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Implementing an Enhanced Recovery After Breast Surgery Protocol to Reduce Opioid Use

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Data collection was completed by the above authors along with Dr. Mark Schmidheiser, of Atlanticare Health System. Data analysis was completed by the authors. The data reported in this article will be presented via a virtual poster presentation due to the concurrent COVID-19 pandemic, at the annual University of Pennsylvania Doctor of Nursing Practice presentation. The authors have no conflicts of interest to disclose and no funding was received. Any questions, concerns, or correspondence related to this article should be sent electronically to the following email: kelseyre@nursing.upenn.edu.

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Abstract

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Keywords

breast surgery, mastectomy, enhanced recovery after surgery, opioid, narcotic, pain

Disciplines

Anesthesiology | Nursing | Perioperative, Operating Room and Surgical Nursing | Plastic Surgery | Quality Improvement | Surgery

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Author Note

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Abstract

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Implementing an Enhanced Recovery After Breast Surgery Protocol to Reduce Opioid Use

More than half of breast cancer surgery patients experience chronic pain post-surgery (Chiu et al., 2018). Post-surgical pain which lasts longer than one to two months after surgery is defined as chronic pain (Lovich-Sapola et al., 2015). Nationally, in 2017 there was a 35 percent increase in the number of breast cancer surgeries performed (Offodile et al., 2019). Nurse anesthetists and anesthesiologist are well-positioned to design and lead the implementation of evidence-based practices that will lead to improved pain management perioperatively, while ensuring patient safety.

Chronic post-surgical pain often starts as an unresolved episode of acute pain, which is most commonly treated unimodally with opioids, leading to inadequate pain control, long-term opioid use and possible opioid dependence disorders (Lovich-Sapola et al., 2015). According to the Centers for Disease Control and Prevention, prescription opioids contribute to 46 deaths a day (2019). Prescription opioids have a direct role in the national opioid crisis and contributed to 35 percent of all opioid related deaths in the United States in 2017 (Centers for Disease Control and Prevention, 2019).

Acute surgical pain transitions to chronic pain in a series of physiological events. Mediators are released due to inflammation and/or cell damage that can occur due to surgery (Fregoso et al., 2019). These mediators activate primary afferent A delta and C fibers, causing nerve depolarization and generation of action potentials. These signals travel and eventually synapse in the somatosensory cortex where pain is perceived. When free nerve endings are continuously activated due to the increased release of mediators, which can occur with persistent

post-surgical pain, these pathways can be altered (Fregoso et al., 2019). Persistent exposure to inflammatory mediators can decrease A delta and C fiber thresholds, making depolarization more likely, which can lead to hyperalgesia. Due to this excitable state, increased glutamate is released, which causes a prolonged depolarization leading to normally non-painful stimuli to be perceived as painful (Fregoso et al., 2019). This is called allodynia. In the past, pain was usually treated post-operatively.

As the understanding of pain pathways has increased, current literature suggests that pain should be treated preventatively, before surgical trauma, rather than reactively. Preventing pain signaling from occurring initially can lead to a decrease in the incidence of chronic pain (Lovich-Sapola et al., 2015). One way to accomplish this is through regional anesthesia. When local anesthetics are injected around the nerves that innervate the surgical area, afferent nerve signals are blocked (Fregoso et al., 2019). This process allows for a decrease in nerve depolarization and less action potentials generated, leading to less nociceptive stimulation and less nerve sensitization (Fregoso et al., 2019). Altering pain transduction in this way is theorized to reduce changes in the central nervous system and reduce the development of chronic pain (Fregoso et al., 2019).

AtlantiCare is a health system within the Geisinger Health Group, and is in Atlantic County, New Jersey. In 2019, AtlantiCare performed 247 breast procedures in their operating rooms across both campuses of the health system. According to the State of New Jersey, in 2019 Atlantic County had 180 drug related deaths and 28,888 opioid prescriptions dispensed. In comparison, in 2013 Atlantic County had 84 total overdose related deaths (The State of New Jersey, 2020). The Anesthesia Department at AtlantiCare Medical Center is looking for ways to decrease opioid administration in the perioperative setting. Geisinger Health Group made

mitigation of opioid misuse a top priority within their organization. Throughout the health system, Geisinger decreased opioid prescriptions by 50 percent (Geisinger Health, 2019). The Anesthesia Department at AtlantiCare is working toward similar goals with the adoption of Enhanced Recovery After Surgery Programs (ERAS) and has had success in many other surgical service lines. ERAS protocols call for opioid minimization during the operative period by providing evidence based multimodal pain relief.

Synthesis of current literature suggests the use of ERAS techniques such as pre-operative administration of gabapentin and acetaminophen, along with regional anesthesia, for patients undergoing breast surgery, to reduce post-operative pain and opioid consumption (Rojas et al., 2018). Abdallah et al. (2014) conducted a randomized controlled trial in which one group received standard anesthesia care, while the other group had regional anesthesia prior to incision. The regional anesthesia group had less pain immediately post-operatively, on post-operative day two, and on discharge, along with less intra-operative morphine milligram equivalent (MME), consumption (Abdallah et al., 2014). Similarly, Yao and colleagues found in their randomized control trial that the group that received regional anesthesia had lower pain scores for the first 24 hours postoperatively, compared to a control group that received standard care (2019). Cohort studies by Rojas et al. (2018), Matsumoto et al. (2018) and Chiu et al. (2018) examined the use of a multimodal ERAS guideline for breast surgery, all of which resulted in a statistically significant decrease in total opioid consumption for those patients undergoing breast surgery.

Multimodal analgesia is a cornerstone of any ERAS pathway. ERAS pathways have been utilized for many years in specialties like colorectal surgery, however ERAS associated with breast surgery is a relatively novel concept. While many of the aspects of the ERAS bundle remain the same, enhanced recovery after breast surgery is reliant on regional anesthesia.

Regional anesthesia works to anesthetize the area being operated on for long-term multimodal pain relief without additional opioid (Afonso et al., 2017). Advances in regional blockage duration with the use of long-acting local anesthetics such as liposomal bupivacaine has revolutionized the quality of pain control the peripheral nerve block can provide, with duration of a single block lasting for 24-72 hours (Afonso et al., 2017).

Currently, there is no ERAS protocol for breast surgery at AtlantiCare. Given the considerable number of breast surgeries performed at the Hospital Center each year, the Anesthesia Department has identified a need for an evidenced based ERAS protocol due to the potential for perioperative improvement for patients undergoing breast surgery. This evidence-based practice project designed and implemented an ERAS for breast surgery protocol with the goal of decreasing total opioid use by patients during their perioperative course.

Methods

Context

AtlantiCare Medical Center has two campuses. The campus in Atlantic City has seven operating rooms and 244 total patient care beds. The campus in Pomona, NJ has 12 operative rooms, a hybrid operating room, and 349 total patient care beds. Both hospitals are designated comprehensive stroke centers and the Atlantic City campus is a designated Level II trauma center. The Anesthesia Department at AtlantiCare is comprised of 31 anesthesiologists, 44 certified registered nurse anesthetists, and three physician assistants. The post anesthesia care unit is staffed by 29 registered nurses who work closely with the Anesthesia Department to care for patients post-operatively and manage acute, post-surgical pain.

The literature review illuminated key aspects of ERAS implementation which were previously unrealized, such as the importance of multidisciplinary buy in. Although the

anesthetic management intraoperative is almost solely at the discretion of the anesthesia provider, a variety of different teams play a part in the patient's hospital stay. Communication is needed so all members providing patient care, including the surgical team and nursing staff, are aware of the ERAS protocol being implemented. This project will follow the Plan-Do-Study-Act model.

Staff awareness of the described protocol will help to contribute to the success of this project. This will be accomplished via electronic communication, as a specific website will be created for the ERAS for breast surgery protocol, and simply added to the website and cell phone application already utilized by staff for ERAS pathways in other service lines. This also will allow for staff to be fully informed of all the aspects of the protocol and allow for efficiency. The equipment that will be used, such as the ultrasound machines, along with medications and the technology used, is already established. Therefore, the health system will not incur any additional costs.

This project will also face barriers. Initially there may be concern for lack of support from the surgeons due to the increased anesthesia time needed in the operating room at the beginning of the case to perform the regional anesthesia techniques. Next, this project may face a lack of staff buy-in and information fatigue due to a concurrent worldwide pandemic. At the time of implementation, there is also concern that the staff will be resistant to change and will not be motivated to learn or perform new regional anesthetic techniques or follow new guidelines. Lastly, due to the concurrent COVID-19 pandemic and resulting social distance guidelines, we were unable to hold a nerve block workshop to educate the providers on how to perform PEC 1 and PEC 2 regional nerve blocks.

Interventions

After a literature review was performed, an ERAS for breast surgery protocol was developed. AtlantiCare's Anesthesia department has an established webpage for ERAS protocols. Staff utilize this online ERAS pathway for different surgical specialties through this established webpage. The ERAS for breast surgery protocol will be published on the webpage to be accessed by the Anesthesia Department. See appendix 1 for the protocol in its entirety. Prior to posting the protocol in the app and the established webpage, the anesthesia staff was notified via email to increase awareness for the protocol, just as they have done in the past when a new protocol is added.

The ERAS for breast surgery protocol has listed interventions that can be broken down into three stages: pre-operative, intra-operative, and post-operative (see Figure 1). Pre-operatively, the patient will receive 1000mg of Acetaminophen and 600mg of Gabapentin by mouth if not contraindicated (Chiu et al., 2018; Rojas et al., 2018). Intraoperatively, ultrasound guided peripheral nerve blocks pectoralis one (PECS I) and pectoralis two (PECS II) will occur prior to surgical incision. These regional anesthetic techniques will be encouraged to be completed with the use of ultrasound. The PECS I block calls for injection of chosen local anesthetic between the pectoralis major and pectoralis minor muscles, which provides analgesia to the medial pectoral nerve and the lateral pectoral nerve. The PECS II block is achieved when local is injected between the pectoralis minor and the serratus anterior muscle, providing anesthesia to the upper intercostal nerves (Afonso et al., 2017).

For additional pain control, if the patient did not receive Acetaminophen by mouth in the pre-operative stage, give Acetaminophen intravenously. If the surgical team agrees, administer 15-30mg of Ketorolac intravenously toward the end of the procedure (Chiu et al., 2018). If the patient requires opioids, minimize the use of long-acting agents. Postoperatively, continue opioid

minimization by using opioids as rescue therapy only, and not as first line treatment for pain in the PACU.

Study of the Interventions

In order to assess the impact of the ERAS protocol, a retrospective chart review was performed. All patients who present for breast surgical procedures at AtlantiCare will be considered as eligible subjects. The outcome of interest is the comparison of total opioid administration in morphine equivalents of two groups: breast surgery patients' pre-implementation of protocol and breast surgery patients' post-implementation of protocol. The hypothesis of this project is that patients who receive care after the implementation of the ERAS for breast surgery protocol will require less opioids during their time under the direct care of anesthesia providers.

The available data included in this analysis is strictly from the anesthesia charting system. This collects data starting at the moment a member from the anesthesia team assumes care of the patient and brings the patient into the operating room, continuing throughout the intraoperative period and in the immediate post-operative period. The data collection will end when the anesthesia provider transports the patient to the PACU, gives report to the PACU nurse assuming care of the patient, and a final set of vital signs are obtained. Once the anesthesia provider deems the patient is stable, the PACU nurse will assume care and the anesthesia charting system no longer collects patient data.

The pre-implementation period of this project is December 1, 2019 through March 1, 2020, and thus just prior to the decrease of surgical volume due to the COVID-19 pandemic. The protocol was implemented on August 10, 2020, and post implementation data was collected from this time until November 1, 2020. There is a gap between the pre- and post-intervention

data due to a decrease in surgical volume and the institution halting new protocols during the COVID-19 pandemic.

Measures

Total opioid use

Total opioid use is measured by total morphine milligram equivalents (MME) to provide a standardized comparison. The MME was calculated by converting the total dosage of the various opioids administered into milligrams of morphine using the following conversion equation: 10mg morphine= 0.1mg fentanyl= 1.5mg hydromorphone (Macres et al., 2013). Data was retrospectively collected from the patient's anesthesia record and was manually checked for both completeness and accuracy by both reviewers. All patients who have breast procedures at the institution after the implementation of the ERAS pathway will be included, regardless if all components of the protocol are followed.

Patient characteristics

Categorical data was also obtained. All the patients were female in both the pre- and post-implementation group. The average American Society of Anesthesiologist (ASA) score was 2 for both groups as well. The mean weight for the pre implementation group was 77.2kg and 79.8kg was the mean weight for the post implementation group. The total intravenous fluid administration mean was 1079 mL and 929 mL, respectively. The mean estimated blood loss (EBL) for the pre group was 27 mL, and EBL for the post group was 31 mL. The types of breast surgery that were included in this project are simple mastectomy or mastectomy and lumpectomy and breast reconstruction surgery with or without tissue expander. The pre-implementation group had 19 patients undergo simple mastectomy or mastectomy and lumpectomy, and five patients undergo breast reconstruction surgery, for a total of 24 patients. The post-implementation group

had 16 patients undergo simple mastectomy or mastectomy and lumpectomy, and 11 patients undergo breast reconstruction surgery, for a total of 27 patients.

Analysis

The total MME dosage is the main outcome of the proposed study. For comparison, the median MME pre- and post-implementation are compared due to outlier data. Given the numeric nature of the outcome of interest and considering that the MME values for the pre- and post-implementation period will be obtained from two independent samples, a Mann-Whitney-U ($p=0.05$) analysis was performed. Run charts including pre- and post-implementation are used to show a visual change in MMEs being used over time intraoperatively, in PACU, and in total. Run charts' show data over time, either via summarized data over weeks, months, etc., or via consecutive events or procedures (Perla, Provost, & Murray, 2011). The X-axis in the run charts for this project display all patients from both groups in chronological order of their surgery.

Ethical Considerations

There are no conflicts of interest for this project. The Institutional Review Board (IRB) at both University of Pennsylvania and Geisinger Health deemed this project exempt, as this is a quality improvement project. IRB approval was needed due to the sensitive nature of the data being collected. The data collected is the total narcotic consumption a patient receives during their anesthesia care. This information was gathered via a report from pharmacy that was generated by our staff lead, an anesthesiologist who currently has privileges to analyze narcotic consumption data for the Anesthesia Department. The data that was obtained is data that is based on this projects' criterion: all breast surgeries that are preformed system wide within the specified dates. This information is generated by the electronic health record, and includes patient's age, gender, type of surgery, medications administered by anesthesia, intravenous fluid

administration, and estimated blood loss. He then de-identified the data, assigned each patient a random number, and sent the data to the main investigators for analysis. The data provided is de-identified, aggregate data on medication dosage (in total milligrams) that is routine and standard care.

Results

All administered opioids were converted to MME to standardize results for analysis. Due to the presence of outliers in our data, and small sample size, we compared the median of the MMEs of our pre- and post-intervention groups. Intraoperatively, the pre group had a median MME of 20 (mean=18.9) and the post group had a median of 15 (mean=17.9). In PACU, the pre group had a median MME of 4 (mean=4.6), and the post group had a median of 0 (mean=3.9.) In total MMEs, the pre group had a median of 20.8 (mean=23.6) and the post group had a median of 15 (mean=21.9). See Table 1.

A Mann-Whitney U test was completed to determine MME differences between pre- and post-intervention groups. Distributions pre- and post-intervention groups were similar as assessed by visual analysis. Median MMEs did not show a statistically significant difference between the two groups intraoperatively ($p=0.406$), in PACU ($p=0.306$), or in total ($p=0.148$). See table 5. In reviewing the run charts regarding intraoperative, PACU, and total MME administration, all show a decrease in the median after the project was implemented. See Table 2, Table 3, and Table 4, respectively.

Discussion

Summary

Overall, there was a decrease in the median in the post intervention group intraoperatively, in the PACU, and in total. Though the decrease was not statistically significant,

any decrease in opioid administration can be seen as a positive outcome. It is well known that opioid use can lead to addiction. This can be attributed to opioids effects at the mu receptor, which is the receptor that allows for pain relief. The mu receptor is found at locations within the brain that not only alter pain signaling, but also can alter emotions, activate the brain's reward center, and cause feelings of euphoria, all of which contribute to the addictive nature of opioids (Rojas et al., 2018). Opioids have other untoward effects, such as nausea, constipation, and other poor effects that are of interest for cancer patients such as altered immune function via impaired NK and T-cells, increased growth of tumor cells, and promotion of metastasis and angiogenesis (Rojas et al., 2018). The less opioids the patient required; it is possible that the patient experienced less pain, along with a decrease in experiencing the other negative effects of opioids.

Another key finding was discovered while reviewing Table 3. The first twelve cases immediately following implementation had 0 MMEs administered in PACU. This shows an initial change in behavior, which is attributed to the education provided to the staff regarding the ERAS protocol itself, its' goals, and the research behind it. Unfortunately, this change was not sustained. This initial change shows promise and suggests that a second Plan-Do-Study-Act cycle should be considered. This should include an in-person education session for the anesthesia staff, along with education provided to the PACU RNs.

Interpretation

This project did not show a statistically significant decrease in opioid use, as many other ERAS for breast surgeries studies have (Abdallah et al., 2014; Chiu et al., 2018; Rojas et al., 2018). Due to the lack of staff education, many patients did not receive PECS I and/or PECS II blocks. Though this was realized early on within the project, due to institutional limitations on gatherings and outside vendors due to the COVID 19 pandemic, this problem was difficult to

solve. An educational PowerPoint regarding the blocks was created and distributed, along with links to reputable educational regional anesthesia websites with videos. Yet without the hands-on training of the anesthesia providers, many were reluctant to perform them on patients. This led to only four patients receiving the regional nerve blocks in the post intervention group.

This protocol did start a conversation within the anesthesia department regarding opioid sparing techniques. Though many providers did not perform the regional anesthetic piece of the protocol, many breast surgery patients did receive Tylenol and there was an increase in the use of pre-operative gabapentin by mouth. There was also an increase in use of ketamine, which is another opioid sparing technique. Though the use of ketamine was not included in the protocol created, but it is an opioid sparing technique the providers within the institution are already familiar with.

Limitations

This evidence-based practice project had limitations. The project was implemented in August 2020, during the COVID-19 pandemic. At this time providers were overwhelmed by new information, as best practices regarding the virus were still being investigated and established. The anesthesia department was disseminating information via email, and often providers would receive multiple emails a day with new and/or updated information. This led to information overload and fatigue regarding new information. Many also were not interested in the intervention as it did not focus on COVID-19, as many practitioners were fully focused on changes that affected corona patients only at this time. There was a decrease in surgical volume due to the pandemic. Also, due to the above, the institution was not allowing outside vendors to provide in-services, which was originally planned to help educate the staff about the PECS I and PECS II nerve blocks. Lastly, there was a lack of buy in of one of the breast surgeons within the

institution. All of these factors lead to a small sample size during the three-month implementation phase.

Conclusion

This evidence-based practice project adds to the already existing body of literature describing the benefits of an ERAS program for breast surgery patients. It is encouraged for other institutions who do not have an ERAS protocol for breast surgery patients to consider the protocol that has been created (see Appendix 1). This has been generated after an extensive review of the literature and encompasses the three stages of surgical care: pre-operative, intra-operative, and post-operative. Once a protocol has been established, securing both input and buy in from the breast surgeons, anesthesia department, and surgical nursing staff is key. The equipment needed for the care suggested, such as medications and ultrasound, are already commonly found in most hospitals and surgical centers in the United States.

In order for this project to remain sustainable within the institution, more providers will need to be educated regarding how to perform the PECS blocks, as this was our biggest barrier. In the future, it is planned to hold a workshop in which anesthesia providers will be taught about the block and be given the opportunity to practice with the ultrasound. This was unable to be completed during the initial project due to the coronavirus pandemic and the guidelines limiting in door gatherings. Once this is completed, and the providers become more proficient, it will take less time to complete and care will be more efficient. It will also allow more patients to be provided with this regional anesthetic technique as part of their anesthetic/pain management plan.

An ERAS protocol for breast surgery patients has the potential to improve patient care, decrease opioid use, and possibly even decrease chronic pain post operatively, as it has been

displayed in various other studies (Abdallah et al., 2014; Chiu et al., 2018; Rojas et al., 2018). Though this did not produce the same results, many lessons were learned. The importance of provider education, along with multidisciplinary buy in, is highlighted in this project. Without it, the project will not be as successful. The introduction of this protocol within the institution started a conversation among providers regarding opioid sparing techniques they were already comfortable with, such as pre-incision Tylenol administration and other non-opioid pharmacologic interventions. In conclusion, the decrease in median MMEs at each stage of care, intraoperatively, PACU, and in total, is a positive outcome.

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Figure 1
ERAS for Breast Surgery Summary

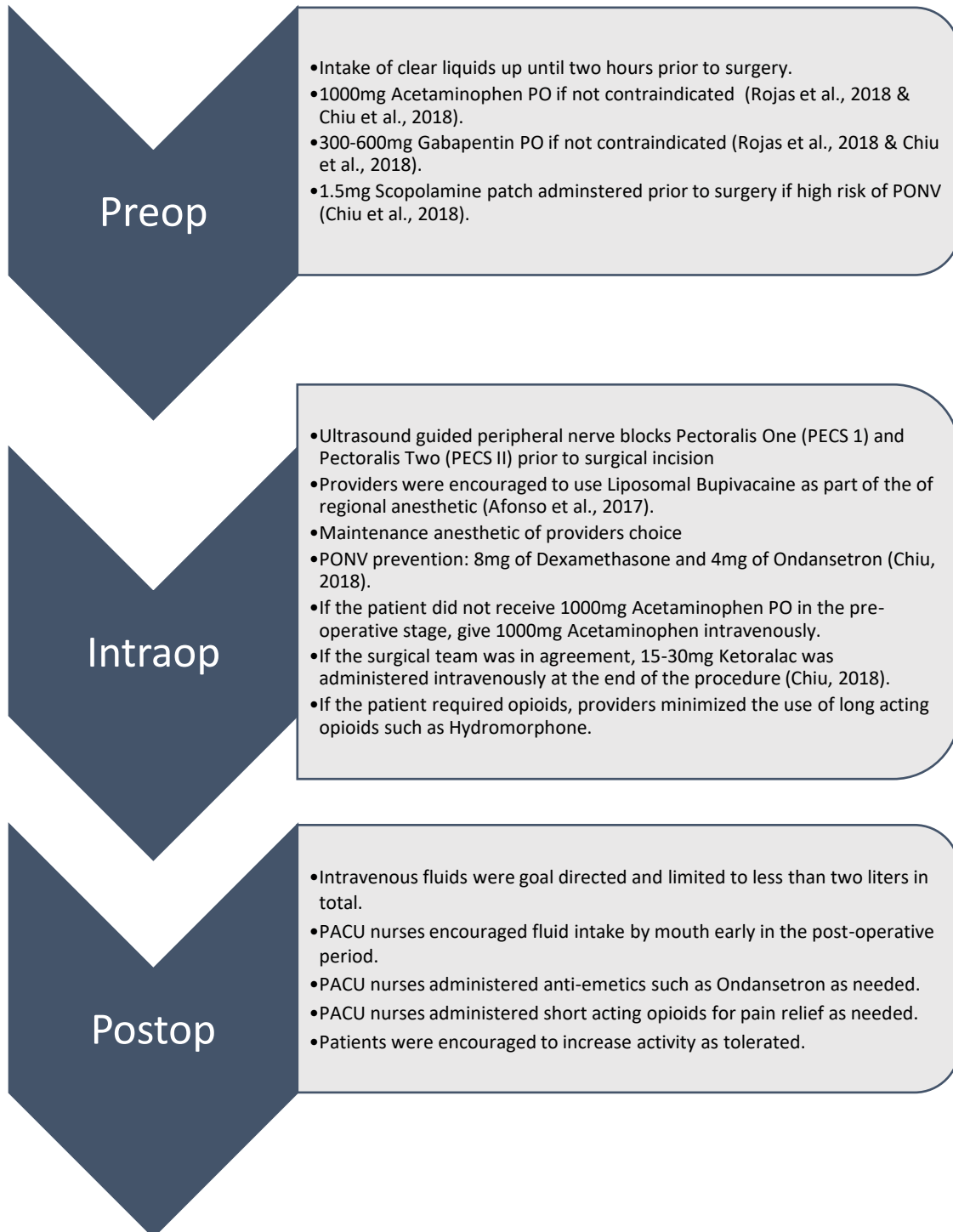


Table 1
Median MMEs Pre and Post Implementation

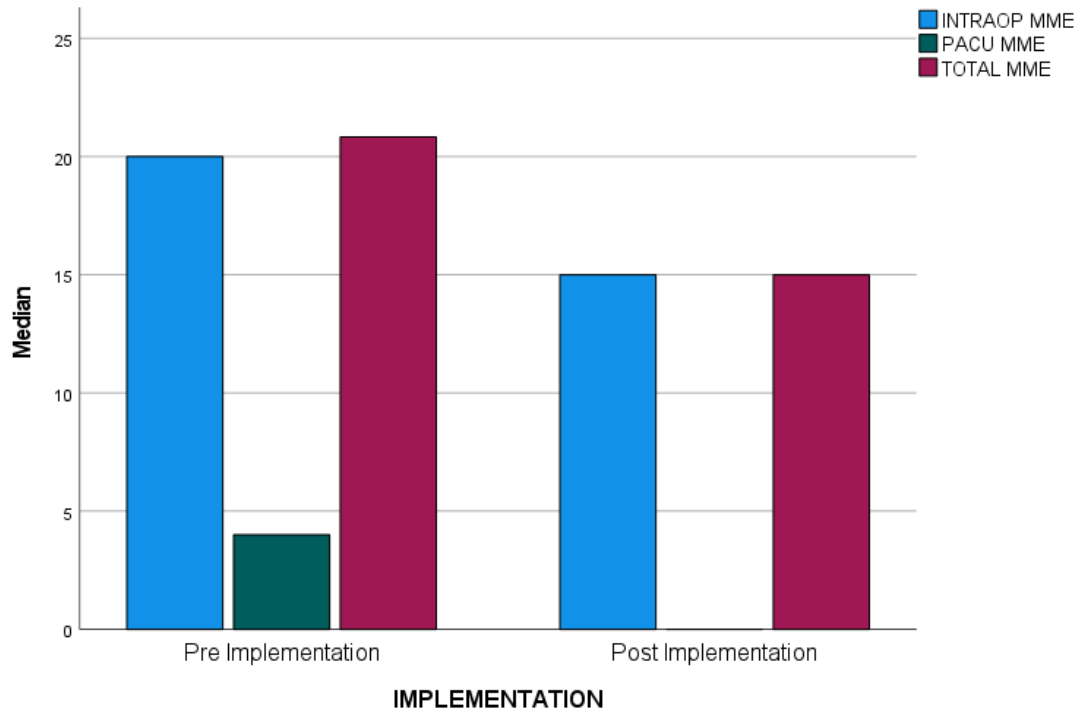


Table 2

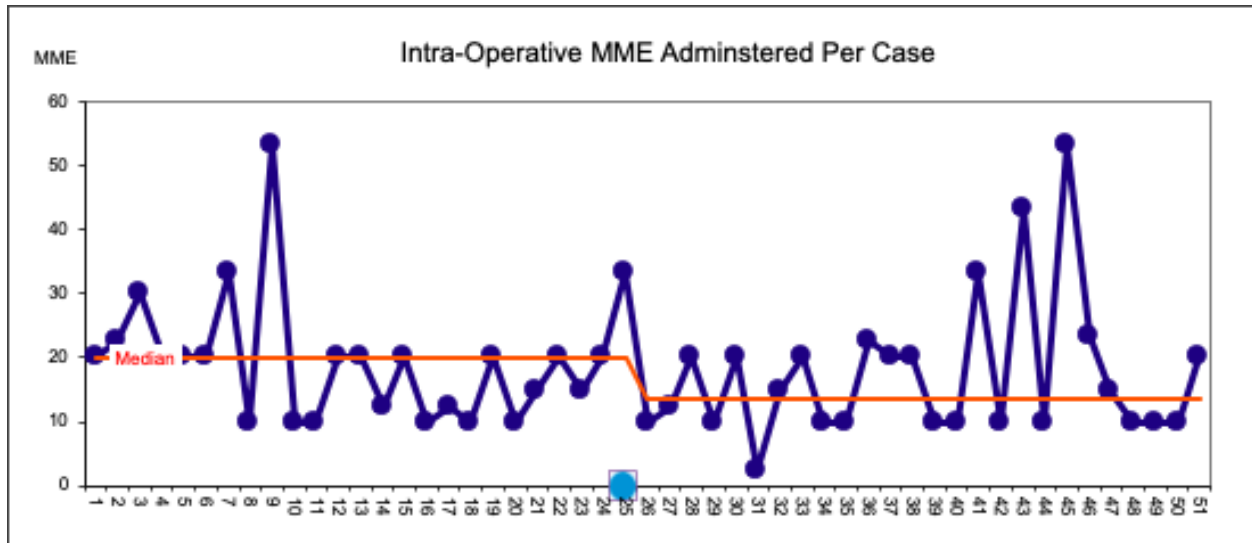


Table 3

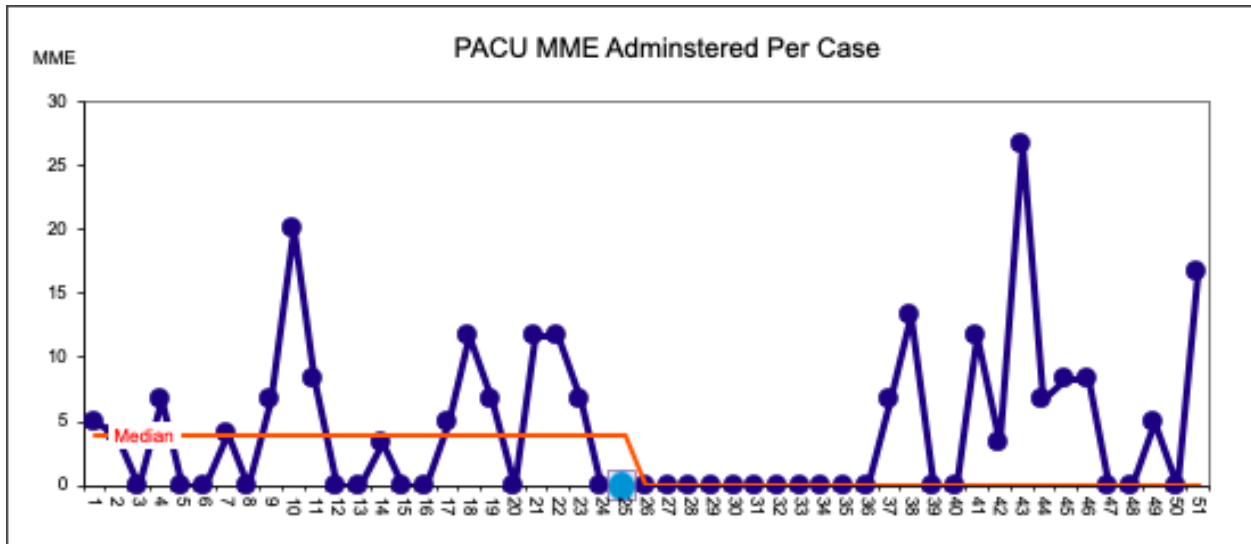


Table 4

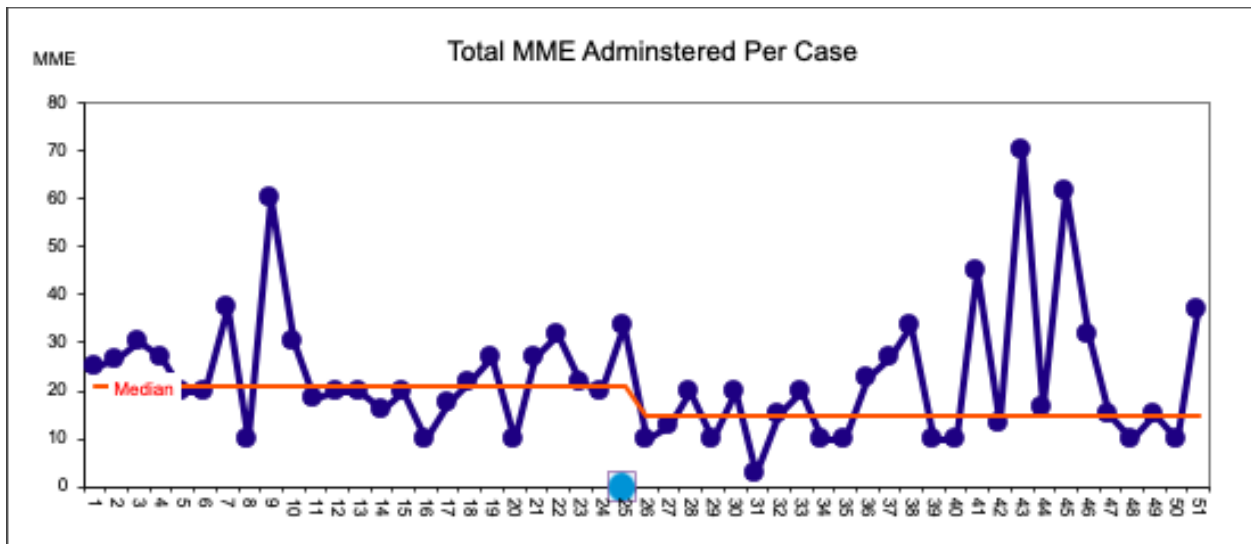


Table 5
Mann-Whitney U Test

Hypothesis Test Summary			
	Null Hypothesis	Test	Sig. ^{a,b}
1	The distribution of INTRAOP MME is the same across categories of IMPLEMENTATION.	Independent-Samples Mann-Whitney U Test	.406
2	The distribution of PACU MME is the same across categories of IMPLEMENTATION.	Independent-Samples Mann-Whitney U Test	.306
3	The distribution of TOTAL MME is the same across categories of IMPLEMENTATION.	Independent-Samples Mann-Whitney U Test	.148

a. The significance level is .050.

b. Asymptotic significance is displayed.

Appendix

ERAS for Breast Surgery Protocol

Pre-Operative

- Clear PO intake up until 2 hours before surgery
- Acetaminophen 1000 mg PO
- Gabapentin 600 mg PO (consider 300 mg in elderly or decreased renal function)
- Scopolamine patch 1.5 mg transdermal if high risk PONV

Intra-Operative

- Ultrasound guided peripheral nerve block after induction of anesthesia and before incision
 - Pectoralis (Pecs) type 1 and type 2 block
 - 0.2% ropivacaine or 0.25% bupivacaine
 - Inject 10mL between pectoralis major and pectoralis minor (Pecs 1)
 - Inject 20mL between serratus anterior and pectoralis minor (Pecs 2), for a total of 30mL of local anesthetic
 - If performing bilateral blocks, ensure the toxic dose of the local anesthetic chosen is not reached. Max dose 2-2.5 mg/kg bupivacaine (not to exceed 175 mg total dose)
 - Consider the addition of liposomal bupivacaine to the Pecs block. Defer if surgeon plans to inject liposomal bupivacaine during procedure.
- Maintenance Anesthetic
 - Consider TIVA if patient is particularly at risk for PONV
- Minimize the use of long acting opioid narcotic
- Consider Dexamethasone 8 mg (avoid Dexamethasone in diabetic patients) and Ondansetron 4 mg if not contraindicated
- Consider IV Acetaminophen if not given preoperatively
- Consider 15-30 mg of Ketorolac if acceptable to surgeon

Post- Operative

- Conservative IV fluid management. Limit IV fluid to <2L
- Ondansetron PRN
- Opioids PRN
- Early PO fluid intake
- Continued use of PO Acetaminophen