kytril), were administered 0.1 mg IV intraoperatively, which is one-tenth the recommended dose (Cerenex pharmaceuticals, 1995).

Many variables identified in the literature as risk factors for PONV and indications for preventive intervention were supported by the findings of this study. Risk factors for PONV, which were supported by this study, include gender and obesity. The benefit of reducing the incidence of PONV is apparent. The high incidence of PONV identified for postoperative patients in this study illustrate how healthcare providers can improve quality of care for this population of patients. Due to the high incidence of PONV, patients experience a poor quality of care when health care providers do not effectively prevent this postoperative complication.
Betty Neuman’s Systems Model (1995) was used as a major portion of the framework for this study. Factors that may have impacted the outcomes of this postoperative sample during the selected study period include age, gender, and BMI. Neuman (1995) categorized factors, such as these, as intrapersonal factors. The patients who had a laparoscopic cholecystectomy surgical procedure encountered any or all of these factors. Intrapersonal factors that influence the response of PONV include age, gender, and obesity. PONV itself was viewed as the degree of reaction resulting from the stressor of the surgical procedure, anesthesia, and hospitalization.

PONV was the measured degree of reaction for this study. Primary prevention interventions were employed, the administration of a 5-HT3 serotonin receptor antagonist, particularly, granisetron hydrochloride (Kytril), IV intraoperatively was intended to allow the person to avoid nausea and vomiting, maintaining system stability. The primary focus of this study was on primary prevention through the administration of granisetron hydrochloride (Kytril) IV intraoperatively in order to prevent the occurrence of PONV. A secondary focus considered those who received another 5-HT3 serotonin receptor antagonist, dolasetron myselate (Anzemet) IV intraoperatively which has the same action as the focused drug. Of the total sample of 97 patient medical records reviewed for this study, 46 received the 5-HT3 serotonin receptor antagonists, with 26 receiving granisetron hydrochloride (Kytril) IV and 20 receiving dolasetron myselate (Anzemet) IV intraoperatively. Based on the expectation of interruption of the nausea and vomiting cascade by the primary intervention (prophylactic antiemetic), according to physiologic theory of nausea and vomiting, the researcher believed that these 46 patients would have either complete protection from the reaction or a reduced degree of reaction (PONV). Since the outcome was not prevention of PONV, except to a small degree, this would indicate to the researcher either the intrapersonal factors had a greater influence than anticipated, the intervention was not of adequate dose, or uncontrolled variables were intervening.

Secondary prevention interventions are aimed at the treatment of existing symptoms. The research hypothesis of this study was that a 5-HT3 serotonin receptor
antagonist, particularly, granisetron hydrochloride (Kytril) is effective at decreasing the frequency of PONV in all patients receiving laparoscopic cholecystectomies, who received this class of medication intraoperatively, during the first 24 hours postoperatively. Neuman (1995) advocated secondary prevention when a stressor penetrates normal lines of defense, to attain wellness through strengthening resistance, thus promoting reconstitution. Secondary prevention is used for wellness attainment, by protecting the basic structure through strengthening the internal lines of resistance (Neuman, 1995). Secondary prevention was not the primary focus of this study. However, the administration of rescue antiemetics as secondary prevention to treat PONV postoperatively occurred in the patients who did experience the degree of reaction.

The flexible line of defense, signified by the outer ring of Neuman’s model (1995), represents a protective buffer for preventing stressors from having an invasive effect on the client system. As Neuman (1995) implied, it is essential to strengthen the flexible lines of defense through primary prevention strategies in order to promote client wellness by stress prevention and reduction of risk factors through health promotion strategies (Fawcett & Neuman, 2002). The primary focus of this study was on primary prevention through the administration of 5-HT3 serotonin receptor antagonists, intended to promote wellness of the cholecystectomy patients. The flexible line of defense was drawn closer to the normal line of defense among the patients whose risk factors for PONV were high, indicating to the researcher very careful assessment of these factors must be done preoperatively, and interventions modified accordingly, or wellness promotion will not be effective.

Neuman’s model (1995) is concerned with stressors which disrupt system stability. Stressors are identified as possible risks to the body’s flexible and normal lines of defense. An individual’s degree of reaction to a stressor is dependent upon the time of occurrence of the stressor, the individual’s present and past condition, the nature and intensity of the stressor, and the amount of energy required by an individual’s adaptation to the stressor. The goal of this study, utilizing this model, was to promote optimal wellness of individuals through the maintenance and/or attainment of system stability.
with the prevention of PONV. Unfortunately, the primary prevention intervention was not so effective as expected and 31 of the 46 treated patients experienced nausea and vomiting anyway, requiring secondary interventions to strengthen their lines of resistance.

*Physiology of Nausea*

The physiology of nausea was also effective in guiding this study. For the purpose of this study, the stressor was identified as the acute episode of illness, along with anesthesia and surgery. The degree of reaction, postoperative nausea, results from the stimulation of the vomiting center, which controls and coordinates nausea and vomiting. This response is especially problematic for laparoscopic cholecystectomy patients and healthcare providers, and is observed in this study through occurrence of PONV.

Primary prevention strategies were an essential component in assisting the client to reconstitute and return to a level of stability. In this study, this was accomplished through the administration of a 5-HT3 serotonin receptor antagonist IV intraoperatively. This treatment regimen was implemented intraoperatively, prior to the stimulation of the vomiting center. The administration of 5-HT3 serotonin receptor antagonists was effective to an extent, as evidenced by the higher percentage of patients who were free from PONV in this group. Therefore, it is evident that prevention, using a 5-HT3 serotonin receptor antagonist, assisted with the sample’s ability to maintain, or return to, a level of stability. However, even though the blockade of the serotonin receptors prevents the nausea cascade, studies have determined the recommended dose (Cerenex pharmaceuticals, 1995), and in this study granisetron hydrochloride (Kytril) was given at a dose reduced by tenfold from the recommended dose, and was less likely to have an optimum preventive effect.

To contribute further to the development of advanced practice nursing, the investigator incorporated both models used in this study into what she visualized as the theoretical impact and treatment of laparoscopic cholecystectomy surgical patients in regards to PONV (See Figure 5.1). This framework was not fully supported by this researcher’s findings, though adding the influence of extrapersonal factors would improve it. The primary prevention intervention was clearly interfered with by
extrapersonal factors, such as cost of granisetron hydrochloride (Kytril), which may have dictated the dose, and hospital policies which removed the drug from the formulary before a large sample could be tested; all of these modified or prevented expected outcomes. As a result of the findings from this study, it is clear that the primary prevention interventions need to fit with each individual’s risk factors for PONV. When each of these factors are identified, such as age, gender, and BMI, a dosage range for antiemetics could be used for those with a high risk of PONV. This was not done for the patients included in this study. Those patients who did receive an intraoperative prophylactic antiemetic, either a lower than any recommended dose of granisetron hydrochloride (Kytril) or the minimal dose of dolasetron myselate (Anzemet), risk factors were not taken into consideration in predicting PONV (Goodin & Cunningham, 2002).

*Figure 5.1 Theoretical Impact and Treatment of Laparoscopic Cholecystectomy Patients and PONV*
Assumptions

The assumption that the sample adequately represents the targeted population was supported. Those patients who did, and those who did not, receive a 5-HT3 blocking agent intraoperatively were matched on the risk factors for PONV, which were age, gender, BMI, and type of surgery (laparoscopic cholecystectomy). This researcher relied on the accuracy of retrospective data contained in the inpatient and outpatient medical records. The assumption that the data obtained are accurate was neither supported nor unsupported by this study. The assumption that the nurse accurately administered and documented the use of the antiemetics can only be considered in light of the extreme care expected of all nurses in documenting precisely and accurately. Nurses are taught that if an assessment or intervention is not documented, it must be considered “not done.” The assumption that the nurse accurately assessed and documented each patient’s report of postoperative nausea was supported to the extent that there was some postoperative documentation of assessment of PONV on both the PACU and Nurses Notes within all the medical records reviewed.

Limitations

The limitations presented in Chapter 1 continue to be evident. This study was limited to patients admitted to an acute care hospital located in North Florida, with 657 inpatient acute beds, and approximately 300 laparoscopic cholecystectomies per year. This study was limited to laparoscopic cholecystectomy patients who met inclusionary criteria, which included those who had this surgical procedure during the specified time period. Another limitation related to the analysis of PONV. The time period assessed for patient report of PONV was 24 hours. This is a limitation due to the fact that the patient population consisted of both inpatients and outpatients; thus the outpatient population was not assessed for the full 24 hours following surgery for PONV. The data may not be applicable to different patient populations, lengthier or different surgical procedures or anesthetic techniques. A major limitation of this study was that it was designed to determine whether a dose-response relationship existed for granisetron hydrochloride (Kytril) IV intraoperatively and PONV when the dose was set a priori at 0.1 and PONV,
regardless of individual risks and characteristics. Also, another limitation of this study is the limited number of surgical patients who received this treatment, when a policy removed the drug from the formulary after only 30 patients had been included.

Implications for Nursing

The nurse is responsible for assuring that the needs of patients are recognized and addressed through coordination. In dealing with the collaborative problem of PONV, the nurse contributes nursing expertise to the decision-making process within the health care system. Applications of nursing roles are described as they relate to the problem of PONV in the surgical patient and the use of granisetron hydrochloride (Kytril).

The implications for nursing that result from this study include the emphasis for the need for accurate individualized assessment, treatment, and documentation of nausea and vomiting. The importance of preventing PONV cannot be overemphasized, as it clearly improves postoperative patient outcomes. Prevention of PONV also reduces a patient’s LOS, thereby reducing cost and disruption of the patient’s life and daily activities. In regards to healthcare providers, a patient’s LOS affects the stress nurses experience in acute care settings. With today’s nursing shortage, when patients have a longer LOS, nurses have an increased responsibility, especially when analyzed using nurse-patient ratios. In other words, there are fewer nurses to care for more patients.

Clinical Expert/Advanced Practiced Nurse

The advanced practice nurse maintains responsibility for making contributions to quality health care, particularly for vulnerable populations, such as individuals at risk for PONV. The intervention of the advanced practice nurse in the acute care setting, should be directed towards identifying gaps between the provision of health care and patient outcomes. Strategies should be employed, whereby protocols are developed that include standards of care supported by research and evidenced-based practices, which will ultimately enhance practice standards and improve patient care and outcomes (Snyder & Mirr, 1999). Advanced practice nurses should continue to broaden their knowledge base through research activities that will guide the practice of the health care team and should continue to identify key practice problems in the acute care setting.

There is always the assumed risk that complications may arise following surgical procedures. Nausea and vomiting are two complications reported after surgery. The
prevention of PONV not only increases patient satisfaction, but also provides cost-effective care (Watcha, Bras, Cieslak, & Pennett, 1995). While caring for patients, nurses are responsible for assuring that needs of patients are recognized and addressed. This is achieved through coordination with other health team members within the health care system (The American Society of Post Anesthesia Nurses, 1992).

*Advanced Practice Nurse Leader/Administrator*

Nurse administrators in the inpatient setting are ultimately responsible for ensuring positive patient outcomes. The primary focus of today’s health care providers is to deliver cost-effective care and ensure patient satisfaction. Nurse administrators have the duty and responsibility to empower and align with advanced practice nurses to research and consider the cost benefit of employing strategies to improve outcomes of the postoperative population, such as the utilization of case management. Case management of this patient population, has the potential to deliver safe, cost-effective care plans that have the capacity to support both the patient and clinical nurse in achieving optimal postoperative outcomes. Quality improvement studies will focus on areas that require interdisciplinary collaboration to improve standards of care and the strategies to be developed to meet benchmarks. Nurse administrators can be integral in shepherding protocols and order sets for physicians to adopt and follow for the purpose of providing research-based care in preventing PONV.

*Advanced Practice Nurse Educator*

Nurse educators have a critical role in regard to postoperative education. Their role is pivotal in raising the awareness and increasing the knowledge base regarding the impact of PONV on patient outcomes. Nursing curricula at the undergraduate and graduate level should incorporate the importance of primary, secondary, and tertiary prevention strategies in caring for postoperative patients in the outpatient and inpatient settings. Providing healthcare professionals with continuing education opportunities may result in improving the assessment, treatment, and documentation skills for this patient population. Since PONV impacts all postoperative areas of care, advanced practice nurses should be responsible for providing continuing education for patients at risk for PONV, those with an occurrence of PONV, as well as the health care providers for this patient population.
Recommendations for Future Research

Findings from this study indicate the need for future research studies. Further research is needed to add validity to these findings and for new questions to be posed.

A follow up study could examine a larger number of patients receiving 5-HT3 serotonin receptor antagonists, including granisetron hydrochloride (Kytril) and dolasetron myselate (Anzemet) intraoperatively, but the dosage for each should be individualized and based on published recommendations. Also, a larger number of patients identified as at-risk for PONV, such as those with a history of PONV or those undergoing other types of surgical procedures should be analyzed. Utilizing an experimental or quasi-experimental design, confounding variables could be better controlled, such as the type of anesthesia used, pain management medications, comorbidities, and length of surgery. The experimental group could receive granisetron hydrochloride (Kytril) and the control group could receive no intraoperative antiemetic. Further research could also analyze the effectiveness of different 5-HT3 serotonin receptor antagonists on PONV. Also, individuals trained to identify the occurrence and intensity of PONV could record observations in order to assure interreliability and accuracy of data. The implementation of new policies for the prophylactic treatment of PONV will require ongoing education for the nurses, physicians, and patients; therefore, educational studies need to be conducted. Also, ongoing assessment and review of surgical patients will be needed in order to ensure adherence to new policies. The findings from this study will be shared with the selected hospital along with the identified need that more research will need to be conducted in order to determine the effectiveness of 5-HT3 blocking agents for this surgical patient population.

Summary

The retrospective comparison of PONV for laparoscopic cholecystectomy patients revealed that those patients who received a 5-HT3 serotonin receptor antagonist, particularly, granisetron hydrochloride (Kytril), as well as dolasetron myselate (Anzemet) intraoperatively, had better outcomes than those who did not. With the continued need for laparoscopic cholecystectomy surgical procedures as the main treatment for acute and chronic cholecystitis, the effective assessment of risk factors for, and prevention of, PONV cannot be ignored by health care providers. Health care providers must be
proactive in the prevention of PONV. The occurrence of PONV delays the recovery of postoperative patients, reduces patient satisfaction, increases postoperative pain, prevents the adherence of pathway expectations, and affects the cost effectiveness of patient care. The surgical population is dependent on health care professionals to provide accurate and effective medical management. Health care professionals must be educated and empowered with the skill and knowledge of how to care appropriately for the surgical population in order to improve their postoperative outcomes.
APPENDIX A

DEMOGRAPHIC AND POSTOPERATIVE DATA FORM (DPDF)
APPENDIX B

A PRIORI WAVIER LETTER
August 31, 2004

To Whom It May Concern:

I would like to take this opportunity to communicate our support of the thesis titled, *Prevention of Postoperative Nausea*, being conducted by Susie Chuites, BSN, RN, a graduate student at Florida State University. Upon approval by the Institutional Review Board at both Florida State University and Tallahassee Memorial HealthCare, Ms. Chuites will have access to post surgical patient charts to conduct the necessary retrospective chart reviews.

We are happy to be able to support the research efforts and initiatives of the graduate students at Florida State University.

Sincerely,

Marsha Player, MSN, ARNP
Executive Director of Case Management
Tallahassee Memorial HealthCare
850-431-2360
marsha.player@tmh.org
APPENDIX C

FLORIDA STATE UNIVERSITY

INSTITUTIONAL REVIEW BOARD APPROVAL LETTER
Office of the Vice President For Research
Human Subjects Committee
Tallahassee, Florida 32306-2763
(850) 644-8673 · FAX (850) 644-4392

APPROVAL MEMORANDUM

Date: 9/23/2004

To:
Susie Chuites
1549-1 Coombs Drive
Tallahassee, FL 32308

Dept.: NURSING

From: John Tomkowiak, Chair

Re: Use of Human Subjects in Research
Prevention of Postoperative Nausea

The forms that you submitted to this office in regard to the use of human subjects in the proposal referenced above have been reviewed by the Secretary, the Chair, and two members of the Human Subjects Committee. Your project is determined to be Exempt per 45 CFR § 46.110(b) 8 and has been approved by an accelerated review process.

The Human Subjects Committee has not evaluated your proposal for scientific merit, except to weigh the risk to the human participants and the aspects of the proposal related to potential risk and benefit. This approval does not replace any departmental or other approvals, which may be required.

If the project has not been completed by 9/22/2005 you must request renewed approval for continuation of the project.

You are advised that any change in protocol in this project must be approved by resubmission of the project to the Committee for approval. Also, the principal investigator must promptly report, in writing, any unexpected problems causing risks to research subjects or others.

By copy of this memorandum, the chairman of your department and/or your major professor is reminded that he/she is responsible for being informed concerning research projects involving human subjects in the department, and should review protocols of such investigations as often as needed to insure that the project is being conducted in compliance with our institution and with DHHS regulations.

This institution has an Assurance on file with the Office for Protection from Research Risks. The Assurance Number is IRB00000446.

Cc: Jeanne Flannery
HSC No. 2004.635
APPENDIX D

INSTITUTIONAL REVIEW BOARD APPROVAL LETTER
FROM THE SELECTED HOSPITAL
October 12, 2004

Susie Chuites, BSN, RN
1549-1 Coombs Dr.
Tallahassee, FL 32308

Dear Ms. Chuites:

I have reviewed your research proposal, “Evaluate the Effectiveness of Intraoperatively Administered Serotonin 5 HT3 Receptor Antagonists (Granisetron Hydrochloride [Kytril]) on Postoperative Nausea and Vomiting (PONV) for Patients Receiving Laparoscopic Cholecystectomy.”

This project meets the criteria for an Expedited Review and you may proceed with your study as soon as it is practical for you to do so.

At the completion of your study, please send a copy of your final paper to the Medical Staff Office at Tallahassee Memorial so that it may be summarized and presented to the Institutional Review Board of Tallahassee Memorial.

Sincerely,

Richard MacArthur, M.D., MS
VP/Chief Medical Officer
Administrative Liaison/IRB
REFERENCES


BIOGRAPHICAL SKETCH

Susie Chuites, BSN, RN is a 1997 graduate of Florida State University School of Nursing. She was born March 25, 1974 in Tallahassee, Florida and attended Leon High School. Upon graduating with a baccalaureate degree in nursing, she worked as a Clinical Nurse on the Angie Deeb Cancer Unit at Tallahassee Memorial Healthcare. She returned to Florida State University for her Masters degree in Nursing in 2000. She is currently still employed by Tallahassee Memorial Healthcare and is the Oncology Clinical Case Manager.