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An Evidence Based Educational Module on the Efficacy of Single-shot Intrathecal Morphine in Minimizing Postoperative Opioid Requirement in Abdominal Surgery Patients: A Quality Improvement Project

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ABSTRACT

Acute postoperative pain is a complex, physiological reaction to tissue injury. It remains a challenge for anesthesia providers and health care practitioners to create a balanced multimodal approach to treat it. Ineffective management such as undertreatment and overtreatment of postoperative pain leads to poor patient outcomes. Emerging as a favorable option in clinical practice is the use of Intrathecal Morphine (ITM) before induction of general anesthesia. It is a simpler and quicker neuraxial technique with a lower rate of failure. [1]

Morphine was the first opioid approved by the US Food and Drugs Administration (FDA) for spinal administration, and it is also the most common epidural opioid used.[1] ITM is now deemed by many as the gold-standard single-dose neuraxial opioid and is extensively used in the perioperative setting due to improved analgesia, greater duration of action, and dose-sparing effects compared with its administration via the systemic route.[1,2]

BACKGROUND

Introduction

Hospitalization often requires pain management for trauma-related injuries, for underlying conditions such as cancer or in the post-surgical setting. Moreover, evidence suggests that inadequate management of acute pain, which was recognized as an issue beginning in the 1990s, can progress to chronic pain.[6] Opioids provide effective dose-dependent pain relief with minimal toxic effects and can be administered via various delivery systems, including oral, parenteral, transdermal, epidural, and spinal.[2] However, there is an increasing report of errors in the acute postoperative pain management, prescribing, and inadequate monitoring of patients on opioid therapy leading to serious side effects and adverse events.[7] Despite guidelines recommending prudent prescribing and monitoring of hospitalized patients who are receiving

opioids, evidence suggests that patient safety risks persist, including over-sedation leading to respiratory depression and possible death. In addition, the widespread use in hospitals and discharging patients on opioids can lead to long-term use, misuse, and potential dependence and addiction.[6]

In response to the opioid crisis, the U.S. Department of Health and Human Services (HHS) is focusing its efforts on five major priorities [8]:

1. Improving access to treatment and recovery services
2. Promoting the use of overdose-reversing drugs
3. Strengthening our understanding of the epidemic through better public health surveillance
4. Providing support for cutting-edge research on pain and addiction
5. Advancing better practices for pain management

One of the interventions to advance better practices for pain management is the Enhanced Recovery After Surgery (ERAS) protocol. The ERAS protocol incorporated in most healthcare systems in the United States includes a personalized, safe, and effective pain management plan to help prevent opioid addiction, which is an ongoing public health crisis in the United States.[9] ERAS engages patients in their care before, during, and after their hospitalization.[9] ERAS also relies on collaborative care between all individuals involved in the patient's surgical journey, including anesthesiologists, rehabilitation therapists, nurses, and neurosurgeons, to improve clinical outcomes and optimize a safe recovery.[9] Various pain management techniques have been adopted since the advent of ERAS to address the reduction of opioid administration during the postoperative period. One of the techniques is the administration of single-shot intrathecal morphine.[10]

Problem Statement

Around 841,000 people have died since 1999 from a drug overdose. Moreover, in 2019, 70% of drug overdose deaths involved an opioid.[5] Opioids are substances that work in the body's nervous system or in specific receptors in the brain to reduce the intensity of pain. Overdose deaths involving opioids, including prescription opioids, heroin, and synthetic opioids (e.g., fentanyl), have increased exponentially from 1999 to 2019.[5]The misuse of and addiction to opioids, including prescription pain relievers, heroin, and synthetic opioids such as fentanyl, is a severe national crisis that significantly affects public health as well as social and economic welfare.[6]

The Centers for Disease Control and Prevention estimates that the total economic burden of prescription opioid misuse alone in the United States is $78.5 billion a year, including healthcare costs, lost productivity, addiction treatment, and criminal justice involvement.[7] The opioid epidemic in the United States has become a public health crisis with devastating consequences, including increases in opioid misuse and related overdoses and the rising incidence of neonatal abstinence syndrome due to opioid use and abuse during pregnancy.[7] The increase in injection drug use has also contributed to the spread of infectious diseases, including HIV and hepatitis C.[6]

Scope and Consequences of the Problem

The cost of opioid abuse is not confined to health care. Many experts have estimated the direct and indirect costs that the opioid epidemic imposes on our society. In addition to its devastating impact on families and communities, the opioid epidemic is costing the U.S. economy tens of billions, if not hundreds of billions, of dollars annually.[6] Several studies have provided more comprehensive estimates, including the workplace and criminal justice burdens

attributable to the opioid crisis.[6,7] Health economists Howard Birnbaum and Alan White estimated all three categories of costs to total $8.6 billion in 2001.[7] While policymakers look for ways to stem the opioid epidemic, economists have been offering valuable insights on the impact of the crisis on the macroeconomy.[7] For example, in 2017, Princeton economist Alan Krueger examined the relationship between opioid prescription rates per county and the decline in labor force participation, estimating that the opioid epidemic could be responsible for 20 percent of the decline in men's labor force participation. Goldman Sachs economists similarly concluded that the opioid epidemic is likely contributing to the decline in prime-age labor market participation. [5] Alex Hollingsworth and Kosali Simon from the University of Indiana and Christopher Ruhm from the University of Virginia found that higher unemployment rates at the county level are associated with higher opioid death rates and increased emergency room visits.[5]

An early 2011 analysis yielded an estimate of $53.4 billion in health care, workplace, and criminal justice costs associated with opioid abuse in 2006.[7] In 2016, CDC researchers incorporated the cost of lost productivity from premature deaths due to opioid overdoses, estimating the total economic impact of the opioid epidemic to be $78.5 billion in 2013.[7] At the local level, task forces have been established from New Hampshire to Alaska to understand the local impact and identify strategies for tackling the epidemic.[7] Outside of government, the American Medical Association (AMA), various medical specialty groups, and researchers at universities around the country are working to evaluate and develop policy interventions, treatment options, and medical alternatives.[3]

One of the treatment options that reported a significant decrease in opioid requirements, especially in the postoperative period, is the administration of single-shot intrathecal morphine. [8]A single dose of intrathecal morphine (ITM) has advantages for postoperative pain control. [8]

This approach is associated with improved quality of analgesia and decreased systemic opioid use compared with IV-PCA alone or intrathecal local anesthetics without morphine, thus minimizing the potential for renal toxicity, sedation, and respiratory depression. ITM has been effectively used to control postoperative pain due to abdominal surgery, prostatectomy, transurethral resection of the prostate, and hepatectomy.[8] Although the efficacy of ITM has been reported in many kinds of surgery, most healthcare systems in the United States have not incorporated its use as part of their pain management protocol.

Knowledge Gaps

Morphine is a drug commonly administered via the epidural or intrathecal route.[2] It is regarded by many as the gold-standard single-dose neuraxial opioid due to its postoperative analgesic efficacy and prolonged duration of action.[11] The discovery that opioid receptors are localized within lamina II of the dorsal horn in the CNS suggested that exogenous opioids could be administered via the neuraxial route to produce analgesia.[2] Many published reports of intrathecal and epidural morphine administration in humans have since been published, and in 1984 preservative-free morphine received US FDA approval for neuraxial administration.[11] Neuraxial morphine is now extensively used in the perioperative setting due to improved analgesia, greater duration of action, and dose-sparing effects compared with its administration via the systemic route.[12] Analgesia delivered via the neuraxial route lasts longer than the systemic route, with effects persisting 12–24 hours and longer following administration.[2] Recognized benefits of neuraxial opioids, when compared with intravenous administration, include better postoperative analgesia, increased functional ability, earlier ambulation, and earlier return of bowel function.[12] Furthermore, unlike with neuraxial local anesthetics, there is negligible motor, sensory or autonomic blockade associated with neuraxial opioids.[2] Neuraxial

morphine is now extensively used in the perioperative setting due to improved analgesia, greater duration of action, and dose-sparing effects compared with its administration via the systemic route.

Proposal Solution

This review aims to gather available evidence and appraise each study's results regarding the efficacy of single-shot intrathecal morphine in decreasing postoperative opioid use in patients undergoing abdominal surgery. The proposed solution of the research is that the findings will be incorporated in an evidence-based Enhanced Recovery after Surgery (ERAS) protocol. [8] Enhanced Recovery After Surgery (ERAS) refers to a patient-centered, evidence-based, multidisciplinary team-developed pathways for a surgical specialty and facility culture to minimize the patient's narcotic requirement, decrease surgical stress response, optimize their physiologic function, and facilitate recovery. [2] This study seeks to answer the PICO (i.e., patient population, intervention or issue of interest, comparison intervention or group, and outcome) question: In (P) Anesthesia providers taking care of patients requiring major abdominal surgery, (I) Intrathecal Morphine (ITM) Education Module (C) No ITM education module (O) Increase knowledge and implementation of ITM.

Theoretical Framework

The foremost step in a research project is framework development. As the quality improvement topic is selected, it is essential to recognize theories and frameworks to guide theoretical ideas into application.[13] A middle-range theory (MRT) framework will help conduct this scholarly project. The middle-range theory is characterized as a theory that exemplifies the connection among concepts to a specific situation which then can be implemented into clinical practice.[14]

Wilson et al., also stated that applying middle-range theories into research is easier because they are testable, less abstract, simple to understand, and can be incorporated into daily practice comprising assessments and interventions. One of the concepts in MRT is the theory of comfort for outcomes research.[14] The main idea of this theory is that healthcare professionals meet unmet needs in stressful situations.[14] The use of ITM is an evidence-based practice intervention to reduce postoperative pain. If the intervention is proven to enhance comfort, in comparison to baseline, it is deemed successful. Thus, sequential positive patient outcomes are directly related to patient satisfaction and, theoretically, how MRT is applied in this scholarly project.[14]

METHODOLOGY

Information Sources and Search Strategy

A systematic search for published full reports of randomized, controlled trials that compared a single intrathecal dose (with variation of doses) of morphine with epidural bupivacaine, a placebo subcutaneous injection of saline, or no treatment in patients undergoing major abdominal surgery under general anesthesia. Included in this search are studies published from 2006-2020, written in the English language, with full text availability. The databases employed for the search included The Cumulative Index to Nursing and Allied Health Literature (CINAHL), PubMed Central (PMC) and MEDLINE (ProQuest).

Four Randomized Control Trials (RCT) were included in the study, three RCTs were double blinded, one single blinded RCT and one with a placebo group. All studies included adult patients. RCTs were published between 2006 and 2020, with sample sizes ranging from 15 to 45 patients. Four different analgesic methods were assessed in comparison to intrathecal analgesia: epidural analgesia, placebo, patient-controlled analgesia, intravenous opioid.

A PICO format question was used to help develop the keywords and concepts used to search each electronic database. The search terminology included block terms for (intrathecal morphine, analgesia, major abdominal surgery), (opioid use or opioid abuse), (peri-operative or preoperative or post-operative terms or surgery).

The literature search and screening methodology is outlined in Figure 1 in a PRISMA flow diagram. As of 24 October 2021, the search was current. The Medline (ProQuest) database yield 113 articles, CINAHL resulted in 142, and the PubMed database revealed 92 results. A total of 280 articles were retrieved from all 3 databases. Duplicates were removed, leaving 78 to be evaluated.

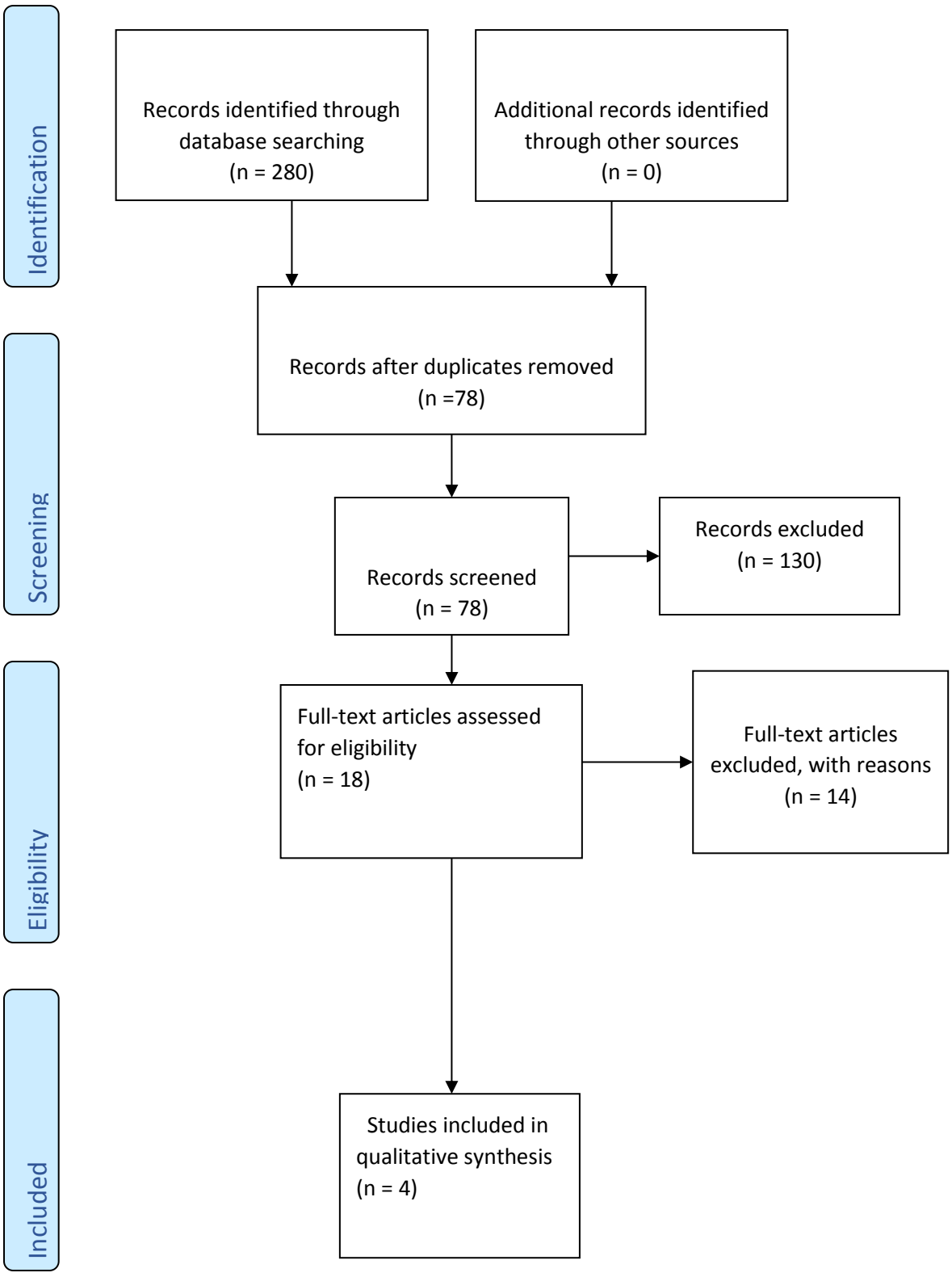

Figure 1. PRISMA Flow Diagram

Study Selection and Screening Method

The studies were extracted systemically and were carefully evaluated utilizing the Johns Hopkins research evidence appraisal tool. John Hopkins' rating structure includes 5 levels of evidence. Level 1 involves RCTs and systematic review of RCTs with or without meta-analysis. Four Level 1 RCTs were included within the quality improvement project.

According to the John Hopkin's rating structure, Level 2 includes quasi-experimental studies while Level 3 are nonexperimental studies and systematic reviews of a combination of RCTs and quasi-experimental studies. Level 4 requires the opinions of respected authorities and nationally recognized experts of scientific evidence. And lastly, Level 5 is composed of case reports, clinician experience, and literature reviews.

The level of evidence is also described as high, good, or low. Evidence that is deemed high is data that is reliable, with enough control and sufficient sample size for analysis.

If it has comparatively precise outcomes with a reasonable sample size, some monitoring, and definite conclusions, an article is considered a good ranking evidence. A 'poor' standard ranking has no evidence with findings that are not accurate, insufficient sample size for the analysis, and a conclusion that cannot be drawn.

Refer to Table 1 for a summary of the individual studies and describes each study's characteristics. Each RCT was assigned a ranking based on the John Hopkins research evaluation tool. The information collected and assessed from each article included: (1) study type and sample size, (2) comparing the use of ITM and its analgesic success, (4) Level of Evidence (5) Results with dose given and time of analgesia duration.

RESULTS AND DISCUSSION

Table 1. Summary of Individual Studies

Author (Year)	Purpose	Research Methodology And Level of Evidence	Measures	Sampling	Results	Conclusions
Fares et al (2014)	To evaluate, compare and evaluate analgesic efficacy of ITM 0.2 mg, 0.5 mg, and 1 mg in patients undergoing major abdominal cancer surgery	Randomized, Double Blind Control Trial Level I	ASA I-III cancer patients aged 30-50 years old and scheduled for major abdominal surgery were included in the study. Excluded were patients with known allergy to the study drug and those with significant systemic disorders that can alter the perception and assessment of pain	Utilizing an online research randomizer, ninety (90) patients were randomly divided into three groups with a sample size of (*n=30)* depending on the ITM dose received *Group I- ITM dose of 0.2 mg *Group II- ITM dose of 0.5 mg *Group III- ITM dose of 1mg	Group II (ITM 0.2 mg) respondents showed prolonged request for rescue analgesia (5.21 h, $P <$ 0.001). Lower postoperative pain scores were demonstrated by Group II and Group III compared with reported outcomes of Group I	The trial showed that Group III- 1 mg dose ITM received superior analgesia for 48 hours compared with 0.2 mg and 0.5 mg ITM with a non-significant difference in the incidence of side effects.
Hein et al (2012)	To explore the effectiveness of adding ITM with varying doses at 0, 100, 200, or 300 mcg to intrathecal bupivacaine on the first	Randomized Placebo Double-Blind Control Trial Level I	The study was conducted in two hospitals Danderyd Hospital (n=100) And Karolinska University Hospital (n=44) between 2005 and 2008.	Blocked randomization via a computer-generated list to one of four groups: ITM 100, 200, 300 mcg or an equal volume, 1 ml of saline (placebo) each	The addition of intrathecal morphine to a fixed dose of 12 mg bupivacaine resulted with a reduced 24-hour post-operative morphine consumption	200 mcg ITM as an adjunct is sufficient as an opioid sparing treatment

	postoperative 24 h patient controlled analgesia consumption after abdominal hysterectomy under general anesthesia		144 women ASA I-II between 30 and 70 years of age scheduled for abdominal hysterectomy. Patients that were excluded are those with chronic pain, ASA III-IV and contraindications to spinal anesthesia or ITM.	to be added to hyperbaric bupivacaine 0.5%, 2.4 ml (12 mg) to a total volume of 3.4 ml		
Blay et al (2006)	To test the hypothesis of combining low dose ITM with multimodal post operative management associated with general anesthesia of patients undergoing abdominal aortic surgery	Prospective Single Center Double Blind Randomized Clinical Trial Level I	A total of 42 patients scheduled to undergo elective abdominal aortic surgery were recruited. Patients with chronic respiratory insufficiency, coagulation abnormalities, infection at puncture site and allergies to morphine were excluded.	32 patients were randomly assigned to 2 groups. Control Group n= 16 (General anesthesia alone) ITM Group n= 16 (General Anesthesia plus intrathecal morphine)	Intraoperative data were comparable between the 2 groups Lower need for postoperative analgesia and longer requests for rescue pain medication for ITM group compared to the Control group	There is improvement with regards to postoperative analgesia in patients undergoing abdominal aortic surgery when ITM is added to treatment
Wan et al (2017)	To compare the use of ITM and epidural bupivacaine (EB) for their analgesia effectiveness after elective	Prospective Single Blinded Randomized Controlled Trial Level I B	32 patients ages between 18-60 years old and ASA I-II undergoing elective abdominal hysterectomy were drafted for this trial.	Randomization was done using a computer-generated table of numbers to two equal sized groups. Group ITM	In comparing pain levels between groups, ITM revealed lower VAS scores and lesser morphine consumption	The ITM proves to be an excellent alternative to epidural analgesia for elective abdominal hysterectomy

	abdominal hysterectomy		Excluded subjects are those with known allergies to the study drugs, contraindications such as coagulation disorder and patients who's on chronic opioid treatment for pain	And Group EB (epidural bupivacaine, followed by sealing the opaque envelop assignment and opened in the operating room. Single Blinded study where the patient and primary investigator knew the intervention (either spinal or epidural)	than Group EB	

Summary of Evidence

A randomized, double-blind control trial by Fares et al., aimed to safely compare the analgesic efficacy of intrathecal morphine (ITM) at different dosing levels for patients undergoing major abdominal surgery. Modern advances in pharmacology and sophisticated drug delivery systems have emerged, but a substantial 80% of postoperative patient surveys still revealed moderate to severe pain complaints.[9] Eventually, these incidents lead to delayed recovery and prolonged hospital stay, amounting to higher costs and reduced patient satisfaction. This study conducted the trial utilizing an online research randomizer to allocate three groups of 30 patients each to receive either 0.2 mg morphine (Group I ITM 0.2 mg), 0.5 morphine (Group II ITM 0.5 mg), or a higher dose of 1 mg morphine (Group III ITM 1 mg).[9]

The Visual Analogue Pain Scale (VAS) was employed to measure the patient's postoperative pain level ranging from 0 to 10 (with 0 = no pain and ten = the worst pain imaginable). [9] The process was standard for all participants; intrathecal administration of ITM was administered in a sitting position; after cleaning the site,1.0 ml of lidocaine 2% was used to anesthetize the landmark identified as L3-L4 interspace subsequently, the subarachnoid puncture was performed with a 25- gauge Whitacre spinal needle.[9] After administering the ITM, patients were induced for general anesthesia utilizing fentanyl 1.5 – 2 μg/kg, propofol 2 – 3 mg/kg, and lidocaine 1.5 mg/kg cis-atracurium 0.15 mg/kg for endotracheal tube intubation. Standard vital signs were monitored throughout the procedure, this integrated the use of electrocardiography, noninvasive blood pressure, SPO2%, temperature, and a Foley catheter was inserted for measuring urine output.[9] Maintenance of anesthesia was done employing isoflurane 1 – 1.5 MAC in 50% oxygen/air mixture and cis-atracurium 0.03 mg/kg bolus given every 30 minutes, respectively.[9] Reversal medications included neostigmine 50 μg/kg and atropine 20 μg/kg. Patients were extubated and transferred to the surgical intensive care unit (SICU). SICU monitoring was done postoperatively, then at 6, 12, 18, 24, 36, 48, 60, and 72 hours after the procedure, inclusive of heart rate, noninvasive systolic and diastolic blood pressure, respiratory rate, and oxygen saturation.[9] Out of the one hundred and eleven patients that were screened, ninety patients consented and enrolled with no dropouts.[9] The main finding of this study is that Group III showed the lowest VAS scores and postoperative pain medication requirements in the first 48 hours, with a non-significant variation between doses after that.[9]

In contrast, Hein et al., employed a prospective randomized-placebo double-blind controlled trial to explore the effect of low dose ITM as an adjunct to 12 mg intrathecal Bupivacaine with post abdominal hysterectomy patients and their PCA morphine consumption in

the first 24 hours. [10] In their investigation, a total of one hundred forty-four (144) American Society of Anesthesiologists (ASA) I-II between 30 and 70 years of age, scheduled for abdominal hysterectomy, were blindly distributed into four groups via a computer-generated list. Groups were ITM 100 mcg, ITM 200 mcg, ITM 300 mcg, and an equal volume, 1 ml of saline (Placebo Group) each to be added to hyperbaric Bupivacaine 0.5 %, 2.4 ml (12 mg) with an aggregate volume of 3.4 ml. [10] The research drug is withheld from the patient and the medical team engaged in their care.[10] Spinal anesthesia was achieved by identifying the L3-L4, L4-L5 interspace as landmarks, confirmed by cerebrospinal fluid flow using a 25 G pencil-point needle.[10] Bupivacaine 12 mg and the study drug was administered, followed by general anesthesia induction.[10] Similar to the previous study, standard procedures in monitoring and the VAS scale to assess pain were also used.[10] Induction and maintenance medications comprised of fentanyl 0.1 mg, propofol 2–3 mg/kg, and atracurium 0.5– 0.6 mg/kg IV and continued with a mixture of oxygen and nitrous oxide – 30/70% with addition of sevoflurane to minimal alveolar concentration (MAC) 1–1.5 after tracheal intubation.[10] In these patients a low transverse incision (Pfannenstiel) was done, if not, they were precluded from participating. [10] The patients were transported to PACU post-extubation and were connected to the PCA morphine pump 1-hour post-anesthesia end. PCA settings were as follows, boluses of 2 mg of morphine, with a lockout time of 6 min and a 4-h maximum of 40 mg.[10]

Outcome measures were recorded at 1, 2, 4, 6, 12, and 24 hours postoperatively, and primarily it quantified the total sum of morphine consumed.[10] Secondary data assessed morphine intake at varying times.[10] This study concluded that ITM reduced accumulated 24 h postoperative PCA use. [10] ITM 100 mcg considerably decreased morphine consumption vs.

placebo for the entire 0–24-time interval post-surgery, but ITM 200 mcg substantially is more effective. An increase to 300 mcg made no difference concerning the quality of analgesia.[10]

In another double-blind randomized study presented by Blay et.al, the hypothesis of ITM efficiency in lowering intraoperative and postoperative opioid requirements of elderly patients undergoing abdominal aortic surgery during the first 48 hours is explored. A total of forty-two patients were recruited and enrolled over 12 months for the trial. Ten patients dropped from the test due to refusal and ITM contraindications.[11] Thirty-two patients were randomized to 2 groups, (1) ITM group (General anesthesia with ITM), (2) Control Group (General Anesthesia alone), one elimination from every group secondary to early death and violation of protocol. Ultimately, the ITM group had 15 participants, and the Control group n=15.[11] The patients were positioned laterally for spinal anesthesia, landmarks L3-L4 or L4-L5 intervertebral space.[11]

The ITM group received 2 mls of diluted (0.1 mg/ml) morphine in the subarachnoid space using a 27-gauge Whitacre needle. On the other hand, the Control group received a 2 ml sterile saline subcutaneously.[11] The interdisciplinary medical team was blinded to these treatments. [11] General anesthesia induction was standardized with these patients, propofol (2 mg/kg) or sodium thiopentone (4 mg/kg), sufentanil (0.1 µg/kg), and atracurium (0.6 mg/kg) to facilitate orotracheal intubation.[11] Anesthesia was maintained with nitrous oxide, sevoflurane (0.6% to 1%), and atracurium (0.3 mg/kg/h).[11] Sufentanil was administered intravenously by a continuous infusion (0.2 to 0.5 µg/kg/h). Dosing for sufentanil and sevoflurane were titrated to need and hemodynamic stability.[11] ASA standard monitoring was followed, inclusive of placing an arterial line, central venous catheter and a foley catheter.[11] All patients in both groups were admitted in the ICU (Intensive Care Unit) for 24-48 hours.[11] VAS was utilized to assess their pain at rest and on coughing every 4 hours during the first 12 hours until 48 hours. The key

finding of this study has shown that low-dose ITM administered preoperatively is significantly helpful in diminishing the need for supplementary morphine for elderly patients after elective abdominal aortic surgery.[11]

Wan et al., on the other hand sought to compare the analgesic effects of ITM and epidural bupivacaine for patients undergoing elective abdominal hysterectomy. As a single-blinded study, the patient and principal investigator is aware of the intervention because it is generally done when the patient is still awake.[12] Thirty-two patients were enrolled, with ages ranging 18-60 years old and ASA class I-II, randomly divided into two groups via a computer-generated table of numbers equating to even-sized groups. [12] Group ITM for intrathecal morphine and Group EB (Epidural Bupivacaine). [12]

Patients were premedicated with oral midazolam (7.5 mg) the night prior to the procedure.[12] Standard monitors are applied and observed; both interventions precede induction of general anesthesia.[12] Group ITM got a single injection of intrathecal morphine (0.2 mg) with 2.5 mL of 0.5% bupivacaine using a 25 G spinal needle, whilst group EB was given the study drug after the epidural catheter is inserted.[12] The loss of resistance technique was demonstrated with an 18 G Touhy needle, testing with 3 mL lidocaine (2%) + adrenaline (1:200,000), and injected via the catheter to confirm placement.[12] Group EB received an aggregate 12 mL of 0.25% plain bupivacaine as an intermittent bolus over 15 min before induction of anesthesia.[12] Induction medications constituted of IV fentanyl (2 µg/kg) and IV propofol (2 mg/ kg) for tracheal intubation and muscle relaxation rocuronium (0.9 mg/kg) was used.[12] With minimal flow ventilation, anesthesia was then maintained with sevoflurane in a 30%–40% oxygen: air mixture. [12] Intra-operatively, analgesia for group EB was continued with an epidural infusion of 0.1% bupivacaine + fentanyl (2 µg/ mL) at flow rates of 6–12 mL/hr.[12]

This study concluded that group ITM had excellent pain control, evidenced by lesser VAS scores in the first few hours of surgery. [12] Patients tolerated movements and ambulated earlier. There were also fewer rescue analgesia needs when compared with the EB group.[12]

Conclusion

Opioids are highly potent centrally acting analgesic drugs for the treatment of pain and Morphine is one the most common used opioids given intravascular or intrathecal. The series of RCTs included in this literature review all yielded the same primary and secondary outcomes. Fares et al., and Hein et al., conducted a study with a varying dose of morphine used, they proved that 0.2 mg and 0.5 mg of ITM is enough to achieve good clinical analgesia and its positive outcomes. Blay et al., compared a control group (General Anesthesia only) with the ITM group (General Anesthesia with ITM), the ITM group showed better results when it comes to requesting rescue analgesia postoperatively. Wan et al., contrasted ITM and epidural bupivacaine (EB), ITM was superior in lessening the VAS scores and rescue morphine consumption. In the setting of ITM administration, it is very effective in opioid sparing for the first 24-48 hours post-surgery. The ideal dose of ITM is a balance between the opposing demands of providing the best possible analgesia while curtailing dose-related undesirable effects.

IMPLEMENTATION

Primary Project Objective

Adequate analgesia is essential for patient recovery after major abdominal surgery. Acute postoperative pain is a complex, physiological reaction to tissue injury. It remains a challenge for anesthesia providers and health care practitioners to create a balanced multimodal approach to treat it. Ineffective management such as undertreatment and overtreatment of postoperative pain leads to poor patient outcomes. Anesthesia providers such as Certified

Registered Nurse Anesthetists (CRNAs) and Anesthesiologists have employed various methods to cater to this problem. Currently, the evidence-based practice for a multimodal approach in postoperative pain for major abdominal surgery patients includes a peripheral nerve block known as TAP Block and administering gabapentin and Tylenol preoperatively.

The primary goal of this Doctor of Nursing Project (DNP) is to identify methods to deliver better postoperative analgesia for patients undergoing major abdominal surgery and provide an educational tool that includes planning, implementation, and evaluation modules. Emerging as a favorable option in clinical practice is the use of Intrathecal Morphine (ITM) before induction of general anesthesia. It is a simpler and quicker neuraxial technique with a lower rate of failure. This scholarly project aims to guide and translate evidence into practice by assessing the needs and educating anesthesia providers regarding the efficacy of ITM.

Setting and Participants

Recruitment

The educational tool for ITM will comprise an interdisciplinary team. Therefore, it is crucial to obtain support from stakeholders. The groundwork study will involve anesthesia providers such as Certified Registered Nurse Anesthetists (CRNAs) and Anesthesiologists. The anticipated sample size will be between 10-15 participants. These participants will be pulled from the Mount Sinai Medical Center (MSMC) list of anesthesia providers. The quality improvement (QI) tool framework will be presented in an online survey and a PowerPoint presentation module with the members of the Anesthesia Department from Miami Beach Anesthesiology Associates (MBAA) at MSMC. This quality improvement educational tool will be concrete, detailed, and well-defined to meet the project purpose.

Description of Approach and Project Procedures

The proposed project will be introduced in an online module to MBAA providers that focus on the perioperative management of patients scheduled for major abdominal surgery. The current information and understanding of the anesthesia provider will be specified using a pre-evaluation tool that will influence the intervention's information and determine the content or subject matter of the intervention. A pre-assessment test will establish this baseline information.

The second part will be a PowerPoint presentation through Zoom. A voiceover PowerPoint regarding the use of ITM in patients undergoing major abdominal surgery will be presented. Anesthesia providers' education is crucial in linking existing gaps in knowledge and supporting the need for additional tools to ensure patients are provided evidence-based care during the perioperative period. The presentation method will offer providers insight into the importance of ITM use during the perioperative period to minimize postoperative opioid consumption.

The next phase of this QI tool will entail an online post-assessment test to evaluate the anesthesia providers learned knowledge and observation regarding the intervention. The provider's feedback regarding the contents of the educational module delivered will determine how this will impact their daily practice.

Protection of Human Subjects

Anesthesia providers participating in the survey will remain anonymous, and the investigator will secure the data using unique code identifiers. In addition, a password and spyware-protected laptop will be utilized to ensure the safekeeping of the information collected. The providers willing to participate will be asked to sign an informed consent, and there will be no untoward risks expected with the study as it will only require time spent by each anesthesia provider in the educational module.

DATA COLLECTION AND ANALYSIS

Quality Improvement Tool

The online survey will include a preassessment and post-assessment test to establish the influence of the educational module presented. These tests will be conducted employing surveys through Qualtrics. The planned survey will consist of 10 questions that will emphasize knowledge and practice. In addition, there will be a means of measurement and comparison. The preassessment questions will assess baseline understanding, whereas the post assessment will define the participant's knowledge from the educational module and determine if it is beneficial in daily practice. The study results will be kept confidential, and the patient's information will remain anonymous throughout the study.

Data Management and Measure

The Doctor of Nursing Practice (DNP) student conducting the educational module will be the primary investigator and responsible for disseminating the QI tool to the MBAA anesthesia providers. Every question will be measured and will document answers to distinguish the knowledge base before and after the educational module. The confidentiality of patients' demographics will be maintained during the study. The impact of the QI tool on the provider's practice will be established by the results of the pre-and post-test survey instruments. Analyzing the pre- and post-assessment results will likely identify patterns that will be used to determine the effectiveness of the educational module and if the module will improve anesthesia providers' knowledge.

IMPLEMENTATION RESULTS AND DISCUSSION

Pre/Post-Test Demographics

The pre-test demographics are shown in Table 2, displayed below.

Table 2: Pre-Test Participants Demographics

Demographic	**N=10 (100 %)**
Gender	
Male	6(60%)
Female	4(40%)
Age	
25-35	5(50%)
36-45	5(50%)
46-55	0 (0%)
56-66	0 (0%)
Ethnicity	
Hispanic	2(20%)
Caucasian	3(30%)
African American	0(0%)
Asian	0(0%)
Other	5(50%)
Position/Title	
CRNA	8(80%)
MD/DO	2(20%)
Years of Experience	
1 to 2 years	2(20%)
2 to 5 years	3(30%)
5 to 10 years	3(30%)
More than 10 years	2(20%)

There were 10 participants in the pre-test demographics. Most of the participants were male (n=6, 60%) and female (n=4, 40%). There were also a range of ethnicities represented: Caucasian (n=3, 30%), Hispanic (n=2, 20%), and other (n=5, 50%). Information was obtained regarding the participant's role at the clinic. It was found that 80% (n= 8) participants were CRNAs and the rest (n=2) 20 % are medical anesthesiologists. The participants were asked about the tenure of time practicing, finding that the practice period ranged: less than one year (n=1, 20%), 1 to 5 years (n=2, 40%), and more than 10 years (n=2, 40%). The participants consisted of DNP-prepared CRNAs (n=8, 60%), MD/DO (n=2, 20%).

Discussion

Pre-Test Confidence in Utilizing Single-shot Intrathecal Morphine in Minimizing Postoperative Opioid Requirement in Abdominal Surgery Patients

The pre-test contained information regarding the utilization of single shot intrathecal morphine in minimizing postoperative opioid requirement in abdominal surgery patients. The majority of the participants (n=10, 100%) felt confident managing a patient undergoing abdominal surgery in the perioperative period. The survey concluded that most participants often (n=9, 90%) employ multimodal analgesia to minimize postoperative opioid requirement in abdominal surgery patients. Of this n=9 or 90%, n=10 or 100 % incorporates the use of a peripheral nerve block (TAP block) and preoperative oral Tylenol and Gabapentin.

Pre-Test Identification of Current Knowledge about Single-shot Intrathecal Morphine in Minimizing Postoperative Opioid Requirement in Abdominal Surgery Patients

The survey focuses on identifying the benefits of an evidence based educational module in utilizing single shot intrathecal morphine for patients undergoing major abdominal surgery.

The participants know that Morphine is the first opiate given intrathecally; the question was correctly answered by all participants (n=10, 100%). When asked about what dose is intrathecal morphine deemed effective, all six participants answered the questions correctly (n=6, 60%). Eight participants (n=8, 80%) Correctly answered the question regarding the duration of intrathecal morphine analgesia.

80 % or n=8 participants agreed that utilizing intrathecal morphine for post operative pain relief is cost effective, moderately safe and a reliable technique with low risk of technical failure.

The participants were asked questions involving the pharmacokinetics and pharmacodynamics of Morphine, and scores generally improved when comparing pre- and post- test.

Table 3 shows the difference in responses from the pre- to post-test.

Table 3. Difference in Pre- and Post-Test Knowledge

Questions	Pre-test	Post- test	Results Difference
What is the first reported opiate given intrathecally?	**100%**	**100%**	**0 %**
At what dose is intrathecal morphine deemed effective?	**60%**	**100%**	**40%**
What is the duration of intrathecal morphine analgesia?	**80%**	**100%**	**20%**
The effective site of action for morphine and other opiates is achieved where?	**80%**	**100%**	**20%**
According to studies, utilizing intrathecal morphine for post operative pain relief is cost effective, moderately safe and a reliable technique with a low risk of technical failure?	**100%**	**100%**	**0%**

Table 4. Utilization of Single Shot Intrathecal Morphine for Major Abdominal Surgery Patients and its role in Minimizing Postoperative Opioid Consumption

	Pre-test	Post-test	Difference
How likely are you to use ITM to minimize postoperative opioid requirement in patients undergoing abdominal surgery?	30%	100%	70%

Table 4. shows the educational module changes in participants' perspectives in utilizing single shot intrathecal morphine when comparing the pre-test and post-test scores. The results suggest that the narrated PowerPoint presentation provided the necessary educational information, leading CRNAs to feel inclined to incorporate intrathecal morphine as part of a multi modal therapy to reduce postoperative opioid consumption.

Post-Test Confidence in the Reduction of Postoperative Opioid Requirements of Major Abdominal Surgery Patients by Utilizing a Single Shot Intrathecal Morphine

Participants were very confident (n=9, 90%) or somewhat confident (n=1, 10%) in managing a patient utilizing single shot intrathecal morphine after completing the educational module. When asked how often the participant had a patient in the perioperative period who received intrathecal morphine, the majority selected rarely (n=9, 90%) compared to sometimes (n=1, 10%).

Limitations

Limitations of the study include the small sample size; the online educational module and survey were emailed to the anesthesia providers of Miami Beach Anesthesiology Associates (MBAA) at Mount Sinai Medical Center. There were 43 emails on the list, and only ten people

completed the survey. A larger sample size is ideal for detecting a statistically significant difference in the findings and one that would reflect MBAA anesthesia practitioners. In addition, the Qualtrics link, which included a voice-over PowerPoint presentation, pre-test, and post-test, was sent online and was only accessible for two weeks; extending the time frame in which the link can be accessed may have yielded more responses. Lastly, the project was disseminated and completed entirely online, inhibiting it from being distributed through other means.

Summary

After the Zoom PowerPoint presentation, scores increased on the post-test from the baseline pre-test scores. Most participants improved their knowledge about the benefits of utilizing intrathecal morphine in reducing post-operative opioid consumption for major abdominal surgery patients, n=9 or 90%. The participants that completed the survey yielded a positive attitude towards implementing ITM for patients undergoing major abdominal surgery. Therefore, the results of this QI project can guide MBAA anesthesia providers to weigh the benefits and potential side effects of utilizing ITM in their practice. Ultimately achieving the goal of providing enough pain management with reduced opioid consumption postoperatively and promoting better patient outcomes.

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Appendix

Appendix A

Mount Sinai Medical Center IRB Approval

Miami Beach Anesthesiology Associates, Inc.

Mount Sinai Medical Center • Division of Anesthesia

February 1, 2022

Dr. Fernando Alfonso, DNP, CRNA, APRN
Assistant Professor
Department of Nurse Anesthesiology
Florida International University

Dr. Alfonso,

Thank you for inviting Mount Sinai Medical Center to participate in Doctor of Nursing Practice (DNP) project conducted by Maelen Bernasor entitled "An Educational Module on The Use if Intrathecal Morphine in Major Abdominal Surgery Patients To Reduce Postoperative Opioid Consumption" in the Nicole Wertheim College of Nursing and Health Sciences, Department of Nurse Anesthesiology at Florida International University. I have given the student permission to conduct the project using our providers.

Evidence-based practice's primary aim is to yield the best outcomes for patients by selecting interventions supported by the evidence. This proposed quality improvement project seeks to investigate and synthesize the latest evidence.

We understand that participation in the study is voluntary and carries no overt risk. All Division of Anesthesia providers are free to participate or withdraw from the study at any time. The educational intervention will be conveyed by a 15-minute virtual PowerPoint presentation, with a pretest and posttest questionnaire delivered by a URL link electronically via Qualtrics, an online survey product. Responses to pretest and posttest surveys are not linked to any participant. The collected information is reported as an aggregate, and there is no monetary compensation for participation. All collected material will be kept confidential, stored in a password encrypted digital cloud, and only be accessible to the investigators of this study: Maelen Bernasor and Dr. Alfonso.

Once the Institutional Review Board's approval is achieved, this scholarly project's execution will occur over two weeks. Maelen Bernasor will behave professionally, follow standards of care, and not impede hospital performance. We support the participation of our Division of Anesthesia providers in this project and look forward to working with you.

Respectfully,

Jampierre (J.P.) Mato, DNP, CRNA, APRN
Executive CRNA Director
SRNA Coordinator/Supervisor
Electronic Mail: Jampierre@bellsouth.net
Mobile Phone: 954-668-6080

4300 Alton Road, Suite 2454, Miami Beach, FL 33140
Office (305) 674-2742 • Facsimile (305) 674-9723

Appendix B

Project Questionnaire with Answers

Pretest and Posttest Questionnaire:

An Evidence Based Educational Module on the Efficacy of Single-shot Intrathecal Morphine in Minimizing Postoperative Opioid Requirement in Abdominal Surgery Patients: A Quality Improvement Project

INTRODUCTION

The primary aim of this QI project is to enhance the knowledge of anesthesia providers in minimizing postoperative opioid requirement in abdominal surgery patients by utilizing single shot intrathecal morphine (ITM) as part of a multimodal anesthesia plan.

Please answer the question below to the best of your ability. The questions are either in multiple choice or true/false format and are meant to measure knowledge and perceptions on intrathecal morphine.

PERSONAL INFORMATION

1. **Gender:** Male ____ Female_____ non-Binary_____
2. **Age:** _____
3. **Ethnicity:**

   Hispanic Caucasian African American Asian Other_____
4. **Position/Title:** _____

5. **Level of Education:** Associates Bachelors Masters Other

_____

6. How many years have you been an anesthesia provider?

Over 10 5-10 years 2-5 years 1-2 years

Questionnaire

1. **How confident do you feel managing a patient undergoing abdominal surgery in the perioperative period?**
    a. Very confident
    b. Somewhat confident
    c. Somewhat unconfident
    d. Not confident at all
2. **How often do you use multimodal analgesia to minimize postoperative opioid requirement in abdominal surgery patients?**
    a. Often
    b. Sometimes
    c. Rarely
    d. Never
3. **If you employ a multimodal anesthetic plan for balanced analgesia, what do you utilize?**
    a. I don't practice a multimodal technique
    b. TAP block
    c. Tylenol and Gabapentin orally given preoperatively
    d. B and C as part of ERAS protocol
4. **What is the first reported opiate given intrathecally?**
    a. Hydromorphone
    b. Fentanyl
    c. Morphine

    Correct Answer: C. Morphine
5. **How available is ITM in your facility?**
    a. It is easily accessible and available

b. I have never heard of ITM use

6. At what dose is ITM deemed effective?

a. 0.7 mg

b. 0.2-0.5 mg

c. 1,000 mcg

Correct Answer: B. 0.2-0.5 mg

7. What is the duration of ITM analgesia?

a. 30 minutes

b. 18-24 hours

c. 10 minutes

d. 72 hours

Correct Answer: D. 18-24 hours

8. The effective site of action for morphine and other opiates is achieved where?

a. Dorsal Horn

b. Ventral Horn

c. Brain Stem

Correct Answer: A. Dorsal Horn

9. According to studies utilizing ITM for postoperative pain relief is cost-effective, moderately safe and a reliable technique with low risk of technical failure? True or False

a. True

b. False

Correct Answer: A. True

10. How likely are you to use ITM to minimize postoperative opioid requirements in patients undergoing abdominal surgery?

a. Most likely

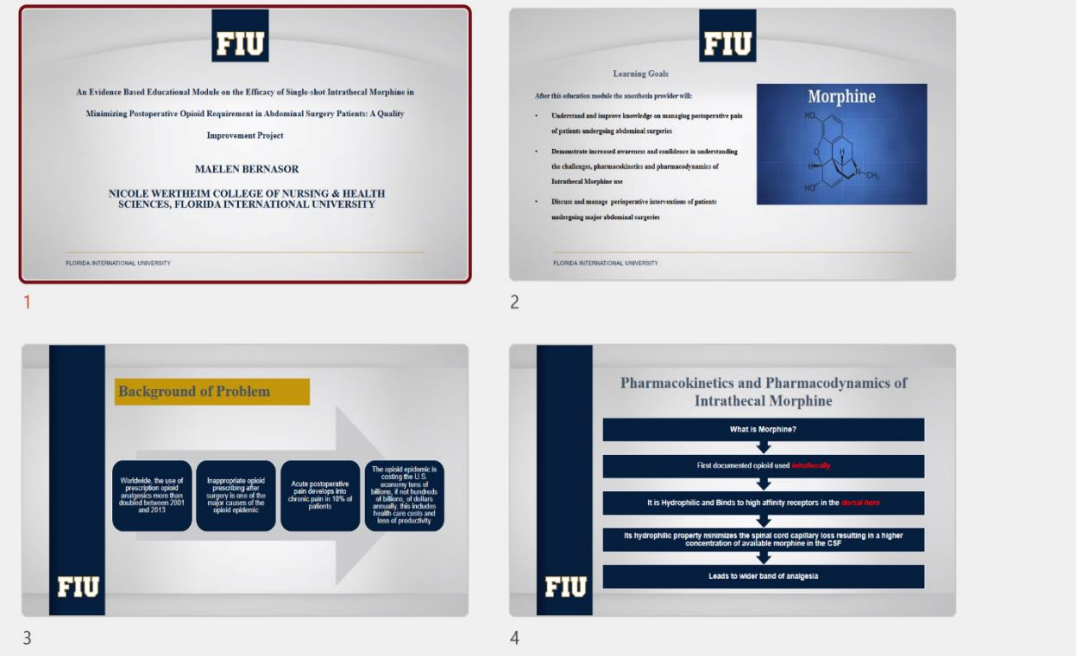
b. Somewhat likely

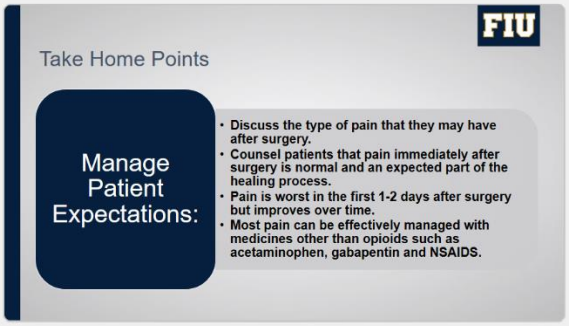
c. Somewhat unlikely

d. Most unlikely

Appendix C

Zoom PowerPoint Presentation

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Take Home Points
Manage Patient Expectations:
• Discuss the type of pain that they may have after surgery.
• Counsel patients that pain immediately after surgery is normal and an expected part of the healing process.
• Pain is worst in the first 1-2 days after surgery but improves over time.
• Most pain can be effectively managed with medicines other than opioids such as acetaminophen, gabapentin and NSAIDS.

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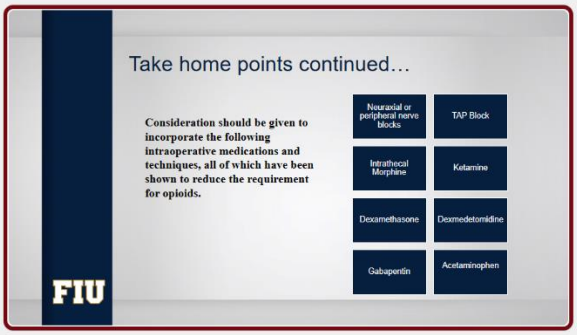
Take home points continued…
Consideration should be given to incorporate the following intraoperative medications and techniques, all of which have been shown to reduce the requirement for opioids.
Neuraxial or peripheral nerve blocks
TAP Block
Intrathecal Morphine
Ketamine
Dexamethasone
Dexmedetomidine
Gabapentin
Acetaminophen
FIU

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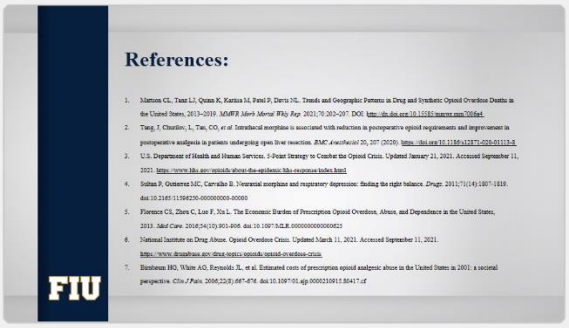
References:
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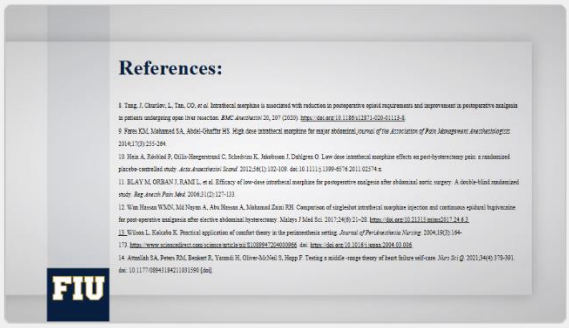
References:
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Appendix D

Florida International University IRB Approval

FIU | FLORIDA INTERNATIONAL UNIVERSITY

Office of Research Integrity
Research Compliance, MARC 414

MEMORANDUM

To:	Dr. Fernando Alfonso
CC:	MAELEN BERNASOR
From:	Elizabeth Juhasz, Ph.D., IRB Coordinator EJ
Date:	March 28, 2022
Protocol Title:	**"An Evidence Based Educational Module on the Efficacy of Single-shot Intrathecal Morphine in Minimizing Postoperative Opioid Requirement in Abdominal Surgery Patients: A Quality Improvement Project"**

The Florida International University Office of Research Integrity has reviewed your research study for the use of human subjects and deemed it Exempt via the **Exempt Review** process.

IRB Protocol Exemption #:	IRB-22-0116	**IRB Exemption Date:**	03/28/22
TOPAZ Reference #:	111562		

As a requirement of IRB Exemption you are required to:

1) Submit an IRB Exempt Amendment Form for all proposed additions or changes in the procedures involving human subjects. All additions and changes must be reviewed and approved prior to implementation.
2) Promptly submit an IRB Exempt Event Report Form for every serious or unusual or unanticipated adverse event, problems with the rights or welfare of the human subjects, and/or deviations from the approved protocol.
3) Submit an IRB Exempt Project Completion Report Form when the study is finished or discontinued.

Special Conditions: N/A

For further information, you may visit the IRB website at http://research.fiu.edu/irb.

EJ