Doctor of Nursing Practice
Final Project
FINAL DRAFT

Preoperative Administration of Acetaminophen for Women Undergoing Hysterectomy Reducing Opioid Consumption in the Postoperative Setting

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PREOPERATIVE OFIRMEV

Date of Submission:

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Abstract

There has been increased attention to pain control as well as patient satisfaction following surgical procedures. The interest in pain control coupled with the growing opioid epidemic has prompted anesthesia providers to utilize protocols that consist of multimodal techniques during the perioperative period to reduce post-surgical pain and improve patient outcomes. The postoperative consumption of opioids among adult patients that received preemptive acetaminophen (Ofirmev) were compared to those that did not to determine the impact of preoperative analgesics. This pain management implementation was measured among female patients that underwent hysterectomies. The sample included 39 female patients that received a hysterectomy (laparoscopic or open). Among the patients studied, there was no clear reduction in postoperative pain medications for those that received preoperative acetaminophen (Ofirmev) as the sole adjunct compared to those that did not receive Ofirmev preoperatively. There was also no definitive decrease in the pain scores or time to first dose of medication in the postoperative period for patients that received Ofirmev compared to those that did not. Data trends prove there is a need for postoperative opioid dosing education among PACU nurses that are administering opioids. There needs to be additional studies with more participants and defined controls to determine the true impact of this new multimodal approach.

Keywords: Postoperative pain, preemptive analgesia, hysterectomy, acetaminophen, opioids, premedication, opioid-sparing effect

Introduction

As healthcare providers, we strive to improve the safety and quality of healthcare. Patients trust us to provide the best care possible, which has many components such as efficiency, patient centered care, and overall satisfaction. It is imperative that such practices now have support of evidence-based findings. Most patients who undergo surgical procedures experience acute postoperative pain, but evidence suggests that less than half report adequate postoperative pain relief (Johnson & Patel, 2019). Preemptive analgesia protocols have been reported to reduce pain scores, decrease opioid requirements, reduce morbidity, shorten length of hospital stays, and promote patient satisfaction. Local anesthetics, opioids, non-steroid anti-inflammatory drugs (NSAIDs) and acetaminophen are all drug groups that can be delivered individually or in combination to deliver a multimodal preemptive analgesia approach for the patient. This translational research project was selected due to lack of clinical studies that have been invested in pain management of gynecological procedures.

Background

Hysterectomy is the surgical removal of the uterus and sometimes the cervix and supporting tissues. It is the most common non-pregnancy-related major surgery performed on women in the United States, with one in three women having a hysterectomy by age 60 (IDPH, 2019). Although treatment of postoperative pain has improved due to a better understanding of acute pain physiology, there are many cases of severe acute pain following surgery. The concept

of preemptive analgesia is a technique that can be implemented preoperatively (within 24 hours of incision) with the goal of reducing pain prior to the painful stimulus with continued coverage through the postoperative period. This concept is achieved by suppressing the effects of central or peripheral sensitization (Herring et al., 2014). Preemptive analgesia protocols have been reported to reduce pain scores, decrease opioid requirements, reduce morbidity, shorten length of hospital) stays, and promote patient satisfaction. The results from this study will help to determine the best method of pain control perioperatively to decrease narcotic consumption and adverse events.

After consulting with the Perioperative Clinical Nurse Specialist (PCNS) and other team members involved in perioperative services at a central Indiana hospital, they concluded there were several clinical gaps regarding consistent practices that decrease opioid consumption during the perioperative period. With the progressive development of analgesics and multimodal approaches, the desired goal is to observe minimized pain in the women that received preemptive medication at the time of the hysterectomy. This project will focus on the administration of acetaminophen (Ofirmev) during the preoperative period for women undergoing hysterectomies (open or laparoscopic).

Problem Statement

This clinical project is relevant to nursing anesthesia practice in several ways. When a plan to implement change based on evidence is suggested, the site must feel confident in the individual providing published literature reviews and the collection of data from patients treated within the perioperative services unit. Other institutions claim patients have reported less pain in

the post-operative care unit (PACU), required minimal opioid administration, and shorter time to discharge when given acetaminophen prophylactically (Steinberg, et al, 2017). This evidence-based practice project will conduct a study of female patients undergoing hysterectomies (open or laparoscopic) to determine if preoperative administration of acetaminophen reduces opioid consumption during the postoperative care period.

Review of Literature

Recently, a strong interest in techniques incorporating multimodal analgesia have been explored by researchers. Acetaminophen (Ofirmev) is a non-opioid agent that is believed to act primarily on the central nervous system by cyclooxygenase-2 inhibition causing an elevation of the pain threshold (Ofirmev, 2019). Steinberg et al. (2017) conducted a systemic review that determined the preoperative multimodal approach allow drugs with different mechanisms of action to provide analgesia and reduce postoperative pain. Additionally, the results showed preemptive doses of acetaminophen in combination with other non-narcotic medications resulted in lower postoperative narcotic requirements. A retrospective study conducted by Herring et al. (2014) found intravenous (IV) acetaminophen usage resulted in a statistically significant 26% reduction in the amount of opioids used during the total perioperative period. Lirk, Thiry, and Bonnet (2019) published a systematic review focusing on pain management after laparoscopic hysterectomies after preoperative administration of acetaminophen and dexamethasone. Findings showed that reduced opioid consumption of the rescue analgesic (oxycodone) was lower in patients that received acetaminophen. Moon, Y., Lee, Y., Lee, J., and Moon, D. (2011) determined that premedication using 2 grams of IV acetaminophen reduced hydromorphone

consumption in patients undergoing abdominal hysterectomy but did not significantly reduce pain intensity. These results from the study might indicate that acetaminophen is less effective in the treatment of postoperative visceral pain compared to somatic pain. Blanton et al. (2017) concluded that the choice to use preoperative analgesics is often based on the financial impact postoperative pain interventions has on the organization. They suggest future research should focus on standardization among studies such as timing of medications, postoperative time points, and pain reporting scales to help develop clinical practice guidelines and recommendations.

Theoretical Framework

Utilizing evidence-based practice (EBP) in the clinical setting follows a systematic approach with specific criteria to guide, evaluate, and change current practices (White, Dudley-Brown, & Terhaar, 2016). EBP is built upon critical thinking, seeking best practices, and finding ways to implement a sustainable change. This project research design will follow the John Hopkins Nursing EBP (JHEBP) Model framework (Appendix A).

The JHNEPB model is a conceptual framework that was developed by an interprofessional team comprised of qualified nursing pioneers. The goal was to develop a practice model that assesses current evidence, translates it, and implements it to achieve a high level of quality care (White, Dudley-Brown, & Terhaar, 2016). The premise of combining education, research, and environment allow for thoughtful and swift implementation of practice changes. This model is ideal for this translational project because it incorporates a problem-solving approach to make clinical decisions from gathered scientific evidence. The JHNEPB

model has three distinct phases, which are known as the "PET" process, which stand for practice question, evidence, and translation.

The JHEBP model is great for this growing organization as it provides a framework that promotes high quality care and patient satisfaction. The goal for this project is to follow trends of those patients that are given acetaminophen (Ofirmev) preoperatively. It is suspected that these patients require less opioids post-operatively which leads to a quicker discharge times, reduced risk of hospital related complications, and higher patient satisfaction. This model also encourages the presence of a stakeholder, which is a Certified Registered Nurse Anesthetist (CRNA) at selected Indiana based hospital. The support of an academic committee and clinical practice mentor are imperative when conducting clinical site research as they will aid the researcher during the data collection and synthesis periods.

Goals, Objectives, and Expected Outcomes

The goal is to determine if the preoperative administration of acetaminophen decreases the need for postoperative opioid consumption by females undergoing hysterectomy. Currently, there is no evidence on whether preoperative analgesics decrease opioid consumption at this clinical site. Also, providers are not agreement if these extra measures improve patient outcomes. The intent of this project is to collect data that will provide evidence-based recommendations for management of postoperative pain. The target audience is a midwestern hospital of clinicians who manage pain during the perioperative period (advanced practice nurses or physicians).

Project Design

A retrospective chart review will be conducted and evaluated to determine the need for change in the perioperative setting. This will be a comparative study with patients who received acetaminophen (Ofirmev) preoperatively, then compared to others that do receive any preemptive analgesics. Data will be de-identified by the researcher and include quantitative information regarding operation type, preoperative acetaminophen administration, opioid consumption and type, and pain scores. Data collection will occur during the preoperative, intraoperative, and postoperative periods to ensure all essential information is captured.

Project Site Analysis

The selected central Indiana hospital is the largest of 6 nonprofit locations in the state's network. The main campus houses over 100 beds with 8 newly designed operating rooms servicing adult, obstetrics, pediatrics, and emergent cases. This translational approach to clinical practice was selected to implement at this facility due to their desire to decrease the prevalence of opioid dependence in the local community. This project addresses a clinical practice intervention that providers can consider if data yields results that improve patient outcomes.

Methods

The retrospective data search will be performed with the guidance of the PCNS and Institutional Review Board (IRB) Chair of the selected Indiana hospital. The data will be collected within a 60-day period from September 1, 2019- November 1, 2019. This is a retrospective chart review. The population size will be dependent upon the number of cases within the specified date range. Any females less than 18 years of age will be excluded. After initial data collection, results will be compiled utilizing graphs and opioid consumption trends. Following the synthesis period, findings will be disseminated to anesthesia providers and

perioperative associates involved in direct patient care. The goal is to establish the impact this preemptive analgesic method can have on improved patient outcomes for those undergoing hysterectomies at this hospital.

Measurement Instrument

The data query will be done via EPIC electronic medical record database with key search items to include: “hysterectomy”, “Main OR”, “female”, anticipating some minimal adjustments to narrow down the chance of ambiguous data. Each patient undergoing a hysterectomy (laparoscopic or open) will have several areas documented in a password protected Excel document. Key data points such as the administration of preoperative medications, type of opioid with total dose and time, as well as pain score will be captured using the Numeric Pain Rating Scale (NPRS) (Appendix C).

Data Collection

In detail, a retrospective chart review will be conducted from dates September 1, 2019 through November 1, 2019 (60-day period) for all hysterectomy procedures conducted in the operating room of the central Indiana hospital. Data will be collected via electronic medical record. Data will include patient age, procedure type, preoperative medications, intraoperative medications, postoperative opioids, postoperative pain score, and allergies. All data will be collected by researcher to be secured on a password protected computer. Patient names will be de-identified, only data to conduct the retrospective comparison study will be captured to adhere

and remain compliant with Health Insurance Portability and Accountability Act (HIPAA) regulations. The HIPAA Compliance Officer has approved the selected data collection methods.

Ethical Considerations

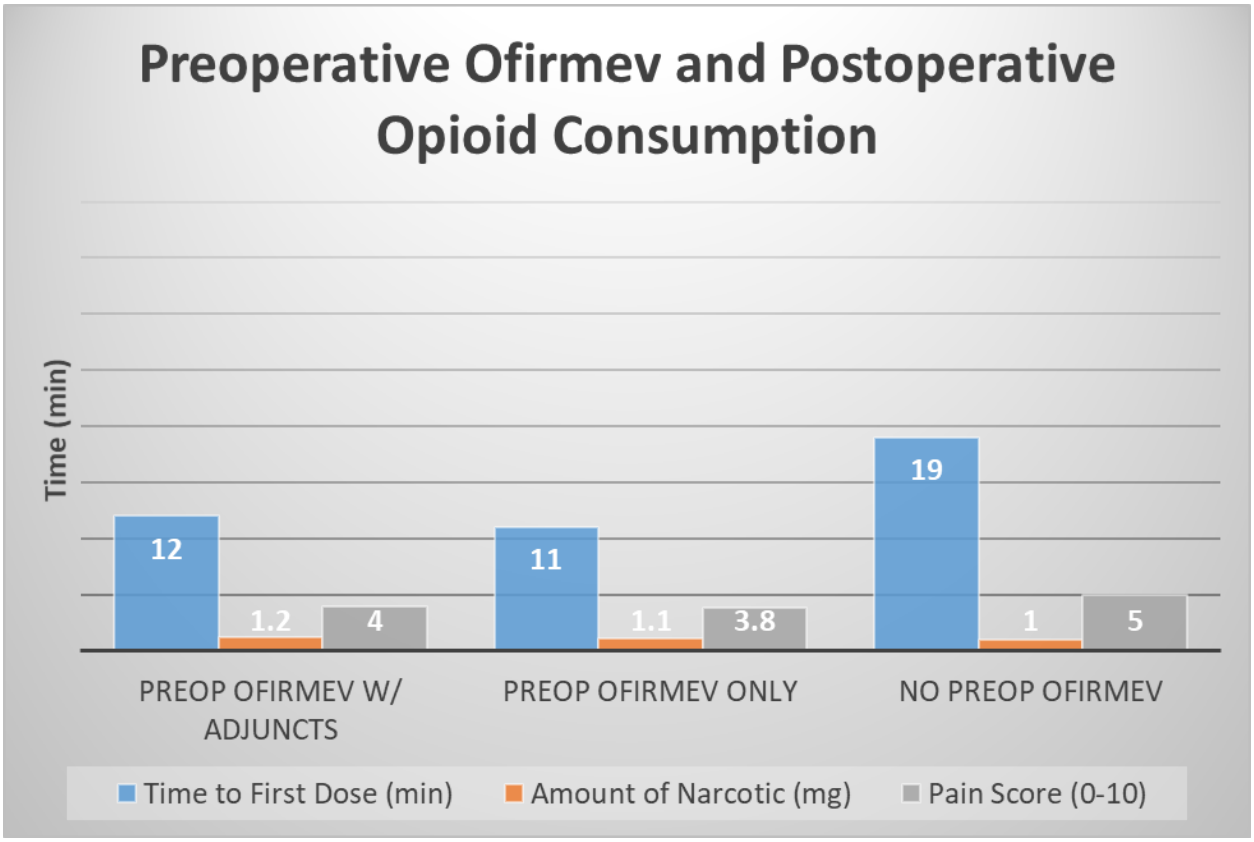
The central Indiana hospital has granted full access to internal data capture system after receiving Institutional Review Board (IRB) approval from both Marian University and the health care organization (Appendix B). There is no conflict of interest between the clinical site and Marian University. There will be no additional harm or risk placed upon subjects. To ensure the safety of private patient information, all data will be stored on a password protected computer only accessible to the researcher and IRB Chair upon request. The principal investigator, faculty chair, and clinical mentor will provide guidance throughout the duration of this clinical project.

Data Analysis and Results

Data was analyzed by comparison of medication administration, accompanied with a bar graph to show distribution of preoperative acetaminophen treatment, opioid consumption, time to first opioid dose, and pain scores (Table 1). Due to the small sample size, statistical analysis to determine probability of test results was performed. No patients were excluded from the study based on criteria. A total of 39 participants were included in the study with 12/39 not receiving preoperative Ofirmev, 3/39 receiving Ofirmev only, and 27/39 receiving Ofirmev preoperatively with other adjunct medications. A total of 25 participants received opioids during the postoperative period. Reported pain scores varied from 0-7 on the Numeric Pain Rating Scale (NPRS). Statistical analysis of the data determined there is no correlation between the administration of preoperative acetaminophen (Ofirmev) and the decrease of opioid

administration during the postoperative period resulting in rejection of the null hypothesis. This conclusion was determined based on an odds ratio of 1.0, 95% confidence interval of 0.68-4.92 and a p-value of 0.04.

Table 1



Limitations to this study included small sample size and inconsistent dosing of opioids in the postoperative setting based on pain scores. Future studies should have a much larger sample size and postoperative guidelines for opioid dosing based on a pain scale range. Another major limitation would be to have a larger control number that only received Ofirmev and no other preoperative medications to ensure reliability of results.

Conclusion

The opioid crisis remains a great challenge. The irrational use of opioids has led to excessive drug dependence and abuse resulting in increased mortality rate and huge economic costs in the United States. Approximately 80% of patients that undergo surgery receive opioid analgesics as the fundamental agent for pain relief (Zhao, Chen, Feng, H & Zhang, 2019). The purpose of this study was to determine if preoperative medications such as Ofirmev would minimize the amount of narcotics required during the postoperative period for women undergoing hysterectomies (open or laparoscopic). The sample size was extremely limited; thus it was difficult to determine if multimodal use of Ofirmev was effective in providing opioid sparing effects. The use of other adjunct medications and Ofirmev together made the data composite harder to assess for validity. Additional variables such as pain score and time to first dose of opioid also showed no direct correlation to the use of Ofirmev preoperatively in this population. The analysis of data determined there to be no statistical significance between the tested variables and rejection of the null hypothesis. These findings are based on actual administration of acetaminophen (Ofirmev), adjunct medications, and subjective pain score using NPRS (Appendix D). Based on the review of literature, there are positive outcomes by implementation of non-opioid medications. However, additional studies must be conducted to determine if Ofirmev as the sole agent is beneficial to women undergoing hysterectomies.

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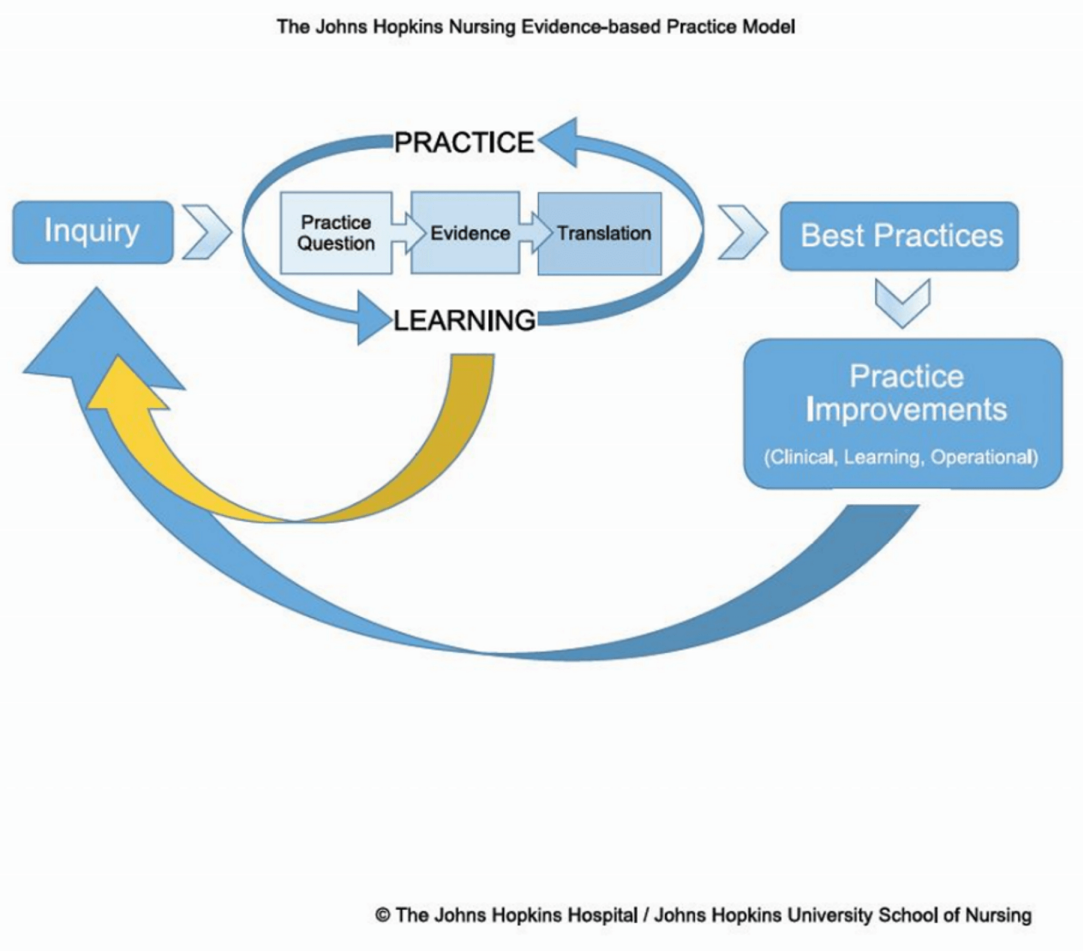
Appendix

Appendix A


The Johns Hopkins Nursing Evidence-based Practice Model
PRACTICE
Inquiry
Practice Question
Evidence
Translation
Best Practices
LEARNING
Practice Improvements
(Clinical, Learning, Operational)
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Appendix B

MARIAN UNIVERSITY
Indianapolis ®

Institutional Review Board

DATE:	October 18, 2019
TO:	Jasmine Kamran
FROM:	Marian University IRB
RE:	IRB Protocol # S19.058
TITLE:	Preoperative Administration of Acetaminophen for Women Undergoing Hysterectomy Reducing Opioid Consumption in the Postoperative Setting
SUBMISSION TYPE:	New Project
ACTION:	Determination of Exempt Status
DECISION DATE:	October 16, 2019

The Institutional Review Board at Marian University has reviewed your protocol and has determined the procedures proposed are appropriate for exemption per category 4, criterion iii of the federal regulations. As such, there will be no further review of your protocol and you are cleared to proceed with your project. The protocol will remain on file with the Marian University IRB as a matter of record.

It is the responsibility of the PI (and, if applicable, the faculty supervisor) to inform the IRB if the procedures presented in this protocol are to be modified or if problems related to human research participants arise in connection with this project. Any procedural modifications must be evaluated by the IRB before being implemented, as some modifications may change the review status of this project. Please contact the office of the Marian University Institutional Review Board at IRB@marian.edu if you are unsure whether your proposed modification requires review. Proposed modifications should be addressed in writing to the IRB. Please reference the above IRB protocol number in any communication to the IRB regarding this project.

Although researchers for exempt studies are not required to complete online CITI training for research involving human subjects, the IRB **recommends** that they do so, particularly as a learning exercise in the case of student researchers. Information on CITI training can be found on the IRB's web-site:
http://www.marian.edu/academics/institutional-review-board

Dr. Bryan Larsen, Chair, Marian University Institutional Review Board

Hendricks
Regional Health

CORPORATE OFFICES
1000 East Main Street
Danville, IN 46122
317.745.4451

Date: October 28, 2019

To: Marian University IRB

Regarding: IRB Protocol # S19.058
Preoperative Administration of Acetaminophen for Women Undergoing Hysterectomy Reducing Opioid Consumption in the Postoperative Setting
PI: Jasmine Kamran

The HRH IRB has reviewed the above study and has approved of the study entering the data collection phase at HRH. All Data will be de-identified and protected so that only the researcher has access

Thank You

Lynn Devich MSN, MBA, RN, ACNS-BC
Chair of HRH IRB

Appendix C

Numeric Pain Rating Scale (NPRS)