

Enhancing the Duration of Postoperative Analgesia with Perineural Dexmedetomidine

Brian B. Bonzo & Michael S. Orbita

Daniel K. Inouye Graduate School of Nursing

The Uniformed Services University of the Health Sciences

LCDR Kenneth Barber

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LCDR Brian Bonzo

Daniel K. Inouye Graduate School of Nursing
Uniformed Services University



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LT Michael Orbita

Daniel K. Inouye Graduate School of Nursing
Uniformed Services University

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Abstract

Phase II Site: Kimbrough Ambulatory Care Center, Fort Meade, MD

Project Title: Enhancing the Duration of Postoperative Analgesia with Perineural Dexmedetomidine

Authors: Michael S. Orbita and Brian Bonzo

Background or Problem: Single-shot interscalene brachial plexus blocks (ISB), using ropivacaine 0.5% and 4 mg of dexamethasone, are routinely administered to patients undergoing arthroscopic shoulder surgery to manage surgical pain. However, perineural dexamethasone provides an insufficient duration of analgesia. Therefore, the anesthesia providers at KACC are searching for an evidence-based perineural adjunct that provides adequate pain control for at least twenty-four hours without a significant cost burden for patients undergoing arthroscopic shoulder surgery.

Clinical Question: Does perineural dexmedetomidine and dexamethasone combined for ISB provide postoperative analgesia for at least forty-eight hours in adult patients undergoing ambulatory arthroscopic shoulder surgery at the Kimbrough Ambulatory Care Center?

Project Design: The focus of our project is to evaluate how perineural dexmedetomidine influences postoperative pain scores and opioid consumption among patients undergoing ambulatory arthroscopic shoulder surgery at KACC, with the goals being a pain score of less than five on postoperative day one and a decrease in opioid consumption in comparison to the current practice. Pre-implementation data will be collected to evaluate the efficacy of perineural dexamethasone. Patients will be instructed to record their pain severity and total opioid pill consumption daily for five days.

Analysis of Results: The data were analyzed to compare the outcomes in three categories: current pain, maximum pain, and opioid pills taken. Each outcome was evaluated using the two sample t-tests comparing pre versus post-intervention periods. Mean (SD) totals pre versus post-intervention were 16 (8) versus 14 (6) for current pain scores ($p=0.5$), 25 (10) versus 24 (7) for maximum pain scores ($p=0.6$), and 10 (8) versus 13 (11) for opioid pills taken ($p=0.4$).

Organizational Impact: Our project aligns with the MHS Quadruple Aim by improving patient outcomes and well-being and providing patient-centered care. It also aligns with current DHA initiatives to reduce the number of narcotics prescribed and consumed by active-duty service members.

Introduction

Single-shot peripheral nerve blockade is a regional anesthesia technique frequently performed on patients scheduled for orthopedic procedures and helps provide a region of anesthesia at the surgical site. Different local anesthetics (LA) can be used alone or combined with other perineural medications to produce various effects and depend on many variables, such as provider preference, available drugs, and the type of surgery. Interscalene brachial plexus blocks (ISB) are often performed for arthroscopic shoulder surgery, a procedure associated with more severe postoperative pain among our patient population. After reviewing the current literature, we determined that adding 1 mcg/kg of dexmedetomidine to single-shot ISB may reduce the severity of postoperative pain and analgesic consumption by providing a longer duration of analgesia.

Pain management can impact patient outcomes such as recovery, satisfaction, and medical costs. The benefits of regional anesthesia may allow patients to avoid unwanted complications and discomforts of general anesthesia. It also allows site-specific, extended perioperative analgesia, reducing patient morbidity and mortality. Furthermore, peripheral nerve blocks for ambulatory procedures can be cost-effective and may provide an earlier discharge and recovery after surgery.

Problem Synthesis

At the Kimbrough Ambulatory Care Center (KACC), many patients who underwent arthroscopic shoulder surgery are experiencing intense pain. To help manage postoperative shoulder pain, patients can consent to receive a single-shot ISB. Their current medication combination for nerve blocks is ropivacaine 0.5% mixed with 4 mg of dexamethasone. However, they began to notice that the duration of analgesia with dexamethasone was inadequate. They identified the problem during follow-up telephone evaluations twenty-four hours after discharge. Patients reported uncontrolled pain, meaning a pain score greater than five using an eleven-point ordinal scale (0-10) to rate the severity of their pain. They also noted decreased patient satisfaction and increased opioid consumption. Since perineural dexamethasone results in suboptimal outcomes, KACC anesthesia providers are searching for an alternative evidence-

based additive to use in single-shot ISB that provides adequate pain control for at least twenty-four hours without having a significant cost burden for patients undergoing arthroscopic shoulder surgery.

The CDC describes the opioid epidemic in the United States as beginning in 1999, with the rise in deaths caused by opioid overdose attributed to the increase in prescribed opioids throughout the 1990s (Centers for Disease Control and Prevention, 2021). Estimates from 2010, the annual financial cost of pain to society in the United States was estimated to be \$560 to \$635 billion, exceeding the yearly expenses for heart disease, cancer, and diabetes (Gaskin & Richard, 2011). A retrospective study from 2012 in the *Journal of Pain & Palliative Care Pharmacotherapy* assessed over three hundred thousand surgical patients. It evaluated the cost of opioid-related adverse events (ORADE), revealing an average price of \$4,707 per patient (Oderda et al., 2013). Alam et al. (2012) highlighted that using opioids for postsurgical pain control increased the likelihood of long-term opioid addiction, even when used for a short duration. As the opioid epidemic continued throughout the U.S., the Department of Health and Human Services (HHS) declared it a national emergency in 2017, when over 47,000 Americans died from an opioid overdose (HHS, 2021).

Significant efforts within the military health system (MHS) to combat the opioid epidemic began in 2018, with the development and implementation of the opioid overdose education and naloxone distribution program, OEND (DHA, 2018). The mission of OEND was to reduce the harm and severity caused by opioids among service members, their families, and retirees; their primary goal: was to increase the accessibility and use of naloxone among MHS beneficiaries prescribed opioids to those at risk for an ORADE (DHA, 2018). To combat the opioid epidemic, the number of opioids prescribed to MHS beneficiaries has significantly decreased from April 2017 to July 2021, reducing sixty-nine percent (DHA, 2018). One of the primary goals is to reduce the number of opioids patients consumes after discharge for pain control.

Relevance to Military Healthcare

The Military Health System (MHS) Quadruple Aim focuses on enhancing readiness—medically ready military and medical force—to support military operations and humanitarian missions anytime and anywhere. Providing safe, high-quality healthcare for service members and their families can prevent illness and promote resiliency (Health.mil, 2013). Maintaining mission readiness and preserving the military’s fighting force is paramount.

In 2009, military physicians prescribed nearly 3.8 million pain medications—four times more than in 2001. According to the 2015 Health-Related Behaviors Survey, 4% of active duty service members reported misusing prescription drugs (Meadow et al., 2018). The Department of Defense actively conducted prescribing initiatives that helped decrease nearly half the pain relievers used by service members (Lin et al., 2017). The effort to improve other pain control modalities, such as regional anesthesia, may reduce the use and dependence on opioids. Standardizing single-shot ISB using 0.5% ropivacaine mixed with 1 mcg/kg dexmedetomidine and 4 mg dexamethasone into daily practice can help decrease the number of opioids KACC patients use after shoulder surgery. In the ambulatory surgical setting, it provides opioid-free analgesia, which may also improve patient outcomes and reduce the severity of postsurgical pain.

Clinical Question

Does adding dexmedetomidine provide postoperative analgesia for at least forty-eight hours for adult patients undergoing ambulatory shoulder surgery at the Kimbrough Ambulatory Care Center?

Literature Review of Solutions

Search Strategy

We developed the following question to help guide our literature search towards potential solutions: *In adult patients receiving single-shot interscalene brachial plexus blocks for ambulatory shoulder surgery (P), how does dexmedetomidine 1 mcg/kg (I) compared with dexamethasone 4 mg (C) as perineural additives affect the duration of postoperative analgesia and opioid consumption (O)?* We

used the Excerpta Medica database (EMBASE), the Cumulative Index of Nursing and Allied Health Literature (CINAHL), and PubMed to collect articles published between 2000 to 2021 using the following keywords: anesthesia, regional, nerve block, additive, podiatry, orthopedic, surgery, adult, foot, leg, ankle, lower extremity, shoulder, analgesia, pain, dexmedetomidine, dexamethasone. We limited our search results to include articles published after 2000 that were available in English. We also limited our results to the following article types: meta-analysis, randomized controlled trials, reviews, and systematic reviews.

After completing our literature search, 594 articles were imported, and 202 duplicates were removed, leaving 392 articles for the initial screening of titles and abstracts. After the initial screening, thirty articles were selected for full-text review and assessed for eligibility. Twenty-five articles were excluded for the following reasons: wrong intervention, wrong dose, wrong patient population, and wrong setting. Six articles met final inclusion: four randomized control trials and two meta-analysis and systematic reviews. The PRISMA diagram of our literature search is included in Appendix A. We used the Johns Hopkins Nursing Quality of Evidence-Based Practice tool to assign a level of evidence and quality rating for each article. All articles provided a good level of evidence, IB.

Solution Synthesis

Liposomal bupivacaine, or Exparel, debuted in 2012 for local and regional anesthesia use. One limitation of exparel is that the manufacturer does not recommend using exparel for regional nerve blocks other than interscalene brachial plexus blocks. The manufacturer's website states that a 10 mL vial containing 133 mg of exparel costs \$189.37 and is sufficient to perform a single interscalene block. They determined this optimal dose based on their study involving subjects who underwent arthroscopic shoulder surgery. Although this study showed statistical significance in improved pain control for 48 hours after surgery, a single exparel vial costs three times more than a 2 mL vial of dexmedetomidine.

Another potential solution to the problem is the On-Q Pain Relief System. "A long sought-after goal is the ability to extend the duration of analgesia to 72 hours and beyond to prevent the rebound effect

(Avanos, 2021).” Anesthesia providers at KACC have previously approached leadership about purchasing and implementing the On-Q pump into practice as a potential solution to the problem. However, the equipment costs—catheter, infusion pump, medications—for a single patient were unfeasible since KACC currently lacks Defense Health Agency (DHA) funding.

Perineural dexmedetomidine is another alternative solution that may extend the duration of postoperative analgesia and reduce pain severity and opioid consumption while achieving adequate pain control. According to Xu et al. (2018), 0.75% ropivacaine with dexmedetomidine generally yields 60% analgesia, prolongs motor/sensory block, and decreases demand for rescue analgesia (i.e., tramadol, morphine). He et al. (2018) found that the group that received a coracoid approach brachial plexus block using 40 mL of 0.375% ropivacaine with 1 mcg/kg dexmedetomidine requested less rescue analgesia and experienced fewer side effects over the first 48 hours after block administration. In a study by Jung et al. (2018), no significant differences were found in the duration of analgesia nor motor or sensory block between the 20 mL of 0.5% ropivacaine with 2 mL dexmedetomidine (1 mcg/kg group or 1.5 mcg/kg group). 1 mcg/kg dexmedetomidine can achieve the desired analgesic effects without transient hypotensive episodes compared to 1.5 mcg/kg or 2 mcg/kg dexmedetomidine.

Potential Benefits

While producing opioid-free postoperative surgical pain management, dexmedetomidine can also reduce opioid use after hospital discharge. Perineural dexmedetomidine can extend the duration of anesthetic and analgesic effects compared to using local anesthesia alone or when combined with dexamethasone. Managing acute pain during the early postoperative period is important to help decrease opioid consumption and improve patient satisfaction and recovery. Proper administration of peripheral nerve blockade decreases the patient’s pain and minimizes the use of narcotic medications.

Focus Areas

Our project will focus on how perineural dexmedetomidine influences postoperative pain scores and opioid consumption, with the goals being a DVPRS score of less than five at forty-eight hours after block administration and decreased opioid consumption from the pre-implementation baseline.

Business Case Analysis

The current evidence supports the implementation of dexmedetomidine as an additive to single-shot peripheral nerve blocks, which can extend the duration of postoperative analgesia. The advantages of using dexmedetomidine are the availability of the medication in many medical facilities, providers' familiarity with the medication (not a new modality), and the minimal time and resources needed to train and educate anesthesia providers. Dexmedetomidine is a more affordable solution (\$42 per 200 mcg/2 mL vial) than exparel (\$188.37 per 133mg/10ml vial) and the On-Q Pain Relief System. Although the cost of dexmedetomidine may seem high, the benefits outweigh the costs by improving patient outcomes, patient satisfaction, provider satisfaction, and the duration of analgesia. The costs will also be offset by reducing opioid prescription requirements and other costs associated with opioid-related side effects and adverse events.

Organizing Framework

We used the Iowa Model Revised (2017) to guide the development and implementation of our evidence-based project. This model has been adopted widely to direct EBP projects and is renowned for its applicability and ease of use by interprofessional healthcare teams to improve patient and facility outcomes. This model will help us execute our solution to achieve our goals and objectives.

The foundation of the Iowa Model begins with identifying triggering issues with current practices that highlight opportunities for improvement. KACC clinicians determined that the current standard of practice, perineural dexamethasone, is providing an inadequate duration of postsurgical analgesia, making this the triggering issue and priority for the facility and key stakeholders. After the triggering issues were deemed a priority for all parties, we conducted an extensive literature search to gather sufficient evidence,

leading us to our evidence-based solution. The implementation phase of our project involves designing a standardized protocol to pilot the practice change. This includes engaging and preparing key stakeholders, gathering data, and promoting the practice change.

Project Design

General Approach

Our project focuses on extending the duration of analgesia while reducing the severity of postsurgical pain and reducing opioid consumption after discharge among Military Health System (MHS) beneficiaries undergoing ambulatory arthroscopic shoulder surgery at KACC.

Our first step towards achieving our goal includes providing education and awareness on this project for all affected personnel. This will also help to address any barriers or questions. Follow-up data collection after discharge will be collected over a seventy-two-hour period after surgery, at twenty-four-hour time intervals.

Second, we will utilize the defense-veterans pain rating scale (DVPRS), an ordinal scale that our patients will use to rate their pain severity. Patients were informed about the anesthesia team following up postoperatively to evaluate the severity of surgical pain.

Third, we will evaluate the number of pain medications patients take after discharge by having patients record the remaining number of pills at each interval. KACC anesthesia providers already follow a standardized order set for discharge pain medications dependent on the type of procedure. This standardized process eliminates variations that may cause it to be a confounding variable.

Setting and Population

Kimbrough Ambulatory Care Center (KACC) is an outpatient military treatment facility (MTF) located at Fort Meade, Maryland, that performs around 2000 ambulatory surgeries annually for patients older than three months and in twelve different specialties. The majority of them are orthopedic procedures. Anesthesia providers routinely implement peripheral nerve blocks into the anesthetic plan and administer roughly 1700 peripheral nerve blocks annually. The current pharmacologic standard of

practice for single-shot peripheral nerve blocks includes ropivacaine 0.5% with dexamethasone 4 milligrams. We will focus on those undergoing arthroscopic shoulder surgery for rotator cuff repairs because providers notice a higher frequency of uncontrolled pain associated with this particular surgery.

Procedural Steps

We will execute our project in multiple phases. Our project timeline is provided in Appendix C. Phase one of this project has already been completed. It involved identifying triggering issues and an extensive literature review of the current evidence to identify potential solutions.

The second phase involves a two to three-month period. This involves completing the procedural steps to gain IRB approval to execute our EBP project at KACC and collecting pre-implementation baseline data to evaluate the effects of perineural dexamethasone on postoperative pain severity and opioid consumption. We will administer single-shot ISB using ropivacaine 0.5% mixed with dexamethasone 4 mg on patients undergoing arthroscopic shoulder surgery. The time allotment for this phase is to ensure adequate data collection for comparing our intervention to the current practice upon project conclusion.

The third phase involves creating awareness of our project at the facility, engaging key stakeholders, and recruiting subjects. We will implement our solution and gather the necessary data needed to support its use over the current practice.

Data Analysis Plan

Key stakeholders will be well-informed and educated on our project's purpose, goals, and objectives and continuous engagement to ensure comprehension. We will provide education on dexmedetomidine, proper use of the DVPRS, and opioid use. We will also define set time intervals for when to perform follow-up evaluations and for patients to rate and record pain severity.

The first common measurable outcome evaluated in the literature is patient-reported pain severity using an ordinal scale. We will use the Defense Veterans Pain Rating Scale (DVPRS), commonly used in the military healthcare setting. "The DVPRS is a graphic tool clinicians can use to facilitate self-reported

pain diagnoses from patients (Defense & Veterans Center for Integrative Pain Management, n.d.).” Part of our standard operating procedure will include staff and patient education on this scale to ensure an accurate understanding of the DVPRS. The second measurable outcome is to track opioid consumption after discharge. Patients will keep track of the number of opioid pills remaining at each determined time interval. During follow-up evaluations, patients will be asked about their remaining pill count, which will then be recorded. Our overall goal is to have patient-reported DVPRS scores less than five over a seventy-two-hour period and ensure patients self-administer pain medications as ordered and appropriately with their DVPRS scores (Defense & Veterans Center for Integrative Pain Management, n.d.).

We will use descriptive statistics to evaluate the impact of perineural dexmedetomidine. Pre-implementation data will be collected over three months to evaluate the efficacy of the current status quo LA additive, dexamethasone 4 mg, for patients undergoing arthroscopic shoulder surgery. After completing this phase, we will determine the number of patients who will undergo arthroscopic shoulder surgery over the next six months, with the overall goal of recruiting at least thirty patients. We will design and implement a standardized process to ensure our project and results are valid and reliable.

We will use the Mann-Whitney U test to analyze the DVPRS scores and the t-test to analyze pain medicine consumption for both data sets to help us determine the efficacy of our intervention.

Potential Barriers

There is the potential for us to encounter multiple barriers during project implementation. The first barrier is apprehension and resistance from affected department personnel. They may refuse to participate and execute our project for countless reasons. We hope to overcome this barrier by providing awareness and education about this project’s purpose, objectives, and potential benefits.

Another barrier we may face is failing to recruit enough subjects or subjects refusing the intervention. We will attenuate this barrier by continuously engaging patients on all fronts, especially on education as above regarding the purpose and potential benefits of the initiative.

Sustainment and Dissemination Plan

To ensure our project is executed and sustained to the fullest extent, we will develop a standardized process that will become a standardized operating procedure (SOP) signed by executive leadership and made available to all affected personnel. We will train a department champion who will be trained and knowledgeable on all project efforts to ensure all efforts are compliant.

We will provide physical copies containing detailed explanations of the project and answers to any questions. Our SOP will thoroughly explain all steps to ensure the project's success. We will continuously engage all key stakeholders to evaluate our efforts so they can always provide feedback.

HIPAA Concerns and Ethical Considerations

The measurable outcomes for our project will be postoperative DVPRS pain scores and the number of pain medications patients consume after discharge. Personal identifiable information (PPI) (i.e., name, telephone number) protected by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) will be maintained for patient follow-up. The only PPI we used was to find the patient, the type of surgery, and the regional anesthesia they received.

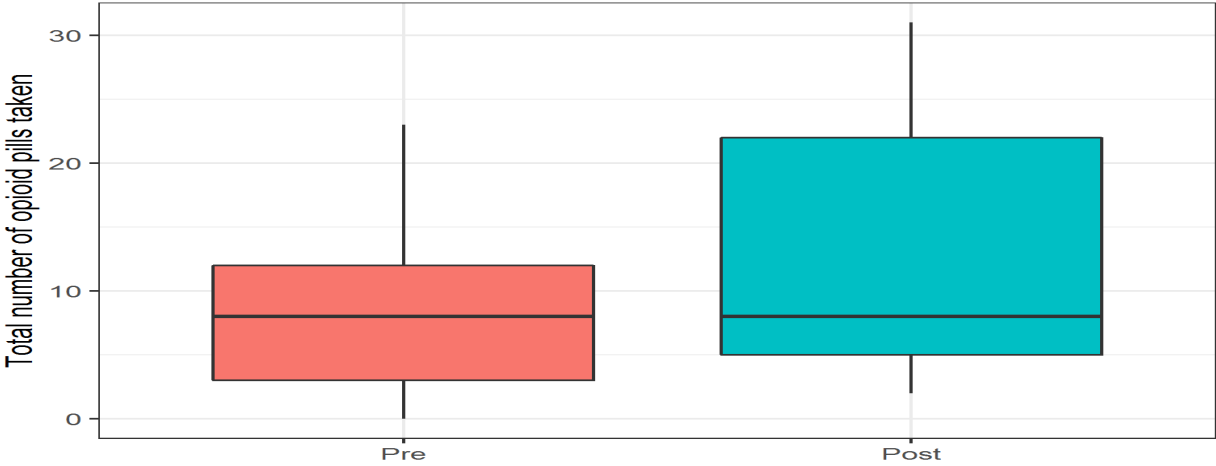
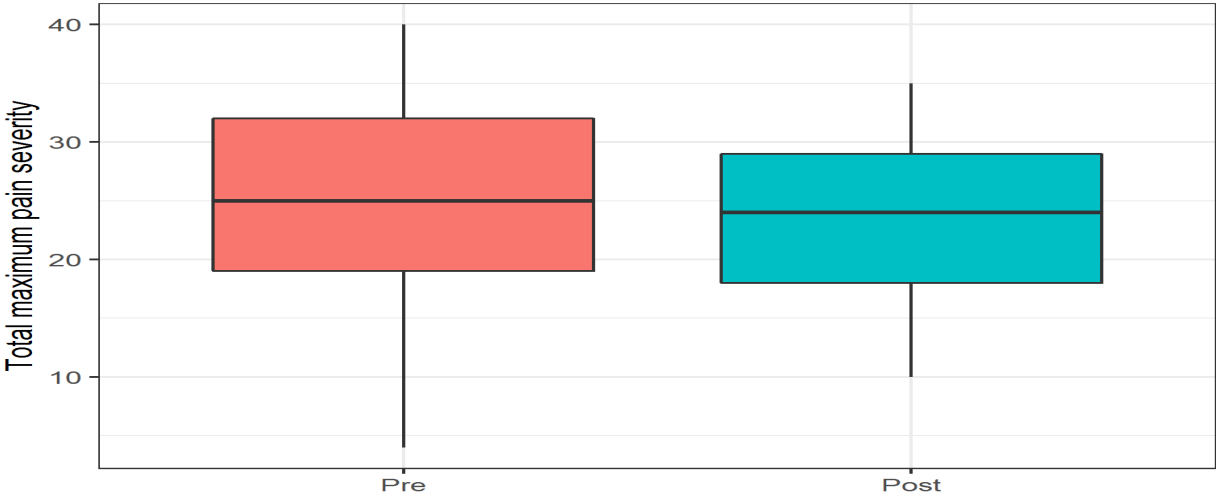
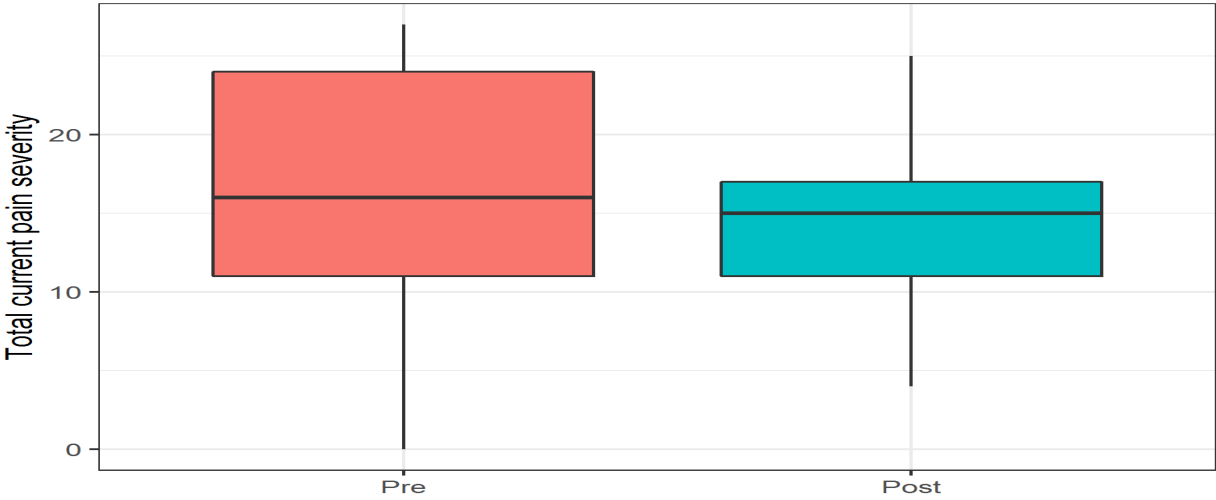
Project Results

During the execution of our project, we were able to follow twenty-six patients who underwent arthroscopic shoulder surgery. With KACC being an ambulatory surgery center without inpatient nor overnight capabilities, each patient had an American Society of Anesthesiologists (ASA) physical status classification of 1 or 2 and was discharged home after meeting PACU discharge criteria. Each patient in the pre-implementation group (n=13) received a single-shot interscalene brachial plexus block using 0.5% ropivacaine 20 mL combined with dexamethasone 4 mg. Each patient in the implementation group (n=13) received a single-shot interscalene brachial plexus block using 0.5% ropivacaine 20 mL combined with dexamethasone 4 mg and dexmedetomidine 50 mcg. The medications used for each block were prepared into a single syringe. The KACC anesthesia staff agreed to use 50 mcg dexmedetomidine dose rather than

the suggested 1 mcg/kg in literature. The lower dose preference accounts for the patient's decreased blood pressure and cerebral perfusion pressure during beach chair position.

ISBs were performed before surgery in the preoperative holding area. Patients were continuously monitored to assess their electrocardiogram, heart rate, oxygen saturation, and non-invasive blood pressure. Supplemental oxygen was also administered via a simple face mask. Patients were placed in the head-up position with their head rotated toward the contralateral side of the site of block administration. Each block was performed under ultrasound to minimize patient harm and for the accuracy of medication deposition at the correct anatomical location. Upon completion, sensory and motor functions were also assessed to evaluate the efficacy of block administration.

The data were analyzed to compare the outcomes in three categories: current pain, maximum pain, and opioid pills taken. The boxplots represent group medians and first and third quartiles, with whiskers extending 1.5 times the interquartile range. Statistical analysis was performed using the two-sample t-tests comparing pre versus post-intervention within five days. Mean (SD) totals pre versus post-intervention were 16 (8) versus 14 (6) for current pain scores ($p=0.5$), 25 (10) versus 24 (7) for maximum pain scores ($p=0.6$), and 10 (8) versus 13 (11) for opioid pills taken ($p=0.4$). Utilizing the defense and veterans pain rating scale (DVPRS), the mean current and maximum pain scores were calculated for each participant over five days and compared by pre versus post-intervention periods using two-sample t-tests. Mean (SD) mean pain scores pre versus post-intervention were 3.2 (1.7) vs. 2.8 (1.2) for current pain scores ($p=0.47$) and 5.1 (2.1) vs. 4.7 (1.5) for maximum pain scores ($p=0.6$). Each participant means current and maximum pain scores over 48 hours pre versus post-intervention calculations were 3.8 (2.0) versus 2.6 (1.3) for current pain score ($p=0.09$), 5.3 (2.1) versus 4.4 (1.1) for maximum pain scores ($p=0.16$), and 5.2 (3.1) versus 5.2 (4.3) for opioid pills taken ($p=0.96$).



Outcome Results Over the First 48-hours After Surgery			
	Pre-Intervention (n = 13)	Post-Intervention (n = 13)	P-Value
Current Pain Severity	3.8 (2.0)	2.6 (1.3)	0.09
Maximum Pain Severity in 24-hour period	5.3 (2.1)	4.4 (1.1)	0.16
Opioid Consumption	5.2 (3.1)	5.2 (4.3)	0.96

Outcome Results Over 5-day Period			
	Pre-Intervention (n = 13)	Post-Intervention (n = 13)	P-Value
Current Pain Severity	3.2 (1.7)	2.8 (1.2)	0.47
Maximum Pain Severity in 24-hour period	5.1 (2.1)	4.7 (1.5)	0.60
Opioid Consumption	10 (8.0)	13 (11.0)	0.40

Analysis of the Results

There was no statistical significance between the two groups with respect to current pain severity, maximum pain severity, and opioid pills taken. However, the intervention group exhibited a slight reduction in current and maximum pain severities. The measurement of current and maximum pain score within 48 hours exhibited a slight prolongation in analgesia among the intervention group. One aspect of note is the marginally greater mean opioid consumption in the intervention group. This could be for several reasons, such as patients taking their opioid medications to treat non-surgical pain or a lack of understanding of the appropriate timing or indication. Another confounding variable is the small sample size which may be related to the low volume of patients who underwent arthroscopic shoulder surgery within the time we allotted for project implementation.

Organizational Impact to Practice & Policy

Improving patient outcomes by prolonging the post-analgesia effects of regional anesthesia continues to be studied. Various studies show the prolonged effects of local anesthetic blocks mixed with a single or multiple adjunct. The 20 ml ropivacaine 0.5% combined with both 4 mg of dexamethasone and 50 mcg of dexmedetomidine exhibited clinical significance. Some providers had concerns regarding the two most common side effects of dexmedetomidine, hypotension and bradycardia. However, adding dexmedetomidine in the intervention group did not significantly affect hemodynamic parameters among our patients. These patients had no recovery delay within the post-anesthesia care unit (PACU).

Our results revealed that the intervention group did experience reduced postoperative surgical pain, although there was no significant statistical significance. However, we met our goal of achieving a pain level less than five during the first 48 hours. The five day patient follow was done within Kimbrough's standard of care. Anesthesia providers at KACC were receptive to the addition of perineural adjunct and expressed willingness to include it in their practice. The practice variability amongst anesthesia will shift to a standardized regional ISB approach, especially for rotator cuff repair.

Future Directions for Research and Practice

The future direction for the research and practice based on the study's outcome will be presented locally to the KACC shareholders and the Uniformed Services University. The advantages of the offered solution established confidence in anesthesia providers about the benefit of using additional adjuncts to help improve post-analgesia. The undesirable effects of dexmedetomidine causing hypotension, bradycardia, and sedation were inconclusive to PACU patients' untimely discharge. No patients from the study required a rescue block from uncontrolled postoperative pain. KACC staff should collaborate with the surgical team to improve discharge instructions for using oral pain medications. Most patients either take oral opioids too early in the absence of pain or delay opioid intake after the ISB block completely dissipates.

Adding dexmedetomidine in regional ISB blocks for rotator cuff repair will improve beneficiaries' health outcome and maintain cost effectiveness. The use of perineural dexmedetomidine in various block applications continues to gain attention among anesthesia providers. Further research is needed to elucidate the advantages and disadvantages of incorporating dexmedetomidine as key adjunct components in local anesthesia solutions for selective surgical procedures.

Conclusion

Postoperative pain has remained a significant challenge for recovery after surgery. There are multimodal approaches to managing postoperative pain. Managing acute postoperative pain during the acute phase can reduce the risk of patients developing chronic pain and opioid dependency. The impact of uncontrolled postoperative impairs patients' healing process and disrupts their activities of daily living. KACC raised concerns about postoperative pain control in patients that had rotator cuff repair. The cost of improving and extending post-analgesia control varies between continuous infusion pain pumps (requires expensive consumables, personnel training, and patient education) versus single-shot ISB blocks. Dexmedetomidine and dexamethasone combined exhibited synergistic effects in enhancing the duration of analgesia in our patient population. With the findings from our project, the practitioners at Kimbrough can implement or introduce this cost-effective option into their practice to improve postoperative analgesia.

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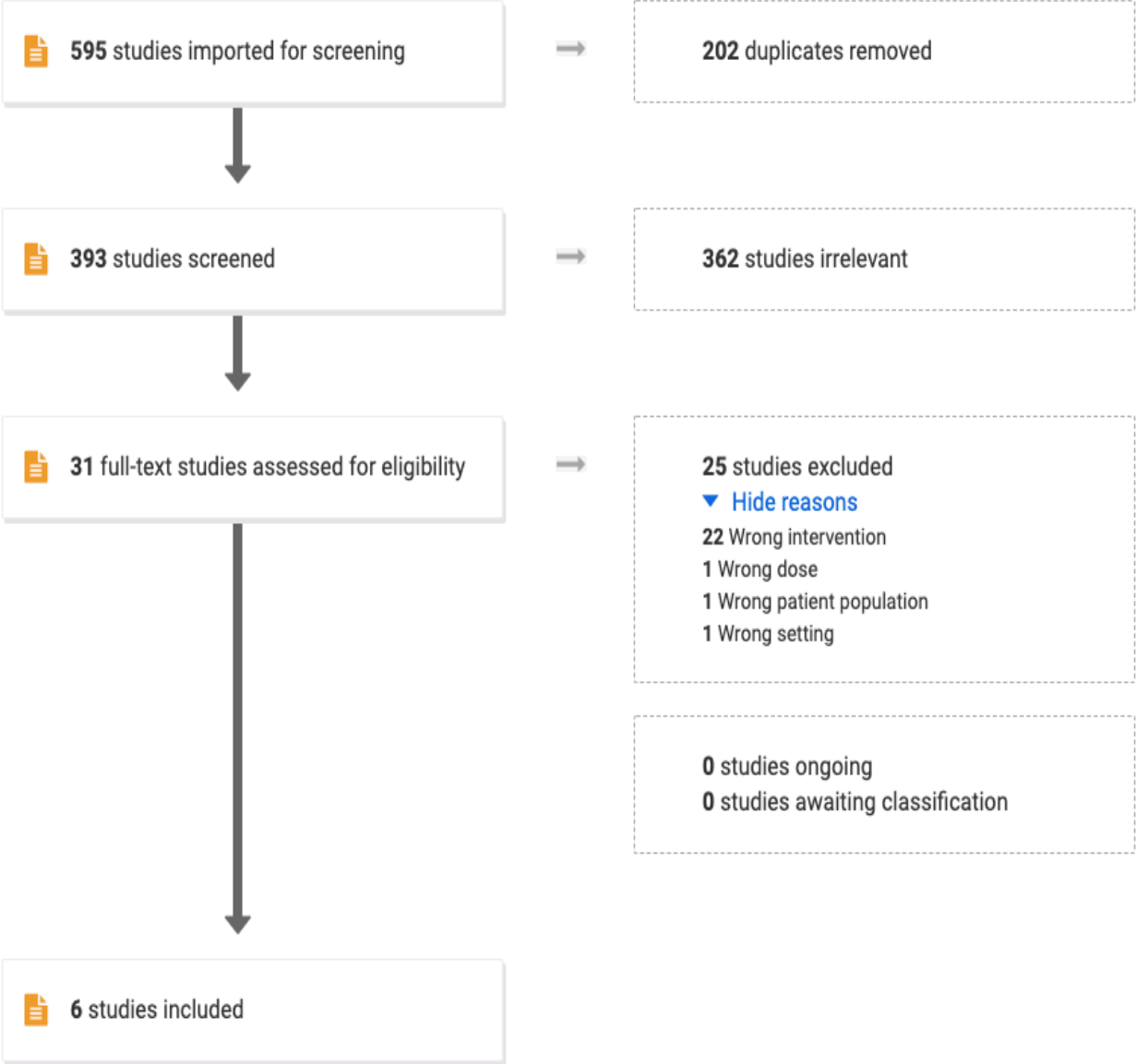
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Appendix A: PRISMA Flow Diagram



Appendix B: Evidence Table

	Purpose, Aims	Research Question/Hypothesis	Study Design	Sample Size	Sampling Plan	IV	DV	Statistical Analysis	Results	Strengths	Weaknesses	JHNEBP Level of Evidence
Abdalla & Brill, 2013	Examine perineural dexmedetomidine as local anaesthetic (LA) adjuvant for neuraxial and peripheral nerve block that can prolong duration of analgesia compared to LA alone.	The prolong effects of dexmedetomidine on neuraxial and peripheral nerve blocks	Systematic review and meta-analysis of randomized controlled trials	n=9 Randomized Control Trials (516 patients)	Utilized PRISMA recommendation to develop manuscript. Identified and examined RCTs related to dexmedetomidine (dexmedetomidine group) added to LA while comparing to LA alone (control group) on neuraxial and peripheral nerve block. Literature search retrieved using US National Library of Medicine database, MEDLINE, the Excerpta Medica database, Embase; Cochrane Database of Systematic Reviews; and Cochrane Central Register of Controlled Trials Database (January 1985-August 2012). Using Jadad score, RCTs evaluated in relation of the effects adding dexmedetomidine with LA versus LA alone.	Peripheral Brachial Plexus additive dexmedetomidine with using long-acting LA such as ropivacaine, bupivacaine, and levobupivacaine. 40 ml of 0.5% levobupivacaine plus 100 mcg Dex in 1 ml 39 ml 0.5% levobupivacaine plus 30 mcg Dex 1 mcg/kg in 2 ml 30 ml 0.33% bupivacaine plus Dex 0.75 mcg/kg in 1 ml	Primary endpoint about sensory block duration. Second endpoint, motor block duration, sensory/motor block onset time, analgesic consumption, time of fist analgesic request, pain score and adverse effects (i.e., hypotension, bradycardia, respiratory depression, and postoperative sedation) of dexmedetomidine.	37 articles included per criteria mentioned above. Methodological quality of all nine trials was good (six with Jadad score 5/5 and three Jadad score 4/5). - 28 RCTs excluded because of intervention examined (n=14), population studied (n=7), active comparator (n=5), study design (n=1), and language publication (n=1) - Nine RCTs included with total 516 patients (274 dexmedetomidine group and 242 control group). among Nine RCTs, five RCTs examine neuraxial dexmedetomidine while four assessed peripheral dexmedetomidine in brachial plexus block.	Sensory block duration: The data signal peripheral dexmedetomidine used in BPB at axillary, supraclavicular, and infraclavicular levels may prolong the mean duration of sensory block by 284 min (95% CI: 1.39, 565.68, P<0.05), a relative increase of 76% compared to LA alone. However, the difference did not reach statistical significance. Heterogeneity among trials in this group was also high (I ² =1; P<0.00001). Perineural dexmedetomidine on BPB resulted in prolongation of motor block duration by 268 min (95% CI: 15.47, 520.06, P=0.04) or 87% and an increase in time to first analgesic request by 345 min (95% CI: 102.68, 587.23, P=0.005) or 70% compared to LA alone. Sensory and motor block onset time were similar for both dexmedetomidine and control group Perineural adjuvant using dexmedetomidine prolong duration of motor block but sensory block did not reach statistical significance. Dexmedetomidine also hasten onset of sensory block in spinal anaesthesia and prolongs the time to first analgesic request in oth spinal and brachial plexus block. The advantage of may offset by an increased likelihood of transient, reversible bradycardia and prolongation of motor block. Primary outcome for peripheral BCP: - Motor block duration: 40 ml of 0.5% levobupivacaine plus 100 mcg Dex in 1 ml - Sensory block duration: 39 ml 0.5% levobupivacaine plus 30 mcg Dex 1 mcg/kg in 2 ml - Time to first analgesic request: 30 ml 0.33% bupivacaine plus Dex 0.75 mcg/kg in 1 ml	Trials included were small and characterized by high levels of heterogeneity thus limit clinical combinability of the source trials and generalizability of the result. Present safety data, limited which may not apply to other block types as local neurotoxicity and systemic uptake are both influenced by site-specific perfusion levels. Generalizability of this review is further limited by publication bias as all source studies originated from Middle Eastern countries which may or may not reflect less stringent IRB and/or editorial board policies. Dose or perineural dexmedetomidine varied between interthecal (3, 5, 10, 15 mcg) and peripheral route route (30, 100 mcg, 0.75 or 1 mcg/kg)	I, B	
Gao et al., 2019	Compare the effect of dexmedetomidine and dexamethasone as an adjuvant for the erector spinae plane block (ESPB) to control postoperative pain after video-assisted thoracoscopic lobectomy surgery (VATLS)		Randomized, controlled, double-blind study	n=90	90 patients schedule to undergo VATLS enrolled in the trial	Preoperative block into the erector spinae (muscle adjacent to transverse process using: Group (R) - 0.5% ropivacaine 30 ml Group (RS) - 0.5% ropivacaine 30 ml with 10 mg dexamethasone Group (RM) - 0.5% ropivacaine 30 ml with 1 mcg/kg dexmedetomidine	Visual Analog Score (VAS) score at various time points: - Waking up in Post-Anesthesia Care Unit (PACU) - After surgery (2, 4, 6, 8, 12, 24, 48, 72 hours) Duration of sensory block First request to use the patient controlled analgesia use Post-surgical hospital stay	The Kolmogorov-Smirnov test was used to determine the normality of data distribution. Continuous variables were expressed as mean +/- standard deviation, and median (25th - 75th percentiles), and categorical variables as counts (percentages). The study compared normally distributed continuous variables among group using one-way ANOVA, and used a least significant difference (LSD) procedure for post comparison, while non normally distributed continuous variables among the groups were compared using the Kruskal-Wallis test. Mann-Whitney U tests were applied for intergroup comparisons when significant difference was detected between the groups. Categorical variables were compared using chi-squared or Fisher's exact test (P<0.05 was considered statistically significant).	Ropivacaine with dexmedetomidine Group (RM) - VAS score lower at wake up and at postoperative (2, 4, 12, and 24 hours) - Longer median sensory blockade (P=0.001) - First request to use PCS machine was prolonged compared to toher group (ropivacaine (R) group and ropivacaine with dexamethasone (RS) group, (P<0.001). - Total PCA use, post-surgical stay, rate of rescue analgesia use were reduced significantly compared to R and RS group.	Pain level and sensory blockade assessment methods used were limited to subjective perception of pain and cold; 1 does not provide objective data regarding pain and sensory blockade.	I, B	
He et al., 2018	Assess the effects of dexmedetomidine on the duration of anesthesia and the effective postoperative analgesia time when it was mixed with ropivacaine for CABPB under dual stimulation		Prospective, randomized, double-blind, controlled trial	n=60	60 patients randomly assigned into 2 group (C and D) using computer. The corresponding randomly assigned patient's number was sealed in an opaque envelop that was opened immediately before anesthesia.	Group C (control): patient received 40ml of 0.375% ropivacaine Group D (dexmedetomidine): patient received 40ml of 0.037% ropivacaine mixed with 1 mcg/kg dexmedetomidine	Duration of anesthesia and postoperative analgesia, comparing group C versus group D	Statistical analysis performed by SPSS (version 17.0, SPSS Inc, Chicago, IL). Quantitative data were presented as frequency and percentage. Normal distribution of data was investigated by Kolmogorov-Smirnov test. Parametric tests performed using either 2-sample Student t test or Chi-square analysis, according to the type of variable. Nonparametric tests were performed using Mann-Whitney U test. Difference was considered statistically significant if P<0.05.	The addition of 1mcg/kg dexmedetomidine to ropivacaine: - Group D (dexmedetomidine) showed longer duration of anesthesia than group C (759 vs 634 P<0.5) - Onset time of sensory and motor blocks were not significantly different between 2 group - VAS was lower in group D at 24 hours after block compared to group C (P<.05) - Lower demand for rescue tramadol during the first 48 hours	Fixed the dose of dexmedetomidine on 1mg/kg, and did not set up gradient doses. In some patients, the block effect was poor in the nonoperative area, without affecting patient comfort during the surgery.	I, B	

Appendix B: Evidence Table

Purpose, Aims	Research Question/Hypothesis	Study Design	Sample Size	Sampling Plan	IV	DV	Statistical Analysis	Results	Strengths	Weaknesses	JHNEBP Level of Evidence
Jung et al., 2018	To investigate the optimal dose of dexmedetomidine in ISB for postoperative analgesia in patients undergoing arthroscopic shoulder surgery	randomized, doubleblind study	n = 100	100 subjects scheduled for elective shoulder arthroscopic surgery. Ultrasound-guided ISB was performed before general anesthesia using 22 mL of ropivacaine 0.5% combined with 1, 1.5, or 2mg/kg of dexmedetomidine (group D1, D2, and D3, respectively) or with normal saline as a control (group R, n=25 per group). Control: 20 mL ropivacaine 0.5% Group R: Control + 2 mL saline Group D1: Control + 2 mL dexmedetomidine 1 mcg/kg Group D2: Control + 2 mL dexmedetomidine 1.5 mcg/kg Group D3: Control + 2 mL dexmedetomidine 2 mcg/kg	Dexmedetomidine 1, 1.5, or 2mg/kg	Duration of analgesia (DOA), numeric pain rating scale (NRS), consumption of additional analgesics during 36h after ISB, durations of motor and sensory block (DOM and DOS), hemodynamic variables, sedation and dyspnea scores	The sample size was calculated based on the assumption that dexmedetomidine would prolong the DOA by 20%. We used the study data published by Esmaglu et al, who showed that perineural dexmedetomidine prolonged the DOA from 887±261 to 1009±164min in patients who had received an axillary brachial plexus block. [10] We assumed mean DOA of 800min, a standard deviation of 170min, and that a 20% prolongation of analgesia would be statistically significant. This calculation established that a sample size of 22 was required in each group for a type I error of 0.05 and a type II error of 0.2. Allowing for a drop-out rate 15%, a total of 100 patients were required. The statistical analysis was performed using SPSS for Windows, version 20.0 software (IBM Corp., Armonk, NY) and R 3.2.4 (R Foundation for Statistical Computing, Vienna, Austria). Numeric variables are presented as the mean and standard deviation and categorical data are presented using counts and percentages. Continuous variables were tested for normal distribution using the Kolmogorov-Smirnov test. For normally distributed data, the statistical analysis was carried out by 1-way analysis of variance followed by Bonferroni or Tukey post hoc test. For non-normally distributed data, the statistical analyses were performed using the Kruskal-Wallis test and the Mann-Whitney test followed by Bonferroni correction of the significance level. The incidences of the categorical data were analyzed using the chi-squared test with Sheffé test for post hoc comparison. Kaplan-Meier survival curves were constructed to compare time to first request for rescue analgesics (when pushing the PCA button) between the groups. A P value < .05 was considered to be statistically significant.	Ninety-seven patients completed the study. The DOS, DOM, and DOA were significantly longer in the dexmedetomidine groups than in group R. The DOA was significantly longer in group D3 than in groups D1 (P=.026) and D2 (P=.039). The DOA was 808.13 ±179.57, 1032.60±288.14, 1042.04±188.13, and 1223.96±238.06 min in groups R, D1, D2, and D3, respectively. The NRS score was significantly higher in group R than in the dexmedetomidine groups 12h after ISB (P<.001) and significantly lower in group D3 than in the other groups 18h after ISB (P=.02). The incidence of hypotension was higher in groups D2 and D3 than in group R during surgery (P=.008 and P=.011, respectively). There were no significant differences in consumption of rescue analgesics, sedation, and dyspnea scores between the study groups. Perineural dexmedetomidine 2mg/kg could be the optimal dose in ISB for arthroscopic shoulder surgery in that it provides an adequate DOA, but this dose was associated with increased risk of hypotension	Study design. Gradient dosing. Population/Sample	Did not measure the time to onset of sensory or motor block. The patients' weights and the proportions of ASA physical status II were higher in the groups that received dexmedetomidine 1 or 2mg/kg than those in the control group. Only assessed pain at rest and not during activity. Did not evaluate the effects of a dexmedetomidine dose above 2mg/kg, because they judged that a higher dose of dexmedetomidine may cause more systemic side effects. "It is not possible to state that 2mg/kg is the maximum possible dose, and further research would be needed to assess the safety and efficacy of perineural dexmedetomidine at doses higher than 2mg/kg.	I, B

Appendix B: Evidence Table

	Purpose, Aims	Research Question/Hypothesis	Study Design	Sample Size	Sampling Plan	IV	DV	Statistical Analysis	Results	Strengths	Weaknesses	JHNEBP Level of Evidence
Vorobeic hik et al., 2017	Updated meta-analysis dexmedetomidine perineural local anaesthetic (LA) adjunct to prolong nerve block duration		Systematic review and meta-analysis of randomized controlled trials	n=37 trials (2007 patients)	34 full-text randomized trials represents preferred reporting items for systematic reviews and meta-analyses (PRISMA) Data extraction included primary author, publication year, comparative group, sample size, nature of primary outcome, nature of surgical anaesthetic, level of brachial plexus block, nerve localization techniques, block characteristic, analgesic effect and dexmedetomidine side-effects. The perineural additives related to dexmethasone and fentanyl were also extracted. The review reported included using standard deviation (SD) via formula $SD=Range/4$ and $SD=QR/1.35$ described by the Cochrane Handbook for Systematic Reviewthe range of interquartile range (IQR)	Perineural dexmedetomidine used in either weight-based doses (0.75 to 1.0 mcg/kg) or flat doses (10 to 150mcg)	Primary outcome - duration (min) sensory block from completion of LA injection to full recovery of sensory Second outcome - from completion of LA injection to resuming full sensory (duration in min) and motor function (duration in min) Duration of analgesic outcome in min via measuring first consumption of morphine (mg) equivalent in the first 24 hours.	Perineural dexmedetomidine on motor brachial plexus block (BPB) prolonged block duration was evaluated in 31 trials at least 58% [50%], (P<0.0001, I2 = 100%) for interscalene Block (ISB); 61% [90%], (P<0.0001, I2 = 100%) for Suprascavicular Block (SCB); 19% [38%], (P<0.0001, I2 = 85%) for infraclavicular Block (ICB) and 11% [35%], (P<0.0001, I2 = 100%) for axillary block (AXB). Overall treatment for all BPB suggested that dexmedetomidine prolongs motor block duration by at least 58% [58%], (P<0.0001, I2 = 100%) or from 6.9 h to 10.1 h. Evidence findings rated high. Perineural dexmedetomidine as a local anesthetic (LA) adjunct on sensory BPB was evaluated in 31 trials. Dexmedetomidine quickens LA onset at least 77% [32%], (P<0.003, I2 = 99%) for ISB; 44% [33%], (P<0.0001, I2 = 94%) for SCB; 38% [31%], (P<0.003, I2 = 0%) for ICB; and 24% [18%], (P<0.0001, I2 = 64%) for AXB. Overall treatment effect for all levels of BPB suggested that dexmedetomidine shorten sensory block onset time by at least 40% [28%], (P<0.0001, I2 = 98%) or from 20.0 min to 10.8 min. Evidence findings rated moderate. Perineural dexmedetomidine as a postoperative analgesia was evaluated in 26 trials, indicated with the first analgesic request to attain a pain (visual analogue score (VAS)) > 3 or > 4 or to first patient report of postoperative pain at surgical site. Dexmedetomidine prolonged duration of analgesia by at least 60% [74%], (P<0.0001, I2 = 100%) for ISB, 69% [91%], (P<0.0001, I2 = 100%) for SCB, 0% [39%], (P<0.0001, I2 = 97%) for ICB; and 12% [33%], (P<0.0001, I2 = 99%) for AXB. Overall treatment effect for all levels of BPB suggested that dexmedetomidine prolong duration of analgesia time by at least 63% [72%], (P<0.0001, I2 = 100%) from 7.5 h to 11.9 min. Evidence findings rated moderate. Combining dexmedetomidine with LA reduced oral morphine equivalent consumption by a mean [95% CI] of -9.6mg [-19.4, 0.1], (P<0.05, I2 = 92%) and -11.6mg [-15.6, -7.6], (P<0.0001, I2 = 30%) for ISB and SCB group. Evidence findings rated low.	Dexmedetomidine adjuncts exhibited 57% (P<0.0001) prolonged sensory block, 58% (P<0.0001) motor block, and at least 63% (P<0.0001) duration. Dexmedetomidine hasten 40% (P<0.0001) sensory block and 39% (P<0.0001) motor blocks. 10.2 mg [-15.3, -5.2] (P<0.0001) morphine consumption reduction, improved pain control and patient satisfaction The 50-60 mcg dose of dexmedetomidine maximized sensory block duration while decreasing hemodynamic side-effects. Using GRADE guidelines there is high evidence that mixing dexmedetomidine with long acting LA used in a BPB (regardless of level), prolong duration of sensory block duration compared with LA alone. Despite variability in dexmedetomidine doses, significant prolongation of sensory and motor blocks and time to first analgesics request were achieved even with the lowest doses (3 mcg intrathecal and 30 mcg peripheral) of dexmedetomidine.	Study design Pooled trials reviewed were assessed under Grades or Recommendation, Assessment, Development, and Evaluation (GRADE) guidelines. GRADE classifies strength of synthesis evidence into four categories: 1. High quality - research unlikely to change confidence in the estimate of the effect 2. Moderate quality - further research likely to have important impact on confidence in the estimate of the effect and may change the estimate 3. Low quality - further research is likely to have an important impact on the confidence in the estimate of the effect and is likely to change the estimate. 4. Very low quality - very uncertain about estimate Literature reviewed conducted all relevant database, limiting to randomized trials.	Some studies lacked sufficient details to evaluate for biases such as generalization as "similar side-effects between study groups" or presentation of haemodynamic outcome data in graphic format. Clinical heterogeneity characterized the data reviewed, originated from different surgical, anaesthetic and analgesic setting Variability in each subgroup (i.e., difference in pain like in shoulder rotator cuff repair versus shoulder arthroscopy) lack sufficient data. Also cariation in postoperative analgesia duration, hypoxemia, and excessive sedation varied between trial, which contributed in observed heterogeneity.	I, A
Xu et al., 2018	Multilevel thoracic paravertebral block (TPVB) with a single dose of dexmedetomidine plus ropivacaine in VATS could prolong the duration of pain relief and improve patient satisfaction without increasing the incidence of adverse events compared with ropivacaine alone		RCT	n = 60	Prospective, randomized, controlled study, single-center university hospital for subjects undergoing VATS under general anesthesia. All subjects received a postoperative TPVB. Group R (n = 30): 0.375% ropivacaine Group RD (n = 30): 20 mL 0.375% ropivacaine plus dexmedetomidine 1 mcg/kg	Dexmedetomidine 1 µg/kg	Pain scores using numeric rating scale (0-10) at rest and when coughing during the first 48 hours postop; dermatomal levels of sensory blockade; patient satisfaction; incidence of adverse event	Assuming that A Decrease in the pain score of 1.1 was clinically significant, 26 patients in each group would be required for a study power of 80% (α = 0.05, β = 0.2). Normality wastestedusingtheKolmogorov-Smirnovanalysis. The chi-square test, Student t-test, Mann-Whitney U-test, or Fisher exact test was used for comparisons between the 2 groups	Median pain scores at rest lower in group RD (1, [0-3]) compared to Group R (3 [2-4]) at postop 48 hrs (p < 0.05). Median pain scores when coughing was lower in group RD (4 [3-5]) compared to group R (6.5 [5-7]) at postop 48 hrs (p < 0.05). Ropivacaine Plus dexmedetomidine used for single-shot, multilevel TPB were found to prolong the duration of analgesia and improve patient satisfaction compared with ropivacaine alone in patients undergoing VATS	Study design	a dose-response study was not performed to check whether higher doses of dexmedetomidine would yield better results without much more complication, small sample size, ASA 1 & 2 patients	I, B

Appendix C: Project Timeline

PHASE 1	PHASE 2		Phase 3	Phase 4
December 2021 - January 2022	January 2022	February - March 2022	April - June 2022	July - August 2022
<p>Steps Already Completed</p> <ul style="list-style-type: none"> ●EBP purpose and team is defined ●Literature review to find an evidence-based solution 	<p>Complete the KACC “Process Map for Internal and External (DNP Students) PI Project Approval”</p> <p>Step 1: Submit Request for PI Determination Form to PI Coordinator</p> <p>Step 2: Meet with Process Improvement Coordinator for Project Discussion</p> <p>Step 3: Verification of current organizational agreement between KACC and the member’s Graduate School of Choice</p> <p>Step 4: IRB Determination Letter submitted and received</p> <p>Step 5: Information briefing to the Performance Improvement Coordinator (and other Stakeholders)</p> <p>Step 6: Decision Briefing to the Command TEam for Project Approval</p> <p>Step 7: Approval Memo on File</p>	<p>Pre-data Collection</p> <ul style="list-style-type: none"> ●Single-shot interscalene brachial plexus block using 0.5% ropivacaine with dexamethasone 4 mg on adult patients undergoing arthroscopic shoulder surgery <ul style="list-style-type: none"> ○DVPRS pain scores ○Opioid consumption ●Data collected will be used as a benchmark to evaluate the efficacy of our proposed solution 	<ul style="list-style-type: none"> ●Create awareness & interest ●Recruit at least 30 participants ●Implement solution: Single-shot interscalene brachial plexus blocks using 0.5% ropivacaine with dexmedetomidine 1 µg/kg on adult patients undergoing arthroscopic shoulder surgery <ul style="list-style-type: none"> ○Data collection <ul style="list-style-type: none"> ■DVPRS pain scores ■Opioid consumption 	<ul style="list-style-type: none"> ●Analyze pre & post data ●Disseminate results ●Integrate & sustain practice change

Appendix D: Data Analysis Plan Table

Population or Event	Variable Name	Variable Description & Type of Measure	Data Source	Possible Range of Values	Level of Measurement	Time Frame of Measurement	Time Frame for Collection	Statistical Test	Decision Rule
IV (Population)	Perineural additive used with ropivacaine 0.5% for interscalene brachial plexus blocks	Process Measure All adult patients scheduled for arthroscopic shoulder surgery will receive the same peripheral nerve block and local anesthetic. The perineural additive depends on the phase of project implementation.	EMR	0 = dexamethasone 4 mg (during pre-data collection phase) 1 = dexmedetomidine 1 mcg/kg	Nominal	Phase 2 Site Dependent	Phase 2 Site Dependent	None	Based on literature & clinical site
DV (Population)	DVPRS Pain Scores	Outcomes Measure Pain scale that will be used to evaluate severity of pain. Scores will be evaluated 24/48/72 hours after surgery	EMR Patient Staff	0-10	Ordinal	Phase 2 Site Dependent	Phase 2 Site Dependent	Mann-Whitney U Test	Based on literature
DV (Event)	Opioid Consumption	Outcomes Measure Determined by asking the subject the amount of pain meds they have left ("pill count").	EMR Patients Staff	0-100%	Interval, Ratio	Phase 2 Site Dependent	Phase 2 Site Dependent	T-test	Based on literature

Appendix E: BCA Worksheet

BUSINESS CASE with VALUE-BASED CARE ASSESSMENT
Proposed Title for Project/Initiative/Opportunity to Improve
Extending Duration of Postoperative Analgesia using Perineural Dexmedetomidine as an Adjuvant in Single-Shot Peripheral Nerve Blockade
Opportunity Statement <i>(Description of proposed project/initiative/opportunity to improve)</i>
The current evidence reveals that adding dexmedetomidine to single-shot peripheral nerve blocks can provide adequate analgesia for 72 hours after surgery. Doing this will reduce the patient’s postoperative surgical pain, reported pain scores, and the amount of prescribed pain medications consumed after discharge.
Business Opportunity/Objectives <i>(Prioritize listing – macro and micro objectives)</i>
<ol style="list-style-type: none"> 1. To reduce the severity of postsurgical pain after orthopedic surgery. The goal is to have patient-reported pain scores < 5 using the Defense & Veteran Pain Rating Scale (DVPRS) for a 48-72 hour period after surgery. 2. To reduce consumption of opioid analgesics. Anesthesia providers at KACC prescribe the same analgesics for all patients undergoing ambulatory shoulder rotator cuff repair surgery.
Potential Impact of the Initiative/Project <i>(Identify outcome metrics & benchmarks/and how objectives align with Quadruple Aim, Value Based Care, and HRO goals)</i>
<p>This process improvement project aligns with the Quadruple Aim of the Military Health System by providing patient-centered care and improving patient outcomes and well-being. It also aligns with current DHA initiatives which is to reduce the amount of narcotics prescribed and consumed by active duty service members for pain control after surgery; dexmedetomidine provides opioid-free analgesia.</p> <ol style="list-style-type: none"> 1. Patient-reported pain scores at 24, 48, and 72 after surgery using the Defense & Veteran Pain Rating Scale (DVPRS) 2. Postoperative consumption of non-opioid and opioid analgesics; Obtain the patient’s current “pill count”.
Alternatives (courses of action) chosen for Analysis
<ol style="list-style-type: none"> 1. Perform single-shot peripheral nerve blocks using ropivacaine 0.5% plus dexmedetomidine 1 mcg/kg on patients undergoing ambulatory surgery for rotator cuff repair of the shoulder. 2. Perform single-shot peripheral nerve blocks using liposomal bupivacaine 3. “Status Quo”: Perform a single-shot peripheral nerve block using ropivacaine 0.5% plus dexamethasone 4 mg on patients undergoing ambulatory surgery for rotator cuff repair of the shoulder. 4. Use indwelling catheters to deliver local anesthetic medications, such as the On-Q Pain Management Pumps
Analysis of Alternatives

Alternative 1:	Perform single-shot peripheral nerve blocks using ropivacaine 0.5% plus dexmedetomidine 1 mcg/kg on patients undergoing ambulatory surgery for rotator cuff repair of the shoulder.	
Pros	Cons	
<ul style="list-style-type: none"> Enhanced duration of postoperative analgesia Reduced postoperative consumption of pain medication Reduced opioid consumption, which is in line with current DHA initiatives Standardized process to demonstrate efficacy and benefits for key stakeholders 	<ul style="list-style-type: none"> Risk for low participation Risk for patient refusal Risk for alternative being ineffective or non-beneficial 	
Alternative 2:	Perform single-shot peripheral nerve blocks using liposomal bupivacaine	
Pros	Cons	
<ul style="list-style-type: none"> Liposomal bupivacaine can provide a duration of analgesia similar to perineural dexmedetomidine 	<ul style="list-style-type: none"> The cost of 1.3% liposomal bupivacaine is \$22.72 per mL. Due to the cost of this medication, KACC leadership would not support its use. 	
Alternative 3:	<i>"Status Quo"</i> : Perform single-shot peripheral nerve blocks using ropivacaine 0.5% plus dexamethasone 4 mg for patients undergoing ambulatory rotator cuff repair of the shoulder	
Pros	Cons	
<ul style="list-style-type: none"> Convenient & familiar for stakeholders No changes in practice 	<ul style="list-style-type: none"> Inadequate duration of postoperative analgesia Patient risks associated with regional anesthesia Risk for increased consumption of opioid and non-opioid analgesics after discharge; increases the risk for opioid-overdose and does not align with current DHA initiatives to reduce opioid prescriptions and consumption among active duty service members 	
Assumptions		
<ol style="list-style-type: none"> Kimbrough Ambulatory Care Center (KACC) performs around 2000 outpatient ambulatory procedures each year; the majority are podiatry and orthopedic procedures. KACC's anesthesia providers perform around 1700 regional blocks each year. The majority are single-shot peripheral nerve blocks using 0.5% ropivacaine with dexamethasone 4 mg, which is the status quo. At KACC, patient-reported pain scores after surgery for rotator cuff repair of the shoulder are >5 at 24 hours after surgery. KACC anesthesia providers follow a standardized process for prescribing the same discharge analgesic medications for patients undergoing surgery for rotator cuff repair of the shoulder Increased duration of analgesia would presumably lower patient-reported pain scores and reduced consumption of opioids after discharge. 		

<p>6. Patients who received 20 mL ropivacaine 0.5% with dexmedetomidine 1 mcg/kg for arthroscopic shoulder surgery reported pain scores <5 over a 36 hour period (Jung et al., 2018).</p>	
<p>Recommendation and Rationale</p>	
<p>Recommendation</p>	
<p>Proposal to recommend alternative #1: Perform single-shot peripheral nerve blocks using ropivacaine 0.5% plus dexmedetomidine 1 mcg/kg on patients undergoing shoulder surgery (Talebi et al., 2021)</p>	
<p>Rationale</p>	
<p>The current evidence shows that patients who received single-shot peripheral nerve blocks using perineural dexmedetomidine had patient-reported pain scores < 5 at 24, 48, and 72 hours after surgery (Gao et al., 2019). Although there is evidence showing liposomal bupivacaine providing a similar duration of analgesia, the financial costs are not feasible.</p>	
<p>Value Based Care - Investment Required by the Organization and the Associated "VALUE" or \$ GAINED.</p>	
<p>I. Quality Projected Based On:</p>	
<p>Improved patient outcomes</p>	<p>Dexmedetomidine provides opioid-free analgesia to control postoperative surgical pain. This has the potential to reduce the amount of pain medications patients consume after discharge. There is also the potential to reduce the incidence of opioid-related adverse events such as inhibition of restorative sleep, airway obstruction, and hypoxemia (Abdullah & Brull 2013). Additionally, prolonging sensory blockade provides patient comfort through the first postoperative night, allowing for early mobilization and reduced risk for pulmonary complications (Gao et al., 2019). Examining the effects of perineural dexmedetomidine for postoperative analgesia has the potential to improve patient outcomes in the setting of ambulatory surgery at KACC.</p>
<p>Patient Satisfaction</p>	<p>The literature shows that patients who received perineural dexmedetomidine reported increased satisfaction, which may be attributed to postoperative surgical pain reduction.</p>
<p>Provider Satisfaction</p>	<p>Providers will not have to worry about troubleshooting any special equipment that patients take with them upon discharge (i.e., indwelling catheters, On-Q Pain Management System). There is a potential loss in productivity when patients are reporting inadequate pain relief 24 hours after surgery and providers diverting time to formulate a solution.</p>
<p>II. Cost Projected Based On:</p>	

Program Design and Development	Dexmedetomidine costs \$42.00 per 200 mcg/vial (Aggarwal et al., 2020) and is widely available in many military hospitals. Its mechanism of action and physiological effects are well known to trained providers who perform peripheral blocks. The program design includes standardized guidelines for application and dosage of LA dexmedetomidine adjunct in shoulder arthroscopic labral repair.
Time to execute process improvement project	All affected personnel will need to adhere to the standardized guidelines developed for this project. Anesthesia providers will need time to adapt to the changes in practice that may be contrary to the status quo.
Supplies Needed	To ensure all involved personnel have the supplies needed to perform the intervention. KACC is ultrasound capable and anesthesia providers routinely administer ultrasound-guided nerve blocks.
Risks and Mitigation Plan	
Risks	Plan
1. Patient refuses intervention	1. Provide patient education on the potential benefits of the intervention
2. Low participation from anesthesia providers	2. Increase department awareness of the project and its potential benefits
3. Block administration causes nerve injury	3. Ultrasound-guided technique for peripheral nerve blocks will be implemented
4. Patient experiences adverse reactions to dexmedetomidine such as hypotension and prolonged sedation	4. Provide supportive care using intravenous fluids and medications. Postoperative monitoring until the effects subside and patients meet discharge criteria
5. Ineffective intervention resulting in no benefit to key stakeholders	5. Achieve maximum participation, standardized process for block administration, and meticulous data collection to determine the efficacy of the intervention
Implementation Plan	
Phase 1:	Gather Evidence

Milestone Description:	Conduct a periodic literature search to find the new information regarding the efficacy of perineural dexmedetomidine on increasing the duration of postoperative analgesia and reducing the severity of postsurgical pain.	
Deliverables	Due Date	Accountable Person
Measurable Goal: Organization, categorization, and critique of the current evidence and literature	One Month	Principle Investigator
Resources Needed		
Access to research databases; time to perform tasks and appraise research articles. Utilize the capabilities of the USUHS Learning Resource Center to mitigate project risks, ensure adequate literature search and appraisal, and organization of results.		
Expected Level of Benefit		
A periodic literature search provides any new evidence to support this process improvement project. Without conclusive evidence, this project would have no purpose nor gain the support needed for execution.		
Phase 2:	Dissemination of findings	
Milestone Description:	Write the proposed project plan and route it through the approval process.	
Deliverables	Due Dates	Accountable Person
Measurable Goal: Produce a professional presentation and submit it through the institution stakeholders and approval process. Fulfill all required steps to gain approval for this process improvement project.	December 2021-January 2022	Principle Investigator & Project Members
Resources Needed		
Time to perform tasks. Access to professional technical support. Mitigate risks by collaborating with colleagues and experts to ensure presentation quality and accuracy. The following are the 7 steps of the "Process Map for Internal & External DNP Students Process Improvement (PI) Project Approval":		
<ol style="list-style-type: none"> 1. Submit the request for PI project determination form to PI coordinator (Appendix A). 2. Meet with the PI coordinator for project discussion. 3. Verification of current organizational agreement between KACC and USUHS. Provisional employee process granted through the education department. 4. IRB determination letter submitted and received 5. Information briefing to the PI coordinator and other stakeholders 6. Decision briefing to the command team for project approval 7. Approval memo on file 		
Expected Level of Benefit		

Dissemination to executive leadership allows the decision for institutional investment. It also describes the importance and viability of the process improvement project.		
Phase 3:	Develop a program for the process improvement project	
Milestone Description:	Develop an evidence-based program to guide the implementation and evaluation of the intervention	
Deliverables	Due Dates	Accountable Person
Measurable goals: Produce standardized procedures and guidelines for the process improvement project.	December 2021-January 2022	Principal Investigator & Project members
Resources Needed		
Time to perform tasks. Ensure all necessary equipment/supplies/medications are available. Recruit patients eligible to receive the intervention. Identify and recruit department personnel to carry out the project. Mitigate risks by engaging department leadership, anesthesia providers, and patients. Patient education to ensure adequate understanding of the DVPRS scale.		
Expected Level of Benefit		
This phase will engage and recruit the key stakeholders and personnel needed for maximum participation, which will help gather the required data needed to demonstrate the efficacy and benefits of the intervention. A standardized process will support the reliability and validity of the results.		
Phase 4:	Execute process improvement project and collect data	
Milestone Description:	Implementation of the process improvement project at the Kimbrough Ambulatory Care Center	
Deliverables	Due Dates	Accountable Person
1-2 month period needed for pre-data collection prior to project implementation. Data for the determined metrics and benchmarks	January 2022	Principal Investigator & Project Members
Resources Needed		
All supplies. Time for pre-data collection. IRB and KACC approval. Access to necessary healthcare informatics systems. Anesthesia providers administer the intervention. Informed consent from eligible patients undergoing orthopedic surgery. Mitigate risks by accurate data collection and continuous engagement of key stakeholders to ensure project compliance. Follow up with patients to track metrics after discharge. Develop and disseminate a survey to evaluate patient and provider satisfaction.		
Expected Level of Benefit		

The data collected during this phase will support the efficacy of perineural dexmedetomidine		
Phase 5:	Process Improvement Project Evaluation	
Milestone Description:	Synthesize & evaluate all data collected for the process improvement project	
Deliverables	Due Dates	Accountable Person
Have data to report to leadership at 6 months and at 1 year after project implementation	Ongoing. Report to leadership at 6 months (July 2022) and at 1 year (January 2023) after project implementation	Principal Investigator & Project members
Resources Needed		
All supplies. Time and resources needed to synthesize and evaluate data. Continuous engagement and involvement of key stakeholders.		
Expected Level of Benefit		
During this phase we will disseminate our results to local staff and all key stakeholders. This phase will help determine whether or not the process improvement project was beneficial and is worth continuing to implement.		

Appendix F: Team Mentor (Committee Membership) Agreement Form



Appendix C: Daniel K. Inouye Graduate School of Nursing
DNP Project Team Mentor (Committee Membership) Agreement Form

DOCTOR OF NURSING PRACTICE PROJECT
DNP Project Clinical Question and Team Mentor (Committee Membership) Agreement Form

Graduation Year:

Name(s) of DNP Project Student Team:

- 1. LCDR Brian Bonzo Phase II Site: AGCNS FNP PMHNP RNA WHNP
- 2. LT Michael Orbita Phase II Site: AGCNS FNP PMHNP RNA WHNP
- 3. _____ Phase II Site: AGCNS FNP PMHNP RNA WHNP
- 4. _____ Phase II Site: AGCNS FNP PMHNP RNA WHNP
- 5. _____ Phase II Site: AGCNS FNP PMHNP RNA WHNP
- 6. _____ Phase II Site: AGCNS FNP PMHNP RNA WHNP

The tentative title of the DNP Project Proposal for this student group is:
Extending the Duration of Postoperative Analgesia Using Perineural Dexmedetomidine: A Process Improvement Project
at the Kimbrough Ambulatory Care Center

Committee Approved DNP Project Clinical Question:
Does adding dexmedetomidine to interscalene brachial plexus blocks provide postoperative analgesia for at least forty-eight
hours for at least forty-eight hours for adult patients undergoing ambulatory shoulder surgery at the Kimbrough Ambulatory
Care Center ?

Names of DNP Project Team Mentors (type the name and obtain signatures):

I agree to serve as a member of the DNP Project Team (Team Mentors) for the above DNP Student Project Team. As a Project Team Mentor, I agree to the duties and responsibilities outlined within the DNP Project Manual which include but are not limited to the provision of consultation and guidance supporting the entire DNP project journey and to ensure the DNP project is of sufficient rigor and demonstrates doctoral level scholarship to meet the requirements for USUHS GSN graduation.

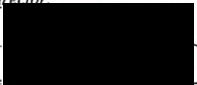
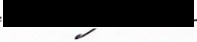
Form Version: 1 Jun 2016

Appendix F: Team Mentor (Committee Membership) Agreement Form



Appendix C: Daniel K. Inouye Graduate School of Nursing
DNP Project Team Mentor (Committee Membership) Agreement Form

NOTE: You may have 3-4 DNP Team Mentors [committee members including your DNP Senior Mentor (Chair)]. The Phase II Site Director may also be a member of the group, as well as other USUHS faculty or others who may serve as content experts. All non-USUHS faculty selected as a Team Mentor must be approved by the DNP Project Director

Senior Mentor (Chair): LCDR Henry Lang Signature:  Date: 1/22/22
Team Mentor (Committee): Maj Jake Tannehill Signature:  Date: 2/16/22
Team Mentor (Committee): _____ Signature: _____ Date: _____
Team Mentor (Committee): _____ Signature: _____ Date: _____

Appendix G: CITI Certificates

Completion Date 16-Apr-2021
Expiration Date 15-Apr-2024
Record ID 42050182

This is to certify that:

Michael Orbita

Has completed the following CITI Program course:

OUUSD P&R Human Research
(Curriculum Group)
Biomed Research Coordinators, Clinical Coordinators, Study Coordinators & Research Administrators
(Course Learner Group)
1 - Basic Course
(Stage)



Under requirements set by:

Office of the Under Secretary of Defense (Personnel and Readiness)



Not valid for renewal of certification through CME.

Verify at www.citiprogram.org/verify/?wbed1c0ab-d3b8-48d1-8b05-bca427611468-42050182

Completion Date 13-Apr-2021
Expiration Date 12-Apr-2024
Record ID 41968407

This is to certify that:


Brian Bonzo

Has completed the following CITI Program course:

OUUSD P&R Human Research
(Curriculum Group)
Biomed Research Coordinators, Clinical Coordinators, Study Coordinators & Research Administrators
(Course Learner Group)
1 - Basic Course
(Stage)

Under requirements set by:

Office of the Under Secretary of Defense (Personnel and Readiness)



Not valid for renewal of certification through CME.

Verify at www.citiprogram.org/verify/?w39d2de18-eea4-4169-ab3d-52eabe1affd6-41968407

Appendix H: USU (VPR) Form 3202N

USUHS FORM 3202N
DANIEL K. INOUE GRADUATE SCHOOL OF NURSING
EVIDENCE-BASED PRACTICE/PERFORMANCE IMPROVEMENT PROPOSAL

VPR Date Stamp

Project Number: GSN-61-13071 (VPR will assign)

Project Title: Extending The Duration Of Postoperative Analgesia Using Perineural Dexmedetomidine At The Kimbrough Ambulatory Care Center

SECTION A: STUDENT POC INFORMATION	
1. Name (Last, First, MI): ORBITA, MICHAEL, S	Student E-mail: MICHAEL.ORBITA@USUHS.EDU
2. Home Address: [REDACTED]	Cell Number: [REDACTED]
SECTION B: COMMITTEE CHAIR / SENIOR MENTOR INFORMATION	
3. Name (Last, First, MI): LANG, HENRY	
4. Telephone: 717-903-5151 Fax: _____	E-mail: HENRY.LANG@USUHS.EDU
5. USUHS Building/ Room No.: GRADUATE SCHOOL OF NURSING	
SECTION C: PROJECT INFORMATION	
6. Attach the Abstract for the proposal, including the following sections: Site Location of the Project, Title, Authors, Background or Problem/Issue, Clinical Question/Purpose, Project Design, Anticipated Organizational Impact/Implications for Practice and also include the Proposed Timeline. Single space the abstract and use Times New Roman font, size 12.	
7. Is this proposal related to an active research project of the Chair/Senior Mentor identified in Section B? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If yes, complete below; if no, proceed to Part 8. Project Number: <u>WRNMMC-EDO-2022-0948, 951247</u> Project Title: <u>Extending The Duration Of Postoperative Analgesia Using Perineural Dexmedetomidine At The Kimbrough Ambulatory Care Center</u> Project Start Date: <u>4/1/2022</u> Project End Date: <u>12/31/2022</u>	
8. Anticipated period of performance: Project Start Date: <u>8/1/2022</u> Project End Date: <u>12/31/2022</u>	
9. Performance Site(s): <u>KIMBROUGH AMBULATORY CARE CENTER, FORT MEADE, MD</u>	
10. Does this project involve any classified information? (Contact the USUHS Security Office for guidance) <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
11. Do you have a funding source for this project? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NA If yes, specify the funding agency and the amount provided:	
SECTION D: SIGNATURES	
The following signatures attest to the validity of the above information:	
<div style="border-bottom: 1px solid black; margin-bottom: 5px;"> [REDACTED] Digitally signed by ORBITA.MICHAEL.SERGIO.1534139485 Date: 2022.11.03 11:18:11 -04'00' Student (Project Point of Contact for the Group) (Signature and Date) </div> <div style="border-bottom: 1px solid black; margin-bottom: 5px;"> _____ Digitally signed by SIMMONS.ANGELA.MARIE.1143313375 Date: 2022.11.22 11:03:07 -05'00' Chair/Program Director (Signature and Date) </div> <div style="border-bottom: 1px solid black; margin-bottom: 5px;"> _____ Digitally signed by SIMMONS.ANGELA.MARIE.1143313375 Date: 2022.11.22 11:03:07 -05'00' Associate Dean for Research, GSN (Signature and Date) </div>	<div style="border-bottom: 1px solid black; margin-bottom: 5px;"> <u>LANG.HENRY.JAMES.1093123979</u> Digitally signed by LANG.HENRY.JAMES.1093123979 Date: 2022.11.18 08:47:31 -06'00' Chair/Senior Mentor (Signature and Date) </div> <div style="border-bottom: 1px solid black; margin-bottom: 5px;"> <u>BARBER.KENNETH.DOUGLAS.1177263644</u> Digitally signed by BARBER.KENNETH.DOUGLAS.1177263644 Date: 2022.11.22 09:51:11 -05'00' Chair/Program Director (Signature and Date) </div> <div style="border-bottom: 1px solid black; margin-bottom: 5px;"> <u>SEIBERT.DIANE.C.1084932279</u> Digitally signed by SEIBERT.DIANE.C.1084932279 Date: 2022.11.22 10:14:12 -05'00' Associate Dean for Academic Affairs, GSN (Signature and Date) </div> <div style="border-bottom: 1px solid black; margin-bottom: 5px;"> <u>ROMANO.CAROL.A.1032050294</u> Digitally signed by ROMANO.CAROL.A.1032050294 Date: 2022.11.22 14:50:29 -05'00' Dean, DKU Graduate School of Nursing (Signature and Date) </div>
In light of the above signatures, the project is approved. <u>WOODBERRY.MITCHELL</u> Digitally signed by WOODBERRY.MITCHELL.WAYNE.1060957114 Date: 2022.12.09 10:12:23 -05'00' <u>L.WAYNE.1060957114</u> USUHS Vice President for Research _____ Date _____	

F. DNP Project Senior Mentor Approved Abstract/Impact Statement Form**PROPOSAL ABSTRACT**

Phase II Site: Kimbrough Ambulatory Care Center, Fort Meade, MD

Project Title: Extending the Duration of Postoperative Analgesia Using Perineural Dexmedetomidine at the Kimbrough Ambulatory Care Center

Authors: LT Michael Orbita & LCDR Brian Bonzo

Background or Problem/Issue: Single shot interscalene brachial plexus blocks (ISB), using ropivacaine 0.5% and 4 mg of dexamethasone, are routinely performed on patients undergoing arthroscopic shoulder surgery to manage surgical pain. Unfortunately, perineural dexamethasone alone provides an insufficient duration of analgesia. Due to suboptimal outcomes with perineural dexamethasone, KACC anesthesia providers are searching for an evidence-based perineural additive that provides adequate pain control for at least twenty-four hours after surgery without having a significant cost-burden for patients undergoing arthroscopic shoulder surgery.

Clinical Question or Purpose: Does adding dexmedetomidine to peripheral nerve blocks provide postoperative analgesia for at least forty-eight hours for adult patients undergoing ambulatory arthroscopic shoulder surgery at the Kimbrough Ambulatory Care Center?

Project Design: Our evidence-based practice project will focus on how the combined use perineural dexmedetomidine and perineural dexamethasone influences postoperative pain scores and opioid consumption among patients undergoing ambulatory arthroscopic shoulder surgery at KACC, with the goals being a DVPRS (Defense and Veteran Pain Rating Scale) score of less than five twenty-four hours after block administration and a decrease in opioid consumption from the pre-implementation baseline. Pre-implementation data will be collected to evaluate the efficacy of perineural dexamethasone alone for comparison. Patients will be instructed to evaluate and record their pain severity and remaining pill count every twenty-four hours over a five-day period.

Data Analysis Plan: Our team expects our evidence-based intervention to reduce the severity of postoperative surgical pain by providing a greater duration analgesia and reducing opioid consumption in comparison to the current practice for ISB at KACC. We will disseminate project results to clinic anesthesia providers and the USUHS Graduate School of Nursing.

Proposed Organizational Impact/Implications for Practice: Our project aligns with the MHS Quadruple Aim by improving patient outcomes and well-being and providing patient-centered care. It also aligns with current DHA initiatives to reduce the number of narcotics prescribed and consumed by active-duty service members after surgery.

ABBREVIATED ABSTRACT

Phase II Site: Kimbrough Ambulatory Care Center, Fort Meade, MD

Project: Comparative analysis of combined perineural dexmedetomidine and perineural dexamethasone compared to perineural dexamethasone alone as additives in single shot interscalene brachial plexus nerve blocks to reduce postoperative pain

Impact: The combined use of perineural dexamethasone and perineural dexmedetomidine in single shot interscalene brachial plexus nerve blocks will reduce the severity of postoperative surgical pain by providing a greater duration analgesia and reducing opioid consumption which are goals that align with DHA initiatives and the MHS Quadruple Aim.

Appendix I: MTF IRB Letter of Determination



DEFENSE HEALTH AGENCY
WALTER REED NATIONAL MILITARY MEDICAL CENTER
8901 WISCONSIN AVENUE
BETHESDA, MD 20889-5600

Date: August 16, 2022

MEMORANDUM FOR: Michael Sergio Orbita, BSN

SUBJECT: Determination of **Not Research**

REFERENCE: Protocol WRNMMC-EDO-2022-0948, 951247, entitled, *Extending The Duration Of Postoperative Analgesia Using Perineural Dexmedetomidine: A Process Improvement Project At The Kimbrough Ambulatory Care Center*

1. The Determination Official has assessed that this project is **NOT RESEARCH** by virtue of the opinion that this project does not meet the definition of research for the purposes of human protection in accordance with (IAW) 32 Code of Federal Regulation 219.102 and DoDI 3216.02.
2. It is your responsibility as the Principal Investigator (PI) or Project Manager (PM) to have complete and accurate knowledge of what your protocol expects you and your team members to do and to ensure compliance by the team with all the obligations and conditions of any agreements associated with your project.
3. It is your responsibility as PI or PM to ensure command and/or departmental approval has been granted before initiating your project. Additionally, you must obtain a data sharing agreement and / or appropriate approval prior to sharing any data outside WRNMMC (or your institution). Investigators conducting case studies or case series are cautioned not to increase the number of study subjects without discussing with a Determination Official and submitting a modification to the approved and determined protocol.
4. Projects deemed to be Quality Management activities at WRNMMC must register and obtain start approval from the Directorate of Quality Management after registering the project with Mr. Victor Mosley, Chief of the Department of Performance Improvement at victor.c.mosley.civ@mail.mil. Other institutions or organizations may have their own Quality management requirements.
4. It is your responsibility as PI or PM to ensure that you all members of your team have training appropriate to their role in the project, that they maintain currency in any training, certification or credentialing requirements, and if relevant, that they declare any conflicts of interest (COI) by completion of an institutional COI form for inclusion in project files. Negative declaration statements are not required. Any preparatory to research attestations should be maintained in project files.
5. If you intend to conduct a survey you must meet or have been exempted from the requirements of the Paperwork Reduction Act of 1995, as delineated in DoDI 8910.01 and DoDI 1100.13. Currently only surveys which are documented in an approved **RESEARCH** protocol

have blanket exemption in the context of this determination. Component specific surveys may fall under component rather than DoD regulatory requirements. Information is available on the DRP intranet website.

6. You are requested to submit any amendments and other pertinent changes that may affect the outcome of this determination such as scope or intent, (or number of study subjects for case studies) or change of Principal Investigator to Department of Research Programs (DRP) via EIRB.

7. Any publication resulting from this work must be cleared through a publication clearance process. See the DRP intranet webpage for most recent WRNMMC publication clearance guidance. Authors from other institutions may need to seek local guidance.

8. POC for this determination is Mr. Brian J Reinhardt, MS. Any questions can be addressed through dha.bethesda.j-11.list.drp-leadership@mail.mil . Please provide your project title and IRB number in any correspondence.

This document has been electronically signed in accordance with all applicable regulations, and a copy is retained within the Department of Research Program system of records.

Appendix J: PAO Clearance/Level of Dissemination Classification

Approval Complete

 USU Pub Clearance (usupubclearance@usuhs.edu) approved the file


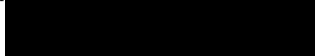
 PAO.WRNMMC.pdf



Appendix K: DNP Project Completion Verification Form

The DNP Project titled:


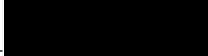
was completed at Enhancing the Duration of Postoperative Analgesia with Perineural Dexmedetomidine by the following:

<i>(type student name)</i>	<i>(signature)</i>	<i>(date)</i>
LT Michael S. Orbita		10 MAY 2023
LCDR Brian Bonzo		10 MAY 2023
_____	_____	_____
_____	_____	_____
_____	_____	_____

The committee verifies that the following components of the DNP project, accomplished by the above students, is of sufficient rigor and demonstrates doctoral level scholarship to meet the requirements for USUHS GSN graduation:

- Presentation of DNP project to the leadership/stakeholders at the Phase II Site,
- Abstract/Impact Statement (*Appendix F*), and
- DNP Project written report.

Verified by:

<i>(type name)</i>	<i>(signature)</i>	<i>(date)</i>	
LCDR Henry Lang		10 MAY 2023	Senior Mentor
LCDR Henry Lang		10 MAY 2023	Phase II Site Director
_____	_____	_____	Team Mentor (if applicable)
_____	_____	_____	Team Mentor (if applicable)

For RNA Students only - add the following additional signature for final verification of project completion:

CDR Kenneth Barber

BARBER.KENNETH.D
 OUGLAS.1177263644
Digitally signed by
 BARBER.KENNETH.DOUGLAS.117726
 3644
 Date: 2023.05.11 10:16:37 -0400

RNA Project Director *(type name)*

(Signature)

(Date)