Dexmedetomidine as an Adjuvant for Spinal Anesthesia in Parturients Undergoing Cesarean Section: An Evidence-Based Educational Module

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ABSTRACT

Title: Dexmedetomidine as an Adjuvant for Spinal Anesthesia in Adult Patients Undergoing Cesarean Section: An Evidence-Based Educational Module

Impact statement: In adult parturients undergoing cesarean section, the administration of intrathecal dexmedetomidine has proven effective in providing an intraoperative sensory and motor block, in addition to prolonged postoperative analgesia.

Background: Cesarean section performed under spinal anesthesia requires adequate analgesia to block visceral pain. Local anesthetic is usually combined with an adjuvant analgesic drug to relieve perioperative pain. Dexmedetomidine, a potent alpha-2 agonist, has emerged as a popular alternative to opioids, and its use in obstetrics has grown.

Objective: This capstone project aimed to explore the impact of intrathecal dexmedetomidine as an adjunct for spinal anesthesia in adult parturients undergoing cesarean section.

Methodology: A literature review was performed to identify primary research studies and systemic reviews about parturients undergoing cesarean delivery using intrathecal dexmedetomidine. Chosen studies were limited to those published beyond 2015. Databases used for source material included PubMed, EMBASE, and CINAHL. The project was conducted in a local community hospital. An online educational module was created to present to anesthesia providers, in addition to pre- and post-surveys to assess the degree of acquired knowledge. Survey answers were anonymous, and data was collected via an online platform.

Results: Dexmedetomidine is an effective non-opioid adjunct for spinal anesthesia for cesarean section as measured by patients' nominal perception of pain; it is also associated with fewer side effects than opioids and has been shown to be safe in both the parturient and fetus.

Discussion: Emerging evidence indicates that dexmedetomidine may be used intrathecally for cesarean section. Current data reveals that intrathecal dexmedetomidine provides similar analgesia to opioids with a more desirable side effect profile. Thus, the use of intrathecal dexmedetomidine for obstetrics presents a suitable option for analgesia during cesarean section. The evidence presented in this capstone project elucidates the use of intrathecal dexmedetomidine and establishes that dexmedetomidine is effective, safe, and lacks the negative side effects of opioids. Of note, the most significant limitations of this study were the small sample size and limited timeframe.

Keywords: Dexmedetomidine, spinal anesthesia, lumbar anesthesia, intrathecal, cesarean delivery, cesarean section, postoperative analgesia

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INTRODUCTION

Background

Spinal anesthesia is the preferred technique for cesarean section due to its rapid onset of action, reliable analgesia, strong motor blockade, earlier hospital discharge, and decreased risk of airway compromise.[1] Spinal anesthesia is administered as a combination of local anesthetic and intrathecal adjuvant drugs. Adjuvant medications reduce the dose of local anesthetic required and improve anesthesia quality.[1-6] A good anesthetic provides both intraoperative and postoperative pain relief.

Pain is transmitted via two classes of nerve fibers: A-delta and C fibers.[7-8] C fibers are responsible for visceral pain, which tends to be diffuse and abiding.[7-8] Cesarean section causes visceral pain since the rectus muscles are pulled apart to visualize the uterus, and the neonate is removed via excess traction and pressure on the uterine fundus.[8] Visceral pain from cesarean section is most profound postoperatively.[8]

Cesarean section requires a sensory block up to the level of T4; this requires a high dose of local anesthetic, which increases the degree of sympathectomy that occurs due to spinal anesthesia.[5] Additionally, local anesthetics alone do not adequately block visceral pain, nor do they provide prolonged postoperative analgesia.[1,5] Therefore, lipophilic opioids, such as fentanyl or duramorph (morphine), have traditionally been used as adjuvants for neuraxial anesthesia to provide analgesia for cesarean section.[1-6] However, opioids are associated with several adverse effects, including respiratory depression, pruritis, drowsiness, urinary retention, nausea, and vomiting.[1-6,9] In particular, duramoprh tends to cause delayed respiratory depression owing to its long duration of action.[9] Alternatively, dexmedetomidine may be used as an adjuvant for neuraxial anesthesia.[1] Evidence demonstrates that dexmedetomidine provides comparable

analgesia to opioids without the unwanted side effects.[1-6,10-11]

Dexmedetomidine, also known as *Precedex*, is a highly selective and potent alpha-2 adrenergic agonist that binds to the presynaptic alpha-2 receptor.[12] It works by inhibiting the release of norepinephrine and terminating the propagation of pain signals.[12] It acts in the spinal cord and the central and peripheral nervous systems.[12] Dexmedetomidine is commonly used intraoperatively as a sedative-analgesic agent because of its many benefits.[12] Dexmedetomidine decreases sympathetic tone, attenuates hemodynamic responses to surgery, reduces opioid and anesthetic requirements, and provides sedation.[1,5,12] Furthermore, dexmedetomidine is a potent analgesic. Indeed, its role in regional anesthesia and pain management has grown in recent years.[12] A significant advantage of dexmedetomidine is that it does not cause respiratory depression.[12] However, when administered intravenously, it can cause profound hypotension and bradycardia.[12] Gertler et al[12] reported that the incidence of dexmedetomidine-induced bradycardia in healthy surgical patients is reported to be as high as 40%. Additionally, intrathecal dexmedetomidine enhances the quality of neuraxial blockade.

Dexmedetomidine suppresses visceral C fibers and hyperpolarizes the neurons of the dorsal horn in the spinal cord to block pain signals.[8,13-14] The dorsal horn is composed of excitatory interneurons (substance P and glutamate) and inhibitory interneurons that transmit sensory information to the brain.[8] By blunting excitatory neurons in the dorsal horn, dexmedetomidine effectively provides a rapid and intense sensory block.[8,13-14] Dexmedetomidine is also beneficial postoperatively since it prolongs the period of postoperative analgesia after cesarean section.[12] Intrathecal dexmedetomidine provides approximately 10-12 hours of pain relief by inducing vasoconstriction at the alpha-2 receptor in the dorsal horn.[5,12] Therefore, dexmedetomidine has emerged as a potential adjunct to spinal anesthesia, given its ability to

provide a dense block and prolonged analgesia.[1,3-5,11] It is widely used in orthopedic, urological, and lower abdominal surgical procedures.[1]

Problem Statement

Fentanyl and duramorph (morphine) have traditionally been used as adjuncts for spinal anesthesia. Fentanyl is used because it is short-acting and interacts synergistically with local anesthetics.[6,11] However, the duration of analgesia is short, typically 1-4 hours.[6] Therefore, duramoprh is supplemented to provide prolonged postoperative analgesia for up to 20 hours.[2,6] However, opioids tend to have a plethora of adverse side effects. When administered intrathecally, fentanyl and duramorph may cause pruritis, shivering, nausea, vomiting, drowsiness, and, most significantly, respiratory depression.[1,2,6] Additionally, opioids readily cross the placenta, thus affecting maternal-fetal disposition and impacting neonatal health.[6] Maternal and neonatal outcomes are equally crucial in obstetrical anesthesia.[6] As such, anesthesia providers have struggled to choose the appropriate adjunct drug for cesarean section that enhances spinal anesthesia with fewer side effects.[6,11]

The side effects of intrathecal opioids are related to the concentration of the drug in the blood or cerebral spinal fluid (CSF) and the degree of lipophilicity of the drug.[9] Most side effects are dose dependent. Fentanyl is highly lipophilic; thus, it quickly penetrates the blood-brain barrier and permeates the spinal cord rapidly.[9] Morphine is also very lipophilic; however, it penetrates the spinal cord slower, which permits more drug to ascend in the CSF.[9] The classic triad of side effects of intrathecal opioids is pruritis, nausea and vomiting, and respiratory depression.[9] Pruritis is the most common side effect of intrathecal opioids; its incidence varies from 0 to 100%.[9] Most cases of pruritis are mild and localized to the face, neck, and thorax; however, severe pruritis occurs in 1% of parturients.[9] The mechanism that causes pruritis is

twofold: cephalad migration of drug in the CSF and release of histamine from mast cells.[9] The incidence of nausea and vomiting is approximately 30% and is also attributed to the cephalad migration of the drug.[9] Respiratory depression is the most severe side effect, occurring in up to 1% of parturients.[9] Respiratory depression may be immediate or delayed. Immediate respiratory depression is due to the systemic absorption of drug, whereas delayed respiratory depression results from cephalad drug migration and subsequent activation of opioid receptors in the brainstem.[9] Respiratory depression is a severe risk to parturients and a danger to neonates since opioids cross the placenta.[9] Shivering is an additional side effect of intrathecal opioids, with a reported occurrence between 10% and 85%.[4,9]

Scope of the Problem

Adequate postoperative analgesia is imperative in cesarean delivery to manage postoperative pain, speed recovery, and optimize patient satisfaction.[6] Although intrathecal opioids have been the mainstay of treatment, emerging evidence demonstrates that opioids may hinder postoperative recovery and increase the risk of maternal and neonatal adverse events.[2-6] Therefore, their side effects—namely shivering, nausea and vomiting, and respiratory depression—may negate their benefit.

Consequences of the Problem

Postoperative shivering can impact maternal metabolic activity and cause metabolic acidosis and increased lactic acid.[4] This may predispose the parturient to hypoxia, which can precipitate cardiovascular and cerebrovascular adverse events.[4] Nausea and vomiting due to spinal anesthesia and opioid administration are other concerns because they can lead to aspiration and pneumonia. Additionally, the side effects of opioids can worsen the maternal stress response, causing catecholamine release and increased cortisol levels.[4] Further, histamine

release from opioids can cause hypotension and tachycardia.[4]

Knowledge Gap

Intrathecal dexmedetomidine has the distinct advantage of eliminating the need for opioids. Dexmedetomidine supplants fentanyl and duramorph because it yields a dense block while providing intraoperative and postoperative analgesia.[1,5] However, the concept of intrathecal dexmedetomidine for cesarean section is relatively new. Therefore, more evidence is necessary to fill the knowledge gaps concerning its use.

The primary concern of administering intrathecal dexmedetomidine is the incidence of hemodynamic instability. Most studies report that intrathecal dexmedetomidine is safe and more effective than local anesthetic alone.[1,4-5,10,13] Evidence also suggests that dexmedetomidine is less likely to cause bradycardia when administered intrathecally.[1,4-5,10,11] This may be due to a smaller intrathecal dose. The optimal clinical dose of intrathecal dexmedetomidine is estimated at approximately 3-7.5 micrograms.[13-14] Existing evidence suggests that this modest dose lacks a significant sympatholytic effect.[13-14] The incidence of hypotension does not seem to be altered.[5,6,10] Nonetheless, there is no strong consensus regarding the effect of dexmedetomidine on hemodynamics. Therefore, more research is necessary to draw a definitive conclusion.

Intrathecal dexmedetomidine has been used successfully for cesarean sections in Asia. However, it is currently not used in the United States. Albeit intrathecal dexmedetomidine has been used for lower extremity surgery, the FDA has not approved its use for cesarean section.[14] Dexmedetomidine is currently used for epidurals in the U.S.,[1] providing adequate analgesia for laboring mothers.

Proposal Solution

Intrathecal dexmedetomidine for cesarean section has several potential benefits. Evidence

demonstrates that dexmedetomidine is an effective adjuvant drug with few side effects. [1-6, 10-11] Therefore, the proposed clinical intervention recommended using intrathecal dexmedetomidine for cesarean delivery. This educational module entailed disseminating research evidence to anesthesia providers. The goal is to educate providers and ultimately persuade them to implement a practice change to help bridge this knowledge-practice gap.

PICO Clinical Question

In adult parturients (P), how does intrathecal Dexmedetomidine (I) compared to intrathecal opioids (C) improve the quality of neuraxial blockade (O) as measured by patient pain perception?

Population (P): Parturients undergoing cesarean section

Intervention (I): Intrathecal Dexmedetomidine

Comparison (C): Intrathecal opioids

Outcomes (O): Improved quality of neuraxial blockade

LITERATURE REVIEW

Summary of the Literature

Dexmedetomidine is a popular analgesic for general anesthesia, labor epidurals, and spinal anesthesia for lower extremity procedures. However, intrathecal dexmedetomidine for cesarean section remains a novel practice. Therefore, this literature review aims to synthesize key studies while identifying common themes and gaps to demonstrate how this capstone project will contribute to existing knowledge on the topic. This review is divided into three main themes consistent with the literature.

Keywords

The PICO components of the question provided the key search terms used to conduct a

Boolean search. The keywords were: “intrathecal,” “dexmedetomidine,” “cesarean delivery,” “cesarean section,” “spinal anesthesia,” and “lumbar anesthesia.” Several databases were searched, including PubMed, EMBASE, and CINAHL. Results were limited to articles published in English between the years 2015 and 2022.

Search Strategy

Each of the articles retrieved was assessed for relevance by reviewing the title, abstract, results, and conclusions using the inclusion and exclusion criteria. Inclusion criteria consisted of primary research studies and systematic reviews that reported the efficacy and safety of parturients undergoing cesarean delivery using intrathecal dexmedetomidine. Studies whose title, abstract, and problem statement addressed the inclusion criteria were reviewed. Articles that best answered the PICO question were favored. Next, the type of study design was considered. Studies featuring high-quality evidence, particularly experimental evidence, were preferentially chosen. The overall search of the selected databases initially yielded 10 relevant studies to be included in this systematic review: 8 randomized control trials (RCT) and 2 meta-analyses. Five additional articles were subsequently retrieved, making a total of 15 studies. All studies included adult patients, with sample sizes ranging from 4 to 300.

Eligibility Criteria

Chosen studies that met the inclusion criteria were documented in the literature matrix below (Table 1). Studies were appraised for quality of evidence. Articles identified in later searches were checked against the articles in the summary table; any duplicated articles were excluded.

Studies were excluded if they focused on parturients aged less than 18 years old, were written in a language other than English, or addressed the use of dexmedetomidine for epidural placement. Of note, several studies concluded that intrathecal dexmedetomidine is safe and

effective for non-obstetric procedures; although these studies were excluded, they were critical to developing the PICO question and formulating the initial search on this topic.

Outcome Measurements

Ample literature addressed intrathecal dexmedetomidine for neuraxial blockade in obstetric anesthesia. Initial evidence suggested that intrathecal dexmedetomidine may enhance the quality of neuraxial blockade, resulting in a rapid onset, prolonged block, and superior perioperative analgesia.[1-6,10,11] Additional research demonstrated that intrathecal dexmedetomidine reduces unwanted side effects, such as nausea, shivering, and pruritis.[1-6,10,11] Thus, the primary outcome measured the quality of spinal anesthesia using intrathecal dexmedetomidine. The secondary outcome measured the incidence of side effects of intrathecal dexmedetomidine. This paper aimed to explore the impact of dexmedetomidine on the quality of neuraxial blockade and degree of perioperative analgesia for adult parturients undergoing cesarean section.

Literature Themes

Intrathecal Dexmedetomidine versus Intrathecal Opioids. One of the main themes of this literature review is the comparison between dexmedetomidine and opioids for cesarean section. The following studies have compared the onset and duration of neuraxial block, the quality of analgesia, and the hemodynamic stability.

The primary endpoints of the literature measured the quality of sensory and motor blockade. Both Qi et al and Sun et al demonstrated that adding dexmedetomidine resulted in rapid onset and prolonged sensory and motor blockade duration compared to opioids.[2,11] However, their methods of analysis slightly differed. While Qi et al measured sensory block duration via a regression time to the S1 segment,[2] Sun et al measured sensory regression to the

T10 level.[11] Li et al also confirmed these findings.[3] However, regarding the quality of motor blockade, Khosravi et al determined that dexmedetomidine and fentanyl provided comparable durations of motor blockade.[6] It is worth mentioning that the study by Khosravi et al used 5 micrograms of dexmedetomidine, whereas Sun et al used 10 micrograms. Therefore, this difference in findings could be ascribed to a higher dose of dexmedetomidine. Evidently, there is no clear and consistent evidence regarding the quality of motor blockade when dexmedetomidine is used instead of opioids. Despite this, the mentioned literature concludes that intrathecal dexmedetomidine provides a better sensory block than opioids.

Secondary endpoints compared the effect of dexmedetomidine versus opioids on the degree of perioperative analgesia. Khosravi et al found that 5 micrograms of dexmedetomidine resulted in superior postoperative analgesia compared to fentanyl.[6] Likewise, Sun et al and Li et al demonstrated that dexmedetomidine, as opposed to fentanyl, enhanced perioperative analgesia with limited adverse effects.[3,11] The mentioned studies measured the duration of perioperative pain relief from the time of injection to the first request for analgesics.

Postoperative pain scores were measured using the 24-hour postoperative VAS scale – the results demonstrated that dexmedetomidine consistently resulted in significantly lower pain scores.[3,6,11] Thus, the studies conclusively demonstrated that dexmedetomidine provides superior analgesia to opioids.[3,6,11] This may be due to dexmedetomidine's affinity for the alpha-2 receptor in the dorsal horn.[4] In contrast, Qi et al found that intrathecal dexmedetomidine and duramoprh provide comparable analgesia and sedation.[2]

Tertiary endpoints of the studies assessed the hemodynamic stability of intrathecal dexmedetomidine compared to opioids. Khosravi et al and Sun et al determined that intrathecal dexmedetomidine and opioids have similar hemodynamic profiles.[6,11] In addition, Sushruth et al

determined that adding dexmedetomidine did not yield significant hemodynamic changes.[1] However, Qi et al and Li et al. found that dexmedetomidine was more likely to cause mild hypotension than opioids.[2,3] All 5 studies determined that dexmedetomidine did not significantly increase the incidence of bradycardia. Undoubtedly, there is contradictory information concerning the hemodynamic stability of dexmedetomidine, which suggests that additional research is necessary. Additionally, Qi et al and Sun et al assessed the effect of dexmedetomidine on fetal circulation; both studies theorized that dexmedetomidine might be safer for neonates than opioids since it is not a respiratory depressant.[2,11] However, the studies acknowledged that their results do not reveal a statistical difference in APGAR scores between dexmedetomidine and opioids.[2,11]

Dosing of Intrathecal Dexmedetomidine. Another common theme in the literature pertains to the optimal dosing of intrathecal dexmedetomidine. A review of the literature demonstrates a broad spectrum of potential doses for dexmedetomidine, ranging from 3 to 10 micrograms. There is no consensus on the appropriate intrathecal dose.

Bi et al. demonstrated that 3 micrograms of intrathecal dexmedetomidine facilitates a superior somatic-visceral block and prolonged postoperative analgesia without producing unwanted side effects.[13] However, this finding is inconsistent with the study by Zhang et al., which found that 5 micrograms of dexmedetomidine speeds block onset, ameliorates the maternal stress response, and provides enhanced analgesia.[10] Zhang et al. concluded that higher doses do not result in better outcomes.[10] Sushruth et al. and Tang et al. reported similar findings.[14] Overall, most of the literature concluded that the optimal dose of intrathecal dexmedetomidine is 5 micrograms.

Safety and Efficacy of Intrathecal Dexmedetomidine. Another theme discovered in the

literature concerns the safety and efficacy of intrathecal dexmedetomidine. Most primary studies concluded that dexmedetomidine might be superior to opioids owing to its lack of adverse effects, including nausea, vomiting, shivering, pruritis, and respiratory depression. Primarily mentioned side effects were shivering and pruritis. Furthermore, secondary meta-analyses by Wang et al, Shen et al, and Miao et al found that patients who received dexmedetomidine had significantly lower incidences of shivering.[4,5,15] Researchers theorized that dexmedetomidine reduces the sensitivity of the temperature regulating center in the hypothalamus by interfering with neuronal electrical conductivity via agonism of the alpha-2 receptor.[5] Shen et al and Miao et al concluded that dexmedetomidine enhanced anesthesia for cesarean section with fewer side effects than opioids.[5,15] This is consistent with findings published by Sushruth et al, Li et al, and Zhang et al.[1,3,10] In contrast, Khosravi et al determined that the incidence of side effects was comparable between dexmedetomidine and fentanyl.[6]

Summary of Evidence

This literature review suggests that dexmedetomidine is a suitable alternative to opioids for cesarean section. However, a critical appraisal of data also reveals gaps in the literature. These include the effects of dexmedetomidine on motor blockade and hemodynamics. The evidence is inconclusive regarding whether dexmedetomidine prolongs the duration of motor blockade. Khosravi et al[6] was the only source identified in this review that offered a dissenting opinion on this matter. As such, more research is necessary to make a definitive conclusion.

Additionally, there is mixed evidence concerning the hemodynamic stability of dexmedetomidine. Arguably, this is the primary concern about its use in parturients. An exaggerated sympathectomy due to dexmedetomidine could be detrimental to maternal and fetal outcomes. This initial review found that at low doses, intrathecal dexmedetomidine does not

significantly alter hemodynamics; however, more research is needed to support this data.

Table 1. Literature Matrix

Citation	Design/Method	Sample/Setting	Major Variables Studied and Their Definitions	Measurement and Data Analysis	Findings	Results	Conclusions	Appraisal: Worth to Practice/Level
Bi et al. 2020. Effect of different doses of intrathecal dexmedetomidine as an adjunct combined with hyperbaric ropivacaine in patients undergoing cesarean section	RCT, double-blind trial Purpose: To determine the optimal clinical dose of intrathecal DEX on neuraxial blockade for cesarean section 75 subjects randomly divided into 3 groups (N = 25) Group R: Hyperbaric ropivacaine Group RD3: Hyperbaric ropivacaine with 3 mcg of DEX Group RD5: Hyperbaric ropivacaine with 5 mcg of DEX	N = 75 Characteristics: Parturients >18 years old, ASA 2 status, undergoing elective cesarean section Location of study: Second Affiliated Hospital of Harbin University (Harbin, Heilongjiang Province, China) Attrition: NR	DV: Group R IV1: Group RD3 IV2: Group RD5	Scale: Interval scale Analysis: Probability values (p <0.05) were deemed statistically significant. Motor block was evaluated with the Bromage Scale. Additionally, the quality of spinal anesthesia, visceral traction response, the quality of abdominal muscle relaxation, and shivering were measured. Specifically, onset time of sensory block to T10, time of motor block recovery, and patient VAS scores (0, no pain; 10, most serious pain) were recorded at 2-, 6-, and 12-hour intervals. Statistical analysis was completed via SPSS 20 software, ANOVA, and x^2 tests. Data were distributed non-normally via a Mann-Whitney U test. Categorical variables were analyzed using Fisher's exact test.	The demographic findings of all parturients regarding age, weight, height, and gestation week were comparable (p > 0.05). The onset times of sensory block to T10, T4 and peak levels in both intervention groups were significantly shorter than those in the control group (p < 0.05). The time of descent of sensory blockade to 2 levels below the injection site were prolonged in the intervention group compared to the control group (p < 0.05). Further, the time of sensory level descent was longer in group RD5 compared to group RD3 (p < 0.05), as was the time of motor block recovery (p < 0.01). There was no statistical difference in recovery time among the groups.	Adding 3 mcg or 5 mcg of intrathecal DEX was associated with a rapid onset of sensory and motor block, prolonged duration of sensory block, improved muscle relaxation, reduced visceral pain, enhanced postoperative analgesia, and significantly fewer side effects, particularly shivering. Additionally, DEX reduced maternal postoperative c-reactive protein (CRP), interleukin-6 (IL-6), and cortisol levels, thus mitigating the maternal stress response, and resulting in improved analgesia.	3 mcg of DEX prolongs the time of sensory block without prolonging the time of motor block. Intrathecal DEX causes hypotension and bradycardia; although there is no statistical difference between the degree of hemodynamic changes between injection of 3 mcg vs 5 mcg.	Level of Evidence: I Strengths and Limitations: Researchers determined that 3 mcg of DEX is sufficient for neuraxial blockade; however, researchers administered 2 mg of morphine via the epidural route at the end of the surgery, thus confounding results regarding postoperative analgesia between injection of 3 mcg vs 5 mcg. Risk/Benefit: Benefits outweigh risks. Feasibility: 3 mcg of intrathecal DEX is adequate for sensory and motor blockade and postoperative analgesia for cesarean section.

DV = dependent variable; ID = independent variable; NR = not recorded; DEX = dexmedetomidine; APGAR = "Appearance, Pulse, Grimace, Activity, and Respiration"; VAS = visual analog scale; ANOVA = analysis of variance; CI = confidence interval; SBP = systolic blood pressure; DBP = diastolic blood pressure; HR = heart rate; MAP = mean arterial pressure; RR = respiratory rate; SpO2 = oxygen saturation; PRISMA = Preferred Reporting Items for Systematic Reviews and Meta-Analyses; PDPH = post dural puncture headache

Citation	Design/Method	Sample/Setting	Major Variables Studied and Their Definitions	Measurement and Data Analysis	Findings	Results	Conclusions	Appraisal: Worth to Practice/Level
Qi et al. 2016. Comparison of intrathecal dexmedetomidine with morphine as adjuvants in cesarean sections	RCT, double-blind trial Purpose: Effect of intrathecal DEX on quality of neuraxial blockade for cesarean section 120 subjects randomly divided into 3 groups (N = 40) Group B: Hyperbaric bupivacaine (10 mg) Group BM: Hyperbaric bupivacaine (10 mg) with morphine (100 mcg) Group BD: Hyperbaric bupivacaine (10 mg) with DEX (5 mcg)	N = 120 Characteristics: Parturients, ASA 2 status, full-term gestation undergoing elective cesarean section Location of study: Shenzhen Maternity and Child Care Hospital (China) Attrition: NR	DV1: Group B DV2: Group BM IV: Group BD	Scale: Ratio scale Analysis: Probability values ($p < 0.05$) were deemed statistically significant. The onset of sensory block was determined using the pinprick method every 2 minutes. Motor block was assessed using the Modified Bromage Scale. Hypotension was measured as a decrease in SBP of more than 30% from baseline or a decrease below 90 mmHg. The extent of muscle relaxation was assessed by the surgeon using a 3-point scale. APGAR scores were measured at 1- and 5-minute intervals and neurologic and adaptive capacity scores (NACS) at 2 and 24 hours were recorded. Sedation was measured via the Ramsay Sedation Scale. VAS was used to determine postoperative pain at 4-, 8-, 12-, 24-, and 48-hour intervals. Statistical analysis was conducted via SPSS software version 19. Categorical covariates were measured via the Chi-squared distribution test and Fisher's exact test, with p values reported at 95% CI. Continuous variables were measured via ANOVA.	The onset and regression time of sensory and motor blockade, postoperative analgesia and side effects were recorded. Group BD showed a quicker onset time and a longer sensory and motor blockade than other groups (BD vs. B and BD vs. BM, $p < 0.05$). The mean time of sensory regression to the S1 segment was longer in group BD > group BM > group B ($p < 0.001$). Group BD demonstrated an analgesia duration time similar to that of group BM, but longer than that of group B ($p < 0.001$). The incidence of pruritus was significantly higher in group BM compared with groups BD and B ($p < 0.001$). Less shivering was observed in group BD than in groups BM and B ($p = 0.009$).	Group BD attained a shorter onset time and longer duration of sensory and motor block. Postoperative sedation and analgesia were comparable between groups BD and BM. Group BD was associated with fewer adverse effects; less shivering and significantly less pruritis than group BM. No statistically significant difference between Apgar scores among the 3 groups.	Intrathecal DEX prolongs motor and sensory block compared with intrathecal morphine in cesarean sections. DEX and morphine provide similar postoperative analgesic effects; however, DEX avoids unwanted side effects otherwise caused by morphine, including nausea, pruritis, and shivering. DEX also has no adverse effects on the neonate. The most significant side effect reported with intrathecal DEX is hypotension and bradycardia, although this incidence is statistically insignificant.	Level of Evidence: I Strengths and Limitations: Researchers demonstrated that intrathecal DEX provides a similar analgesic effect compared with morphine with few side effects. However, intrathecal DEX is not widely used in obstetric anesthesia; thus, the safety of its use requires further study. Also, the formula to measure postoperative analgesia did not consider differences in the weight of parturients, which may affect the assessment of analgesia effects. Risk/Benefit: Benefits outweigh risks. Feasibility: Intrathecal DEX is a reasonable alternative to intrathecal opioids for neuraxial blockade for cesarean section.

Citation	Design/Method	Sample/Setting	Major Variables Studied and Their Definitions	Measurement and Data Analysis	Findings	Results	Conclusions	Appraisal: Worth to Practice/Level
Li et al. 2020. The efficacy and safety of intrathecal dexmedetomidine for parturients undergoing cesarean section: A double-blind randomized controlled trial	RCT, prospective double-blind trial using up-down sequential allocation method Purpose: Effect of intrathecal DEX on quality of neuraxial blockade for cesarean section 300 parturients randomly divided into 3 groups (N = 100) Group B: Hyperbaric bupivacaine Group FB: Hyperbaric bupivacaine with 20 mcg of fentanyl Group DB: Hyperbaric bupivacaine with 5 mcg of DEX	N = 300 Characteristics: Parturients aged 20-35 yrs., ASA 2-3 status, full-term gestation undergoing elective cesarean section Location of study: Affiliated Hospital of Xuzhou Medical University and Feng Xian People's Hospital (China) Attrition: NR	DV1: Group B DV2: Group FB IV: Group DB	Scale: Nominal scale Analysis: Probability values ($p < 0.05$) were deemed statistically significant. The sample size calculation was based on the primary outcome, the duration of sensory block. Sample size was calculated using PASS 15 software. The duration of sensory block was 114.3 ± 28.5 min for group B, 120.1 ± 29.4 min for group FB, 128.8 ± 29.5 min for group DB. Statistical analysis was performed via IBM SMSS 22 software. Numeric variables were categorized by the Kolmogorov-Smirnov test. Normally distributed continuous variables were expressed as a standard deviation and analyzed via ANOVA. The categorical variables were analyzed using the Chi-squared distribution test or Fischer exact test.	The duration of sensory block in groups FB and DB was prolonged compared to group B (95% CI). The duration of sensory block was significantly longer in group BD compared to group FB ($p < 0.001$). Compared with group B, the onset of sensory block in group DB was shorter ($p < 0.001$). Additionally, the onset time of motor block in group BD was significantly shorter compared to the other groups. The duration of motor block was prolonged by 43 minutes ($p < 0.01$) in group BD as compared to 7 minutes in group FB ($p = 0.038$). The quality of postoperative recovery was higher in group DB than in groups FB and B ($p < 0.01$).	Parturients in group DB experienced a longer duration of sensory block and a longer duration of motor block as opposed to those in groups FB and B. Group DB did not demonstrate a statistically significant difference in regard to the onset of motor block as compared to the other groups. However, the onset of sensory block was more rapid in group DB. Parturients in group BD experienced enhanced postoperative recovery than those in the other groups.	Intrathecal DEX for cesarean section delivers a satisfactory sensory and motor block and improves postoperative recovery as compared to the administration of 9 mg of bupivacaine alone. The onset of sensory and motor block is hastened with the addition of DEX, and the duration of sensory block is prolonged. Injection of 5 mcg is a sufficient dose to block visceral fibers and produce prolonged analgesia. However, adding DEX may also prolong the motor block, thus increasing the risk for falls and delaying early rehabilitation of parturients. The incidence of shivering is significantly reduced by adding DEX. DEX is not associated with maternal neurotoxicity.	Level of Evidence: I Strengths and Limitations: Researchers demonstrated the efficacy of intrathecal DEX, but further studies are needed to demonstrate safety. The adequacy of muscle relaxation during surgery was not measured. The optimal clinical dose of intrathecal DEX was not measured, nor was the dose-response reaction of DEX. Information regarding placental transfer was not obtained. The postoperative period was only 30 days; it is unknown if parturients had delayed neurotoxicity. Risk/Benefit: Benefits outweigh risks. Feasibility: Intrathecal DEX is a reasonable alternative to intrathecal opioids for neuraxial blockade for cesarean section.

Citation	Design/Method	Sample/Setting	Major Variables Studied and Their Definitions	Measurement and Data Analysis	Findings	Results	Conclusions	Appraisal: Worth to Practice/Level
Wang et al. 2019. Effect of intrathecal dexmedetomidine on cesarean section during spinal anesthesia: a meta-analysis of randomized trials	Meta-analysis Purpose: Effect of intrathecal DEX on quality of neuraxial blockade for cesarean section Searched 3 databases from 2018-2019. Included only RCTs with a control and intervention group. Inclusion criteria included females undergoing cesarean section with spinal anesthesia.	*N* = 4 out of 144 potential studies Characteristics: Adult parturients undergoing elective cesarean section with spinal anesthesia Setting: Acute care hospital (China) Attrition: NR	IV: Intrathecal DEX DV: Placebo	Data were analyzed via the Review Manager, the Nordic Cochrane Center, and The Cochrane Collaboration to perform a meta-analysis. Heterogenicity was assessed using the I^2 statistic. $I^2 < 50$ indicated the existence of homogeneity; $I^2 > 50$ indicated the presence of heterogenicity. The random effect model for meta-analysis was utilized with 95% CI. The incidence of shivering was compared between the DEX and placebo groups; the heterogenicity test revealed $I^2 = 19\%$. Additionally, the incidence of nausea and vomiting was compared between the DEX and placebo groups; the heterogenicity test revealed $I^2 = 0\%$. The incidence of bradycardia was also compared between both groups with the heterogenicity test revealing $I^2 = 16\%$. Finally, the incidence of hypotension was compared. The heterogenicity test showed $I^2 = 46\%$, which is considered median heterogenicity.	The heterogenicity tests for shivering, nausea/vomiting, bradycardia, and hypotension revealed $I^2 = 19\%$ and $I^2 = 0\%$, $I^2 = 16\%$, $I^2 = 46\%$,. respectively. These results indicate that there is no statistical significance regarding the incidence of shivering, nausea/vomiting, bradycardia, and hypotension with intrathecal DEX vs intrathecal local anesthetic.	Intrathecal dexmedetomidine had no effect on nausea and vomiting ($p = 0.74$), bradycardia ($p = 0.70$) and hypotension during cesarean section ($p = 0.08$). The Incidence of shivering in the DEX group was significantly lower than that in the placebo groups.	Intrathecal DEX reduces the occurrence of shivering during cesarean section. DEX is associated with few adverse effects; it does not significantly increase the incidence of hypotension, bradycardia, or nausea. Adding DEX can reduce the use of opioids postoperatively. DEX administered via the intrathecal route (as opposed to the intravenous route) does not increase the risk of hypotension during cesarean section. Intrathecal DEX has minimal effect on baroreceptor-mediated changes.	Level of Evidence: I Strengths and Limitations: Researchers effectively demonstrated that intrathecal DEX reduces the occurrence of shivering during cesarean section. Further, DEX is not associated with significant adverse effects. However, only 4 RCTs were included in the meta-analysis. Additionally, the sample size of the RCTs was small; thus, conclusions were based on small samples. Only published RCTs were included in the study. All included studies used 5 mcg of DEX; thus, the effect of other doses of DEX was not explored. Risk/Benefit: Benefits outweigh risks. Feasibility: Intrathecal DEX is a reasonable alternative to intrathecal opioids for neuraxial blockade for cesarean section.

Citation	Design/Method	Sample/Setting	Major Variables Studied and Their Definitions	Measurement and Data Analysis	Findings	Results	Conclusions	Appraisal: Worth to Practice/Level
Sushruth et al. 2018. Effect of adding intrathecal dexmedetomidine as an adjuvant to hyperbaric bupivacaine for elective cesarean section	Prospective RCT Purpose: Effect of intrathecal DEX on quality of neuraxial blockade for cesarean section 60 subjects randomly divided into 2 groups (N = 30) Group C: Hyperbaric bupivacaine with 0.9% NaCl solution Group D: Hyperbaric bupivacaine with DEX	N = 60 Characteristics: Parturients aged 18 – 35 yrs., ASA 2 status undergoing elective cesarean section Location of study: Tertiary obstetric hospital in south India Attrition: NR	DV: Group C IV: Group D	Scale: Ratio scale Analysis: Probability values (p <0.05) were deemed statistically significant. The quality of motor blockade was assessed via the Bromage scale. Hemodynamic parameters including HR, SBP, DBP, RR, SpO2, and sedation score were recorded via the Ramsay sedation score. These parameters were measured every 2 minutes up to 10 minutes, every 5 minutes up to 40 minutes, and then every 10 minutes until the end of surgery. Hypotension was defined as any reduction in SBP more than 20% below baseline or a decline less than 90 mmHg. Neonatal APGAR scores were recorded at the first and fifth minutes. VAS was utilized to measure postoperative pain at 30 minutes, hourly for the next 6 hours, and then every 2 hours for 24 hours. Data were analyzed via SPSS version 22. Student's t-test and Chi-squared distribution test were used for continuous and categorical variables.	The time for onset of analgesia to T10 level, time to peak sensory level, time to onset of motor block, and time for maximum motor block was significantly faster in group D (p < 0.01). The maximum sensory level was T5.6 for group D, as compared to T5.7 for group C (p = 0.77). Thus, the maximum sensory levels between both groups were comparable. Additionally, the time for two-segment sensory regression and regression to S1 level was prolonged in group D (p < 0.001). The time of onset of Bromage grade I and IV motor block was more rapid in group D compared to group C (p < 0.01). Duration of both analgesia and motor block was prolonged in group D. There were no statistically significant differences between groups D and C regarding frequency of adverse effects (i.e., hypotension, bradycardia, shivering, and pain).	Time of onset of motor and sensory blockade (measured at the T10 level) was significantly faster in group D. Duration of analgesia was prolonged in group D. 24-hour postoperative pain scores were consistently lower in group D. Neonatal APGAR scores were comparable between groups C and D. There were no significant variations in hemodynamic parameters between either group. The incidence of possible adverse effects in either group was insignificant.	DEX is a useful intrathecal adjuvant to hyperbaric bupivacaine for a cesarean section; it hastens the onset of sensory and motor block and prolongs postoperative analgesia with minimal side effects or hemodynamic changes. Adding DEX also prolongs the motor block. DEX provides moderate hemodynamic stability with minimal sedation. DEX has no adverse effect on APGAR scores. 5 mcg of DEX is a sufficient dose.	Level of Evidence: I Strengths and Limitations: Researchers demonstrated that adding 5 mcg of DEX enhances neuraxial blockade for a cesarean section. However, information regarding the effect of DEX on placental transfer was not obtained. Neurobehavioral effects, including risk for neurotoxicity, were also not obtained Risk/Benefit: Benefits outweigh risks. Feasibility: Intrathecal DEX is a reasonable alternative to intrathecal opioids for neuraxial blockade for cesarean section.

Citation	Design/Method	Sample/Setting	Major Variables Studied and Their Definitions	Measurement and Data Analysis	Findings	Results	Conclusions	Appraisal: Worth to Practice/Level
Shen et al. 2020. Dexmedetomidine as an adjuvant for single spinal anesthesia in patients undergoing cesarean section: A system review and meta-analysis	Meta-analysis Purpose: Impact of intrathecal DEX on quality of neuraxial blockade for cesarean section Searched 8 databases from 2018-2019. Included only RCTs with a control and intervention group. Inclusion criteria included females undergoing cesarean section with spinal anesthesia using DEX as an adjunct.	*N* = 10 out of 782 potential studies Characteristics: Adult parturients, ASA 2-3 status Setting: Acute care hospital (China) Attrition: NR	IV: DEX as an adjuvant for single spinal DV: Neuraxial blockade	Reporting for the systematic review and meta-analysis followed PRISMA guidelines. Analysis: Probability values (p <0.05) were deemed statistically significant. Data were analyzed utilizing RevMan version 5.3. The heterogenicity of trials was assessed using the I^2 statistic, utilized with 95% CI. GRADE levels were used to categorize outcomes (i.e., onset of sensory and motor block, duration of sensory and motor block, APGAR scores, and adverse effects). The GRADE levels of evidence for onset time of sensory and motor block and the duration of sensory and motor block were moderate, while the other results (Apgar scores at 1 and 5 minutes, shivering, hypotension, bradycardia, and nausea and vomiting) had high GRADE levels.	Patients in the DEX group demonstrated more rapid sensory and motor block onset time (p < 0.05). The onset of sensory block measured I^2 = 92%, whereas the onset of motor block measured I^2 = 60%. DEX was also shown to prolong the sensory (I^2 = 93%) and motor block duration (I^2 = 94%, p < 0.05). DEX was also shown to reduce the incidence of shivering (p < 0.05, I^2 = 0%).	The data demonstrate that DEX shortened the onset of local anesthetic and prolonged the duration of the block, with no effect on the neonate. Regression analysis demonstrated no statistical difference in APGAR scores in the DEX group. Additionally, no significant differences were reported for complications (i.e., hypotension, bradycardia, and nausea/vomiting).	Adding intrathecal DEX provides a quicker onset of motor and sensory block, along with a prolonged duration of sensory block. DEX also reduces postoperative shivering and enhances the effect of local anesthetic. Drug-related side effects did not increase. DEX has no effect on the neonate – APGAR scores and umbilical blood pH are not affected. Potential complications of DEX, including bradycardia and hypotension, are statistically insignificant; however, more high-quality studies are required to ensure the dose safety of DEX.	Level of Evidence: I Strengths and Limitations: Researchers elucidated the effects of DEX on neonate safety and the duration of local anesthetic. Previous studies have failed to evaluate this. However, the study reported high clinical heterogenicity regarding different anesthesia techniques and various dosages of DEX. There was a small sample of eligible RCTs, which may cause a small study-effect bias. Further, more studies with a larger sample size are required to verify efficacy. Risk/Benefit: Benefits outweigh risks. Feasibility: Intrathecal DEX is a reasonable alternative to intrathecal opioids for neuraxial blockade for cesarean section.

Citation	Design/Method	Sample/Setting	Major Variables Studied and Their Definitions	Measurement and Data Analysis	Findings	Results	Conclusions	Appraisal: Worth to Practice/Level
Zhang et al. 2022. Intrathecal dexmedetomidine combined with ropivacaine in cesarean section: A prospective randomized, double-blind controlled study	RCT Purpose: Effect of intrathecal DEX on quality of neuraxial blockade for cesarean section and to assess characteristics of spinal anesthesia, hemodynamic changes, adverse effects and neonatal outcomes 120 subjects randomly divided into 4 groups (*N* = 30) Group R: Hyperbaric ropivacaine Group RD1: Hyperbaric ropivacaine with 5 mcg of DEX RD2: Hyperbaric ropivacaine with 7.5 mcg of DEX Group RD3: Hyperbaric ropivacaine with 10 mcg of DEX	*N* = 120 Characteristics: Parturients, aged 20-45, ASA 2-3 status, gestational age >37 weeks undergoing elective cesarean section Location of study: Hospital of Gannan Medical College, at Ganzhou, Jiangxi Province (China) Attrition: NR	DV = group R IV1 = Group RD1 IV2 = Group RD2 IV3 = Group RD3	Scale: Interval scale Analysis: Probability values (p <0.05) were deemed statistically significant. The onset time and duration of sensory block were measured and recorded; sensory block was defined as the absence of nociception at the T8 level. This was measured using the pinprick method. Motor block was measured via the Bromage scale. Duration of motor nerve block was defined as the time it took for Bromage scores to recover from grade I to grade IV. Hemodynamic parameters (MAP, HR and SpO2) were monitored at 5-, 10-, and 20-minute intervals. Adverse reactions such as chills, nausea/vomiting, and hypotension were graded. Specifically, chills were grades using a 4-point scale. Statistical analysis was conducted via SPSS version 23 statistical software. Data was expressed as means and standard deviation, medians and ranges, and percentages. Categorical data was analyzed using the Chi-squared distribution test and Fisher's exact test. Continuous data were compared using ANOVA. If the P value was significant, *post hoc* comparisons were performed.	Parturients in groups RD1, RD2, and RD3 had a longer sustained sensory and motor block than those in group R. However, the block onset was comparable among all four groups. The time for sensory block regression to the level of S1 was longer in groups RD1, RD2, and RD3 compared to group R ($p < 0.001$). Recovery time was longer in groups RD1, RD2, and RD3. ($p < 0.001$). The incidence of chills was also lower in the intervention groups, but there was no significant difference in the incidence of adverse effects (i.e., hypotension, bradycardia, nausea/vomiting, hypoxemia, and pruritis) among the groups ($p > 0.05$). Visceral traction response and APGAR scores were comparable amongst all groups ($p > 0.05$). Phenylephrine dosing was significantly higher in groups RD2 and RD3 than in group R ($p < 0.05$).	Intervention groups experienced prolonged sensory and motor block, quicker block onset, more profound perioperative analgesia, and fewer chills than the control group. The intervention groups also experienced minimal side effects, suggesting DEX does not increase the risk for adverse effects. DEX did not cause significant hemodynamic alterations (i.e., hypotension or bradycardia).	Adding 5 mcg, 7.5 mcg or 10 mcg of intrathecal DEX to hyperbaric ropivacaine during cesarean section relieves intraoperative chills, prolongs sensory and motor blockade, and decreases serological stress indicators, without increasing perioperative side effects. Intrathecal DEX is a safe adjuvant to spinal anesthesia.	Level of Evidence: I Strengths and Limitations: Researchers demonstrated the safety and efficacy of intrathecal DEX at 3 separate doses; however, researchers admitted to having difficulty determining the precise dose of DEX at 5 mcg (0.05 mL) and 7.5 mcg (0.075 mL), which could lead to bias for the data gathered for groups RD1 and RD2. Also, the effects of intrathecal DEX at a dose greater than 10 mcg were not studied. Further, postoperative maternal pain and peak block time were not measured. Risk/Benefit: Benefits outweigh risks. Feasibility: Intrathecal DEX is a reasonable alternative to intrathecal opioids for neuraxial blockade for cesarean section.

Citation	Design/Method	Sample/Setting	Major Variables Studied and Their Definitions	Measurement and Data Analysis	Findings	Results	Conclusions	Appraisal: Worth to Practice/Level
Sun et al. 2015. Comparative evaluation of intrathecal bupivacaine alone, bupivacaine-fentanyl, and bupivacaine-dexmedetomidine in cesarean section	RCT, double-blind trial Purpose: Effect of intrathecal DEX on quality of neuraxial blockade for cesarean section 90 subjects randomly divided into 3 groups (N = 30) Group BV: Hyperbaric bupivacaine Group BvF: Hyperbaric bupivacaine with fentanyl Group BvD: Hyperbaric bupivacaine with DEX	N = 90 Characteristics: Parturients aged 20-35 yrs., ASA 2-3 status, full-term gestation undergoing elective cesarean section Location of study: Attrition: NR	DV1: Group BV DV2: Group BvF IV: Group BvD	Scale: Interval scale Analysis: Probability values (p <0.05) were deemed statistically significant. Statistical analysis was performed for the following variables: the onset of sensory block, maximum sensory block level, duration of motor and sensory block, the onset of post-operative pain, sedation scores, APGAR scores, and side effects.	Patients in group BvD experienced a faster onset of motor and sensory block, prolonged sensory block, and more profound postoperative analgesia, without a significant effect on sedation and APGAR scores (p < 0.05). Also, the incidence of side effects in this group was minimal. Group BvD reported improved VAS scores.	Regression time to the T10 level was significantly longer in the BvD group. Sensory block was also prolonged in this group; however, there was no statistically significant difference in the duration of motor block. Group BvD had improved VAS scores with the least values of 0-3, followed by BvF (1-4). No statistical difference was reported among the groups regarding AGAR scores and neonatal side effects.	The addition of DEX as an adjuvant to hyperbaric bupivacaine in cesarean section provides a denser block, resulting in better intra-operative and post-operative analgesia, without affecting APGAR scores or causing unwanted side effects.	Level of Evidence: I Strengths and Limitations: Researchers effectively demonstrated that the addition of DEX improves the quality of neuraxial blockade without impacting the incidence of side effects. However, they failed to investigate the adequate dose of DEX to produce analgesia. Risk/Benefit: Benefits outweigh risks. Feasibility: Intrathecal DEX is a reasonable alternative to intrathecal opioids for neuraxial blockade for cesarean section.

Citation	Design/Method	Sample/Setting	Major Variables Studied and Their Definitions	Measurement and Data Analysis	Findings	Results	Conclusions	Appraisal: Worth to Practice/Level
Tang et al. 2020. Comparison of the ED50 of intrathecal hyperbaric ropivacaine co-administered with or without intrathecal dexmedetomidine for cesarean section: A prospective, double-blinded, randomized dose-response trial using up-down sequential allocation method	RCT, single-blinded, prospective, randomize dup-down sequential allocation study Purpose: To determine the optimal clinical dose of intrathecal DEX on neuraxial blockade for cesarean section 60 subjects randomly divided into 2 groups (N = 30) Group C: Intrathecal ropivacaine Group D: Intrathecal ropivacaine with 5 mcg of DEX	N = 60 Characteristics: Parturients aged 20-45 yrs., ASA 2 status, >37 weeks gestation, undergoing elective cesarean section Location of study: Department of Anesthesia, Women's Hospital, Zhejiang University School of Medicine Attrition: NR	DV: Group C IV: Group D	Scale: Nominal scale Analysis: Probability values ($p < 0.05$) were deemed statistically significant. The Dixon and Massay sequential method and Probit regression were applied to calculate the ED_{50} of intrathecal ropivacaine in both groups. Sensory level was assessed via a pinprick test using a 17-G needle, recorded every 2 minutes for the first 10 minutes following injection, and then every 10 minutes thereafter. The highest level of sensory and motor block was also recorded. Motor block was assessed via the Bromage scale (0 = no motor loss, 1 = inability to flex the hip, 2 = inability to flex the knee, and 3 = inability to flex the ankle). Shivering episodes were measured using a 4-point scale; adverse effects such as pruritis, hypotension, and bradycardia were also measured and recorded. Pain was evaluated by the VAS scale. Nominal data were analyzed using the Chi-square test, and normally distributed data were analyzed via the student's t-test.	The Dixon and Massay formula demonstrated that the ED50 of hyperbaric ropivacaine was 11.4 mg (95% CI) in group C, as opposed to 9.4 mg (95% CI) in group D ($p < 0.05$). The Probit regression demonstrated that the ED50 of intrathecal ropivacaine was 11.1 mg in group C compared to 9.1 mg in group D (95% CI). There was less shivering in group D than in group C ($p < 0.05$). In addition, there was no statistically significant difference in the onset time of sensory or motor block and the incidence of adverse effects (i.e., hypotension, bradycardia, nausea and vomiting, sedation, and pruritus) between either group.	There was no statistically significant difference in the maximum sensory level achieved between groups D and C ($p > 0.05$). The onset time to the T10 sensory level was also similar. VAS scores were comparable, as well ($p > 0.05$). The occurrence of hypotension, bradycardia, nausea/vomiting, pruritis, PDPH, sedation level, and opioid consumption was comparable between groups D and C ($p > 0.05$). The result of the findings may be due to the up-down sequential method applied to the study; thus, the side effect profiles were not compared.	Intrathecal DEX (5 mcg) reduces the ED50 of intrathecal ropivacaine by approximately 18% for cesarean section in healthy parturients undergoing spinal anesthesia.	Level of Evidence: I Strengths and Limitations: Researchers determined that the ED50 of ropivacaine is reduced by intrathecal DEX. However, researchers did not record the duration of the spinal blockade. Also, the different dose of DEX on the ED50 of intrathecal ropivacaine was not investigated. The ED50 of ropivacaine was detected, rather than the ED95, which is thought to be more clinically significant; thus, studies about the effects of intrathecal DEX on the ED95 of spinal ropivacaine are needed. Risk/Benefit: Benefits outweigh risks. Feasibility: 5 mcg of intrathecal DEX is an adequate dose to reduce the ED50 of intrathecal ropivacaine, while also providing a sufficient motor and sensory block.

Citation	Design/Method	Sample/Setting	Major Variables Studied and Their Definitions	Measurement and Data Analysis	Findings	Results	Conclusions	Appraisal: Worth to Practice/Level
Khosravi et al. 2020. Comparative study of fentanyl vs dexmedetomidine as adjuvants to intrathecal bupivacaine in cesarean section: a randomized, double-blind clinical trial	RCT, prospective double-blind trial Purpose: To determine the optimal clinical dose of intrathecal DEX on neuraxial blockade for cesarean section 100 subjects randomly divided into 2 groups (N = 55) Group B-F: Intrathecal bupivacaine (10 mg) with 25 mcg of fentanyl Group B-D: Intrathecal bupivacaine (10 mg) with 5 mcg of DEX	N = 110 Characteristics: Parturients, ASA 1-2, gestational age >37 weeks undergoing elective cesarean section Location of study: NR Attrition: NR	DV: Group B-F IV: Group B-D	Scale: Nominal scale Analysis: Probability values ($p < 0.05$) were deemed statistically significant. Block onset, duration of analgesia, degree of postoperative pain, presence of hemodynamic changes, APGAR scores, and any adverse effects were evaluated. Hypotension was defined as SBP < 90 mmHg or a reduction in MAP of more than 20% from baseline. Bradycardia was defined as HR < 50 beats/minute. The onset of sensory block at the T4-T6 level was assessed via the pinprick test, using a 25-G needle. The degree of motor block was evaluated via the Bromage scale. VAS was used to assess patients' pain score, scored from 0-10. APGAR scores were measured at 1 and 5 minutes after delivery. Duration of analgesia was defined and noted as the time interval between block onset and the first analgesic request. Data was analyzed via the SPSS software using mean, standard deviation, Mann-Whitney U-test (for variables without a normal distribution), Friedman test, Fisher's exact test, chi-squared test, ANOVA and independent sample t-test (for variables with normal distribution).	Duration of analgesia was significantly prolonged in the B-D group than in the B-F group 428.64±73.39 vs 273.18±61.91 min; p < 0.001). Postoperative pain scores measured via the VAS scale was lower in the B-D group than the B-F group (0.33±0.84 vs 0.51±0.57 min; p = 0.004). Block onset was also faster in the B-D group (98.27±35.95 vs 110.45±37.69 seconds; p = 0.036). There were no statistically significant differences in hemodynamic changes. In addition, no differences in the incidence of side effects were observed (i.e., shivering, nausea/vomiting, and respiratory depression). There was also no statistical difference between the two groups in sensory block level (p > 0.05).	Group B-D experienced more profound perioperative analgesia, a denser block, rapid block onset, and a prolonged duration of blockade without added side effects. Adding 5 mcg of DEX to bupivacaine had a better effect on postoperative pain management than 25 mcg of fentanyl. A major focus of the study was to examine the hemodynamic effects of intrathecal DEX. Hemodynamic parameters were comparable between both groups. Additionally, the frequency of use of ephedrine, phenylephrine, or atropine did not differ significantly between groups B-D and B-F.	The primary outcome of the study is postoperative analgesia. Compared with fentanyl, intrathecal DEX (5 mcg) is more effective in managing postoperative pain for cesarean section.	Level of Evidence: I Strengths and Limitations: Researchers demonstrated that intrathecal DEX is superior to intrathecal fentanyl in cesarean section. Researchers also identified the ideal dose of DEX to achieve neuraxial blockade and provide postoperative analgesia. However, the study did not assess peak block time. Risk/Benefit: Benefits outweigh risks. Feasibility: Intrathecal DEX is a reasonable alternative to intrathecal opioids for neuraxial blockade for cesarean section to provide postoperative analgesia.

Conclusion

The studies in this review include level I evidence according to the Polit-Beck hierarchy of evidence; most studies are experimental, with the remaining studies comprising systematic reviews and meta-analyses. Therefore, these studies revealed compelling evidence to support a change in current practice. Although further research should be conducted, the overall review of the literature concludes that dexmedetomidine is effective for obstetrical anesthesia. Thus, there is sufficient high-level data to answer the PICO question and support the purpose of this capstone project.

CONCEPTUAL UNDERPINNING AND THEORETICAL FRAMEWORK

Goals and Outcomes

An essential component for the successful implementation of a scholarly project is to define goals and outcomes that are specific, measurable, attainable, relevant, and time-bound (SMART).

This project aimed to educate anesthesia providers on using dexmedetomidine for spinal anesthesia for obstetrics. Anesthesia providers shall be provided with an educational module that explains how intrathecal dexmedetomidine can be used in adult parturients undergoing cesarean section.

The quality improvement tool included an educational PowerPoint module about intrathecal dexmedetomidine. A pre- and post-educational online survey was sent to all anesthesia providers. Surveys were collected over the span of two weeks; survey results were analyzed and measured to ascertain providers' willingness to adopt a practice change. The number of providers interested in using intrathecal dexmedetomidine was counted and compared

against metric targets.

The educational module and attached survey were emailed to full-time and part-time anesthesia staff. Microsoft PowerPoint was used to create the educational module, and a link to an online survey was embedded at the end of the presentation. The educational module included the following: the problem statement, relevant background information, the scope of the knowledge-practice gap, research evidence, stratified data from past and ongoing experimental studies, along with case reports and editorials from anesthesia groups who have incorporated intrathecal dexmedetomidine for cesarean section into their practice.

Anesthesia providers were educated on the efficacy, safety, and correct use of intrathecal dexmedetomidine for cesarean section. The educational module incorporated relevant evidence from randomized controlled trials, case studies, and meta-analyses. The estimated time frame to collect and analyze the survey results was 3 months, which was ample time to dispense educational material and aggregate participant responses.

Organizational Factors

The program was structured to evaluate the efficacy of dexmedetomidine as an adjuvant to spinal anesthesia for cesarean section. To adequately perform this study, study participants were asked to complete an educational module and answer a pre- and post-questionnaire. To carry out this task, defined roles and responsibilities were necessary. The doctoral student served as project coordinator and liaison, distributing educational material and being available to answer questions regarding the project. The doctoral student implemented the project under the guidance of a faculty advisor and clinical mentor.

The educational material was disseminated as part of a package that included a pre-survey, educational video, and post-educational survey. Consent forms were distributed to all

eligible anesthesia providers. Upon receipt of the consent forms, the educational survey was sent for completion. A pre-survey was required initially, followed by a 15-minute video presentation that explained the project objective and present the evidence. A subsequent post-test questionnaire was collected, and the results of the survey were reviewed to extrapolate the impact of the educational module.

The ultimate objective of the educational module was to promote translation of evidence into practice. Implementing evidence-based practice can improve patient care, optimize patient satisfaction, and enhance overall healthcare quality. Current evidence suggests that dexmedetomidine offers tremendous promise as an adjunct drug for neuraxial anesthesia by enhancing the quality of a spinal block while eliminating the side effects of intrathecal opioids.[1-6] Admittedly, intrathecal dexmedetomidine for cesarean section is a novel practice that necessitates considerable education. However, the hope is that with continued education and further research, a change in current practice may be welcomed.

Theoretical Framework

Framework development is critical to project implementation to guide theory into application. The theoretical framework that best guided this scholarly project is Lewin's change theory. There are three phases to Lewin's theory: unfreeze, change, and refreeze. During the unfreezing phase, the project leader determines what needs to change, creates the need for the change, and recruits strong leadership support to ensure project viability. The next phase is when the intended change occurs, which necessitates open communication, empowerment, and identification of key stakeholders to facilitate project implementation. The final phase involves refreezing, which is intended to develop ways to sustain the change and provide continuing education to incorporate evidence into practice.

PROJECT IMPLEMENTATION

Project Objective

The primary goal of this Doctor of Nursing Practice (DNP) capstone project was to present evidence that supports the use of intrathecal dexmedetomidine for cesarean section. Dexmedetomidine has evolved as a popular non-opioid adjunct, and despite its popular use in general anesthesia for its sedative and analgesic properties, it has not been widely used in obstetrics. The evidence presented in this educational module suggests that dexmedetomidine is the drug of choice for an opioid-sparing approach. Dexmedetomidine is a central alpha 2 agonist with a higher affinity for the alpha 2 receptor (1:1600).[12] This makes it a superior drug to clonidine and renders it less likely to cause profound hypotension and bradycardia.[12]

This project aimed to propose a practice change to bridge the knowledge-practice gap and promote evidence-based practice. This educational module disseminated research evidence to educate anesthesia providers that work for a community hospital. This module explained how intrathecal dexmedetomidine can be used in adult parturients undergoing cesarean section. A pre- and post-educational survey was issued to anesthesia staff to inquire about their willingness to incorporate intrathecal dexmedetomidine into their practice.

Setting and Participants

The educational module included a PowerPoint presentation about intrathecal dexmedetomidine. A post-educational online survey was attached and sent to all certified registered nurse anesthetists (CRNAs). Surveys were collected over a specified period; survey results were analyzed and measured to ascertain providers' willingness to adopt a practice change. The number of providers interested in using intrathecal dexmedetomidine was counted and compared against metric targets.

Microsoft PowerPoint was used to create the educational module, and a link to an online survey was embedded at the end of the presentation. The educational tool included the following: the problem statement, relevant background information, the scope of the knowledge, practice gap, research evidence, and stratified data from past and ongoing experimental studies. Anesthesia providers were educated on the efficacy, safety, and correct use of intrathecal dexmedetomidine for cesarean section.

Description of Methodology

The first step in implementing this capstone educational project was identifying potential stakeholders and available resources. The primary stakeholders of this project included the chairman and chief of anesthesia services, the vice chief of anesthesia services, and the chief nurse anesthetist. Other key stakeholders included all anesthesia staff, hospital administrators, and the pharmacy department.

The educational module was introduced to anesthesia staff via an online module that addresses the use of intrathecal dexmedetomidine for cesarean section. A pre-evaluation tool was utilized to ascertain each provider's knowledge of the topic. This baseline information aided in identifying knowledge gaps to guide the development of the learning module. The module included a PowerPoint presentation with voiceover. Key components of the presentation included education about the effect of dexmedetomidine on neuraxial blockade and perioperative analgesia. In addition, the presentation included information about dosing, the onset of action, side effect profile, and expected duration of action. The educational module incorporated relevant evidence from randomized controlled trials, case studies, and meta-analyses to demonstrate how intrathecal dexmedetomidine can be used in adult parturients undergoing cesarean section.

The next phase of this project entailed an online post-educational survey. Performance data regarding the efficacy of the educational module was evaluated from survey reports. The goal was for the chosen clinical site to consider using dexmedetomidine for spinal anesthesia for cesarean section. The estimated time frame to collect and analyze the survey results was 3 months, which was ample time to dispense educational material and aggregate participant responses.

Protection of Human Subjects

Anesthesia providers that partook in the post-educational survey remained anonymous. Anonymity was accomplished using unique code identifiers to collect and analyze the data. All data was password protected to ensure confidentiality. Anesthesia providers willing to participate in the educational module were provided with a consent form. The form explained that participants must watch the presentation and partake in the pre- and post-educational module surveys. Additionally, the form disclosed that there are no untoward risks in the study.

Data Management and Analysis

The pre- and post-assessment surveys included 10 knowledge-based questions to determine the educational impact of the presented material. Surveys were sent and collected through Qualtrics. The pre-assessment questions gauged providers' baseline understanding of the topic, while the post-assessment questions inquired about the utility of the educational module, the quality of the presented research, and the degree of interest in the educational module. Thus, the surveys incorporated a method of measurement and comparison.

The cost of potential project implementation and resource availability were analyzed as part of the educational module. Specifically, the cost of each vial of dexmedetomidine was assessed, along with the feasibility of pre-packaging the drug. This portion of the educational

module was critical to determine the practicality and viability of the project.

The doctorate student was the primary investigator of the intended project with the help of a graduate faculty advisor. The doctorate student distributed the educational module via email to study participants. Surveys were collected, and results were analyzed against data metrics to determine the educational quality and potential benefit of a change in current practice.

RESULTS

Data Collection

Anesthesia providers were invited to participate in the educational module. The survey was disseminated via an email invitation to 32 CRNAs. Participants had a 2-week response time limit. Initial results were collected after the first 2 weeks. A subsequent reminder email was curated and sent to remaining participants who did not respond the first time. Data collection was carried out through the Qualtrics platform.

Participant Demographics

Of the 32 potential participants, 10 completed the survey. Ages of the participants raged from 28 to 58, with a mean age of 43 years old. 40% (n = 4) of the participants were male, as opposed to 60% (n = 6) female. Participants were of a range of ethnicities: Caucasian (n = 5, 50%), Hispanic (n = 4, 40%), and other (n = 1, 10%). All participants were CRNAs. The participants were questioned about their level of education. Eighty percent (n = 8) of the participants had a doctorate degree, while 20% (n = 2) of the participants had a master's degree. Participants had various years of experience: 1-2 years (n = 5, 50%), 2-10 years (n = 3, 30%), and more than 10 years (n = 2, 20%).

Table 2. Participant Demographics

Demographic	*n* (%)
Total Participants	10 (100%)
Gender	
Male	4 (40%)
Female	6 (60%)
Ethnicity	
Caucasian	5 (50%)
Hispanic	4 (40%)
Other	1 (10%)
Education	
Master's	2 (20%)
Doctoral	8 (80%)
Position/Title	
CRNA	10 (100%)
Years of Experience	
1 to 2 years	5 (50%)
2 to 10 years	3 (30%)
More than 10 years	2 (20%)

Pretest Knowledge

This section revealed participants' baseline knowledge regarding intrathecal dexmedetomidine. Responses were very mixed. Most participants (60%) could identify the

correct dosage of intrathecal dexmedetomidine. However, only 40% correctly stated the mechanism of action of intrathecal dexmedetomidine. Of the remaining questions, 50% correctly identified the drug's duration of action, 40% correctly named the side effects of the drug, and 40% correctly identified the mechanism of sensory blockade. It is worth mentioning that participants' initial feelings on the topic and their willingness to incorporate the proposed practice change were also assessed. Most participants stated that they were extremely likely to incorporate an opioid sparing technique into their practice (80%). However, responses were varied regarding providers' willingness to use dexmedetomidine specifically in the spinal anesthetic for obstetrical anesthesia.

Posttest Knowledge

There was a noted improvement from the pretest scores, as evidenced in the table below. Most participants answered correctly after having watched the educational video. Notably, there was a 60% increase in knowledge regarding the mechanism of action of intrathecal dexmedetomidine. Similarly, there was a 50% increase in identifying the duration of action of dexmedetomidine. Only a 10% increase was noted in recognizing the side effects of intrathecal dexmedetomidine.

Table 3. Correct Responses

Question	Correct Response	Pretest	Posttest	Difference
Q 1	3 – 7.5 micrograms	*n* = 6 (60%)	*n* = 10 (100%)	40%
Q2	By inducing vasoconstriction at the A-2 receptor	*n* = 4 (40%)	*n* = 10 (100%)	60%
Q 3	10 – 12 hours	*n* = 5 (50%)	*n* = 10 (100%)	50%
Q 4	True	*n* = 9 (90%)	*n* = 10 (100%)	10%
Q 5	True	*n* = 7 (70%)	*n* = 10 (100%)	30%

Q 6	True	*n* = 4 (40%)	*n* = 9 (90%)	50%
Q 7	By hyperpolarizing neurons in the dorsal horn	*n* = 4 (40%)	*n* = 8 (80%)	40%

Summary of Results

The data demonstrates a gap in provider knowledge regarding the use of intrathecal dexmedetomidine for cesarean section. Particularly lacking was knowledge concerning the mechanism of action, mechanism of sensory blockade, duration of action, and specific side effects of intrathecal dexmedetomidine. However, it is important to note that provider knowledge increased significantly as evidenced by the results of the posttest survey. These results revealed that after watching the educational video, participants could answer most questions correctly.

The posttest data also demonstrates a profound increase in providers' desire to expand intrathecal dexmedetomidine use in obstetrical anesthesia. Specifically, 80% of providers stated that they were likely to use a non-opioid adjunct for the spinal anesthetic for cesarean section, 60% stated that they were extremely likely to use dexmedetomidine for the spinal anesthetic for cesarean section, and 90% stated that they were extremely likely to utilize an opioid-sparing approach in their practice.

It is a widely accepted notion that a lack of provider knowledge is a significant hindrance to incorporating a practice change. The data extrapolated from the post-education survey demonstrates a considerable improvement in both provider knowledge on the topic and desire to utilize intrathecal dexmedetomidine for cesarean section. Such data underscores the implicit magnitude of the impact of provider education on influencing anesthetic practice.

Limitations

The most significant limitation of this study is the small sample size. The study was conducted within a small group of anesthesia providers. Admittedly, a larger group would have

been more desirable to extrapolate the data and create generalization to increase the strength of the study. Another limitation was time. Participants had a 2-week response time limit. A longer time interval could have yielded more survey responses. Additionally, the educational module delivery method was limited since the project was offered entirely online.

DISCUSSION

Implications to Advances in Nursing Practice

The United States continues to experience a significant opioid epidemic, which invariably has impacted the delivery of healthcare.[16] In particular, the epidemic has created a problem regarding opioid supply. Recently, there have been countless reported instances of fentanyl shortages in the hospital due to drug abuse in the community.[16] Furthermore, there has been a spike in opioid addiction due to the widespread opioid abuse, which increases the risk of relapse for patients receiving perioperative opioids.[16] While opioids play a critical role in perioperative care, their overuse in the hospital setting can cause more harm, especially for patients who may be more vulnerable.[16] Thus, the opioid epidemic has inevitably led to the advent of opioid-sparing anesthesia. Additionally, the increasing utilization of regional anesthesia offers the unique benefit of sparing opioid use, providing prolonged analgesia and promoting early recovery.[16]

While much attention has been given to the opioid epidemic in general, its effect on the obstetric population has certainly been overlooked.[17] Unfortunately, drug abuse among parturients has become more common. Not only does this impact the health of the mother but the fetus as well. Drug abuse creates a plethora of issues regarding patient care for this population, including high risk pregnancies, instances of preterm births, the presence of congenital defects, and poor newborn health.[17] Additionally, parturient drug abuse creates drug tolerance that makes

it more difficult for anesthetists to provide adequate analgesia for a labor- epidural, as well as suitable post-operative analgesia.[17] Evidently, parturient opioid abuse is ubiquitous; however, its widespread effects on maternal and fetal health are clearly understated. Therefore, it is pivotal to underscore the importance of not only the opioid epidemic and its effect on healthcare practice but the effect of the opioid epidemic on this population.

This capstone project aimed to elucidate the use of an opioid-sparing technique in obstetrical anesthesia. Specifically, this project intended to propose a practice change whereby intrathecal dexmedetomidine becomes accepted as a neuraxial adjunct for spinal anesthesia for cesarean delivery. Dexmedetomidine has become a popular analgesic within the past decade, and evidence continues to support its use in anesthesia. As its notoriety has spread, so has data regarding it use for cesarean section. Current data unequivocally demonstrates that intrathecal dexmedetomidine can provide adequate neuraxial blockade and analgesia while sparing opioid usage.[1-6] Admittedly, more research on the topic is necessary; however, with continued provider education and additional research, the use of dexmedetomidine in obstetrical anesthesia can become a recognized anesthetic practice.

Conclusion

Intrathecal dexmedetomidine is an effective non-opioid alternative that has a promising future in the field of obstetric anesthesia. The evidence presented in this evidence-based educational module capstone project demonstrates that dexmedetomidine is effective and safe and lacks many of the negative side effects of opioids. In summary, dexmedetomidine provides a dense sensory and motor block for cesarean section, in addition to satisfactory intraoperative and postoperative analgesia, as measured by patients' perception of pain.

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APPENDIX A

Letter of Support

Miami Beach Anesthesiology Associates, Inc.

Mount Sinai Medical Center • Division of Anesthesia

S. Howard Wittels MD
Chairman

Hector Davila MSS, MD
Executive Director

Guillermo Garcia MD
Vice Chairman

Sebastian Baquero MD

Christopher Bauer MD
Obstetrics Chief

Vicente Behrens MD

Mario Consuegra MD

Jayanand D'Mello MD
Research Coordinator

Laura Foster MD

Pablo Fumero MD

Pedro Garcia MD
Residency Program
Assist. Director

Howard Goldman MD

Alejandro Guzman MD

Rick Hasty MD

Flor Marin MD

Mark Nakajima MD

Gerald Rosen MD
Residency Program
Director

Jason Wigley MD

Alexander Volsky MD

J.P. Mato DNP, CRNA
CRNA Director & SRNA
Coordinator

Paula Schultz DNP, CRNA
OB-Chief CRNA

February 2, 2023

Valerie Diaz, DNP, APRN CRNA, CAPT, USN, NC
Clinical Assistant Professor
Department of Nurse Anesthesiology
Florida International University

Dr. Valerie Diaz,

Thank you for inviting Miami Beach Anesthesiology Associates to participate in the Doctor of Nursing Practice (DNP) project conducted by Katie Kueser entitled "Dexmedetomidine as an Adjuvant for Spinal Anesthesia in Adult Parturients Undergoing Cesarean Section: An Evidenced-Based Educational Module" in the Nicole Wertheim College of Nursing and Health Sciences, Department of Nurse Anesthesiology at Florida International University. I have granted the student permission to conduct the project using our providers.

Evidence-based practice's primary aim is to yield the best outcomes for patients by selecting interventions supported by the evidence. This proposed quality improvement project seeks to utilize the latest literature to increase providers' awareness regarding the efficacy of intrathecal dexmedetomidine as an adjunct for spinal anesthesia in adult parturients undergoing cesarean section.

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

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

Respectfully,

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

4300 Alton Road, Suite 2454, Miami Beach, FL 33140

APPENDIX B

IRB Approval

FIU | Research & Economic Development
FLORIDA INTERNATIONAL UNIVERSITY

MEMORANDUM

To: Dr. Valerie Diaz

CC: Katie Kueser

From: Carrie Bassols, BA, IRB Coordinator CeB

Date: March 6, 2023

Proposal Title: "Dexmedetomidine as an Adjuvant for Spinal Anesthesia in Adult Parturients Undergoing Cesarean Section: An Evidenced-Based Educational Module"

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

IRB Protocol Exemption #: IRB-23-0089 **IRB Exemption Date:** 03/06/23
TOPAZ Reference #: 112795

As a requirement of IRB Exemption you are required to:

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

Special Conditions: N/A

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

APPENDIX C

Informed Consent

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FIU | FLORIDA INTERNATIONAL UNIVERSITY

CONSENT TO PARTICIPATE IN A QUALITY IMPROVEMENT PROJECT

Dexmedetomidine as an Adjuvant for Spinal Anesthesia in Adult Parturients Undergoing Cesarean Section: An Evidence-Based Educational Module

SUMMARY INFORMATION
Things you should know about this study:

- **Purpose:** Educational module to increase providers awareness regarding the efficacy of intrathecal dexmedetomidine as an adjunct for spinal anesthesia for cesarean section.
- **Procedures**: If the participant chooses to participate, they will be asked to complete a pretest, watch a voice PowerPoint, and then a post test
- **Duration:** This will take about a total of 20 minutes total.
- **Risks**: There will be minimal risks involved with this project, as would be expected in any type of educational intervention, which may include mild emotional stress or mild physical discomfort from sitting on a chair for an extended period.
- **Benefits:** The main benefit to you from this research is increase the participants knowledge on using dexmedetomidine in the spinal anesthetic for cesarean section.
- **Alternatives:** There are no known alternatives available to the participant other than not taking part in this quality improvement project.
- **Participation:** Taking part in this quality improvement project is voluntary.

Please carefully read the entire document before agreeing to participate.

NUMBER OF STUDY PARTICIPANTS:

If the participant decides to be in this study, they will be one of 10 people in this research study.

PURPOSE OF THE PROJECT

The participant is being asked to be in a quality improvement project. The goal of this project is to increase providers' knowledge on the use, efficacy, and safety of intrathecal dexmedetomidine for spinal anesthesia in adult parturients undergoing cesarean section. If you decide to participate, you will be 1 of approximately 10 participants.

DURATION OF THE PROJECT
The participation will require about 20 minutes

PROCEDURES
If the participant agrees to be in the project, PI will ask you to do the following things:
1. Complete an online 10 question pre-test survey via Qualtrics, an Online survey product for which the URL link is provided

2. Review the educational PowerPoint Module lasting 15 minutes via Qualtrics, an Online survey product for which the URL link is provided.
3. Complete the online 10 question post-test survey via Qualtrics, an Online survey product for which the URL link is provided.

RISKS AND/OR DISCOMFORTS
The main risk or discomfort from this research is minimal. There will be minimal risks involved with this project, as would be expected in any type of educational intervention, which may include mild emotional stress or mild physical discomfort from sitting on a chair for an extended period.

BENEFITS
The following benefits may be associated with participation in this project: An increase in participants' knowledge on the use, efficacy, and safety of intrathecal dexmedetomidine as an adjuvant for spinal anesthesia for cesarean section. The overall objective of the program is to increase the providers' knowledge based on the current literature.

ALTERNATIVES
There are no known alternatives available to the participant other than not taking part in this project. However, if the participant would like to receive the educational material, it will be provided to them at no cost.

CONFIDENTIALITY
The records of this project will be kept private and will be protected to the fullest extent provided by law. If, in any sort of report, PI might publish, it will not include any information that will make it possible to identify the participant. Records will be stored securely, and only the project team will have access to the records.

PARTICIPATION: Taking part in this quality improvement project is voluntary.

COMPENSATION & COSTS
There is no cost or payment to the participant for receiving the health education and/or for participating in this project.

RIGHT TO DECLINE OR WITHDRAW
The participation in this project is voluntary. The participant is free to participate in the project or withdraw the consent at any time during the project. The participant's withdrawal or lack of participation will not affect any benefits to which you are otherwise entitled. The investigator reserves the right to remove the participant without their consent at such time that they feel it is in their best interest.

RESEARCHER CONTACT INFORMATION
If you have any questions about the purpose, procedures, or any other issues relating to this research project, you may contact Katie Kueser, BSN, RN at (954)-224-5772 or kkues004@fiu.edu orValerie Diaz, DNP, APRN CRNA, CAPT, USN, NC at (305)-348-9027 or vdiaz@fiu.edu.

IRB CONTACT INFORMATION

If the participant would like to talk with someone about their rights pertaining to being a subject in this project or about ethical issues with this project, the participant may contact the FIU Office of Research Integrity by phone at 305-348-2494 or by email at ori@fiu.edu.

PARTICIPANT AGREEMENT

I have read the information in this consent form and agree to participate in this study. I have had a chance to ask any questions I have about this study, and they have been answered for me. By clicking on the "consent to participate" button below I am providing my informed consent.

APPENDIX D

Proposed Method for Data Collection

Pre-Survey and Post-Survey

INTRODUCTION

The primary aim of this QI project is to increase providers' awareness regarding the efficacy of intrathecal Dexmedetomidine as an adjunct for spinal anesthesia in adult parturients undergoing cesarean section.

Please answer the question below to the best of your ability. The questions are either in multiple choice or true/false format and are meant to measure knowledge on the use of intrathecal Dexmedetomidine for spinal anesthesia for cesarean section.

PERSONAL INFORMATION

1. Gender: Male Female Other _____
2. Age: _____
3. Ethnicity: Hispanic Caucasian African American Asian Other _____
4. Position/Title: _____
5. Level of Education: Master Doctoral (DNP, DNAP, EdD, PhD)
6. Years of experience: Over 10 years 5-10 years 2-5 years 1-2 years

QUESTIONNAIRE:

1. What is the optimal intrathecal dose of Dexmedetomidine for spinal anesthesia?
    a. 6-12 micrograms
    b. 1-2 micrograms
    c. 3-7.5 micrograms
    d. 8-16 micrograms

2. What is the mechanism of action by which intrathecal Dexmedetomidine prolongs postoperative analgesia?
    a. By activating the alpha-2 receptor in the periductal gray matter
    b. By inducing vasoconstriction at the alpha-2 receptor in the dorsal horn
    c. By attenuating sympathetic outflow in the nervous system
    d. By inhibiting the transmission of sensory information and modulation of pain

3. When administered intrathecally, what is the duration of postoperative analgesia of Dexmedetomidine?
    a. 10-12 hours
    b. 3-4 hours
    c. 5-6 hours
    d. 16-20 hours

4. True or false: A distinct advantage of intrathecal Dexmedetomidine for cesarean section is that it does not cause pruritis, shivering, nausea, or vomiting.
    a. True
    b. False

5. True or false: Intrathecal Dexmedetomidine entirely eliminates the need for intrathecal opioids.
    a. True
    b. False

6. True or false: Dexmedetomidine does not cause profound bradycardia when it is administered intrathecally.
    a. True
    b. False

7. How does intrathecal Dexmedetomidine provide a rapid and dense sensory block?
    a. By antagonizing excitatory nociceptors to blunt pain
    b. By hyperpolarizing the neurons in the dorsal horn to block pain signals
    c. By activating inhibitory interneurons to block the transmission of sensory information
    d. By inhibiting nerve transmission by interacting with sodium channels

8. How likely are you to use non-opioid adjuncts in the spinal anesthetic for a cesarean section?
    a. Most likely
    b. Somewhat likely
    c. Somewhat unlikely
    d. Most unlikely

9. How likely are you to use Dexmedetomidine as an adjunct in the spinal anesthetic for a cesarean section?

a. Most likely

b. Somewhat likely

c. Somewhat unlikely

d. Most unlikely

10. In general, how likely are you to incorporate an opioid-sparing approach into your practice?

a. Most likely

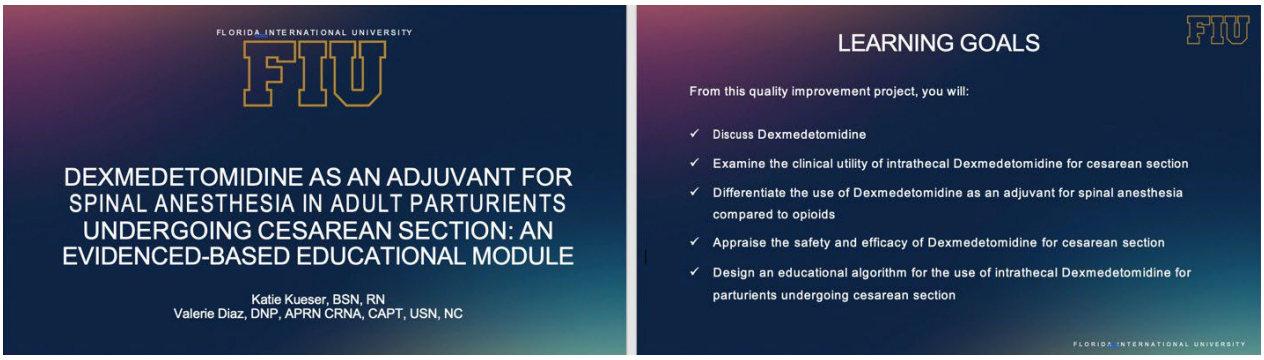
b. Somewhat likely

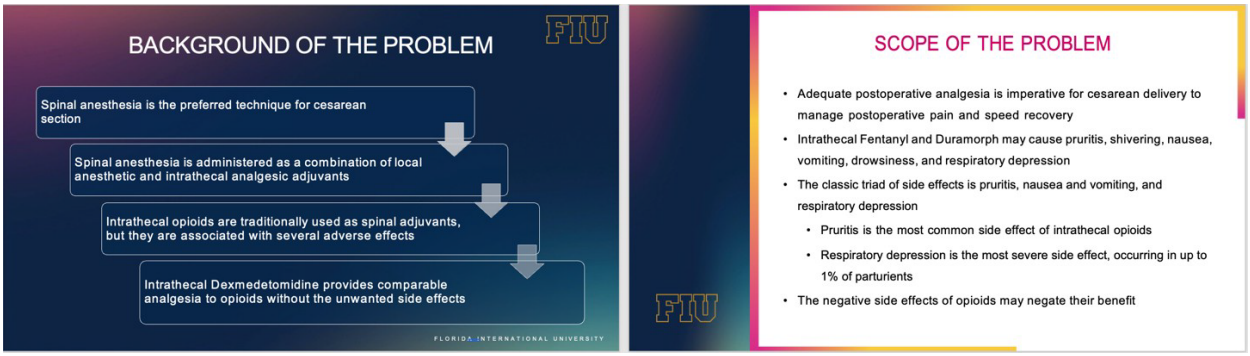
c. Somewhat unlikely

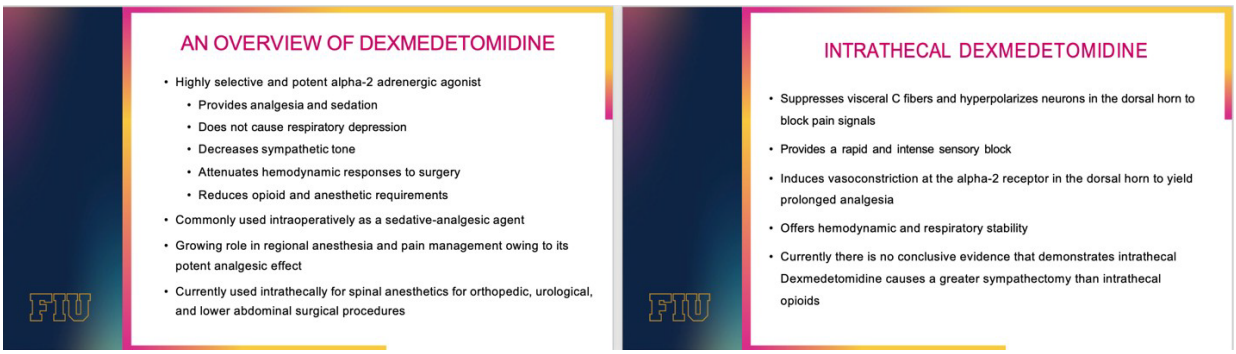
d. Most unlikely

APPENDIX E

Educational Module







INTRATHECAL DEXMEDETOMIDINE FOR CESAREAN SECTION

- Eliminates the need for both Fentanyl and Duramorph – provides immediate intraoperative analgesia and prolonged postoperative analgesia
- Prolongs the period of postoperative analgesia – provides approximately 10-12 hours of pain relief
- The optimal dose of intrathecal dexmedetomidine is approximately 3-7.5 micrograms
  - This modest dose does not cause a significant sympatholytic effect
- Lacks the negative side effects associated with opioids

FIU

INTRATHECAL DEXMEDETOMIDINE VS FENTANYL

Intrathecal Dexmedetomidine demonstrates comparable intraoperative analgesia to Fentanyl

The duration of postoperative analgesia is longer with Dexmedetomidine (10-12 hours) compared to Fentanyl (1-4 hours)

As compared to Fentanyl, Dexmedetomidine does not cause respiratory depression, nausea & vomiting, shivering or impact maternal-fetal disposition

FIU

INTRATHECAL DEXMEDETOMIDINE VS DURAMORPH

Duramorph provides longer postoperative analgesia, up to 20 hours, as compared to Dexmedetomidine (10-12 hours)

Dexmedetomidine is not associated with any instances of immediate or delayed respiratory depression

Duramorph penetrates the spinal cords slower, which permits more drug to ascend the CSF and causes delayed onset respiratory depression

Dexmedetomidine does not cause pruritis, whereas Duramoprh is thought to be the main contributor to postoperative pruritis

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SAFETY AND EFFICACY OF INTRATHECAL DEXMEDETOMIDINE FOR CESAREAN SECTION

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- There is concern regarding the sympatholytic effect of Dexmedetomidine and how this could impact maternal and fetal outcomes
- However, there is no strong evidence that demonstrates intrathecal Dexmedetomidine causes more of a sympathectomy than opioids
- Most primary studies conclude that Dexmedetomidine may be superior to opioids, providing safe anesthesia for cesarean section with fewer side effects

RELEVANCE TO CLINICAL PRACTICE

FIU

- The opioid epidemic continues to pose a problem for health care professionals
- This crisis has inevitably led to the advent of opioid-sparing anesthesia
- Dexmedetomidine is a safe and effective alternative to opioids for sedation and analgesia for obstetric anesthesia
- Intrathecal Dexmedetomidine can enhance neuraxial blockade and provide adequate analgesia while also sparing opioid usage in parturients

TAKE HOME SUMMARY

Dexmedetomidine is a highly selective and potent α2-adrenoceptor agonist, providing sedation and analgesia, while decreasing sympathetic tone

Intrathecal Dexmedetomidine is safe for parturients, yields an effective neuraxial block along with adequate intraoperative and postoperative analgesia without causing respiratory depression

The ideal dose of intrathecal Dexmedetomidine is 3-7.5 mcg. This dose provides a rapid and dense sensory block with prolonged analgesia and lacks significant sympatholytic effects

Intrathecal Dexmedetomidine supplants the need for both Fentanyl and Duramorph for spinal anesthesia for cesarean section

Intrathecal Dexmedetomidine lacks the unwanted side effects of opioids, namely pruritis, shivering, respiratory depression, and nausea and vomiting

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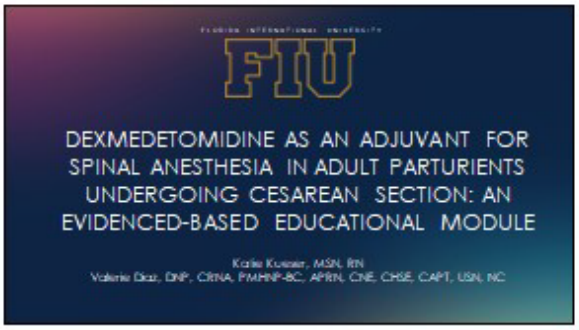
APPENDIX F
DNP symposium



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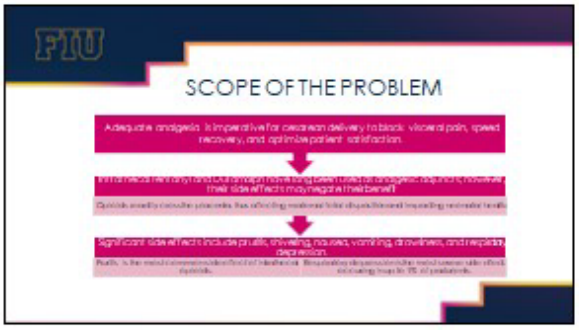

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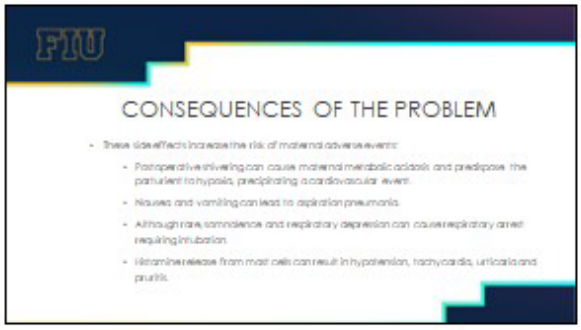

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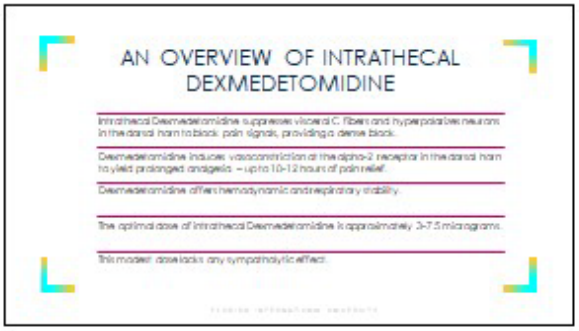

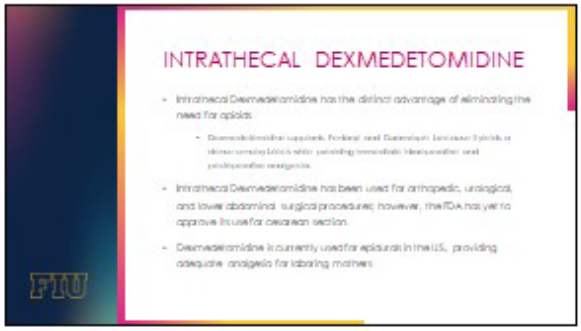


PICO QUESTION
In adult parturients (P), how does intrathecal Dexmedetomidine (I) compared to intrathecal opioids (C) improve the quality of neuraxial blockade (O) as measured by patient's pain perception?
• Population (P): Parturients undergoing cesarean section
• Intervention (I): Intrathecal Dexmedetomidine
• Comparison (C): Intrathecal opioids
• Outcomes (O): Improved quality of neuraxial blockade
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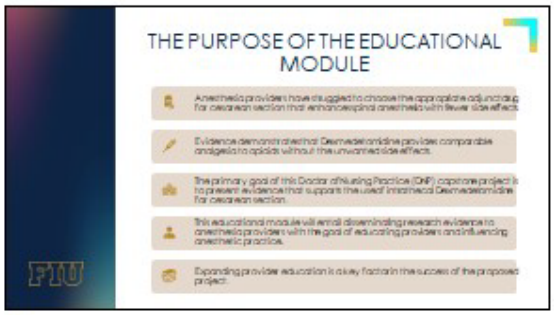
THE PURPOSE OF THE EDUCATIONAL MODULE
Anesthesia providers have struggled to choose the appropriate adjunct drug for cesarean section that enhances spinal anesthesia with fewer side effects.
Evidence demonstrates that Dexmedetomidine provides comparable analgesia to opioids without the unwanted side effects.
The primary goal of this Doctor of Nursing Practice (DNP) capstone project is to present evidence that supports the use of intrathecal Dexmedetomidine for cesarean section.
This educational module will entail disseminating research evidence to anesthesia providers with the goal of educating providers and influencing anesthetic practice.
Expanding provider education is a key factor in the success of the proposed project.
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METHODOLOGY
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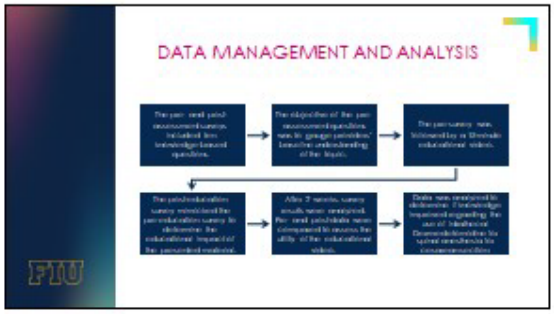
DATA MANAGEMENT AND ANALYSIS
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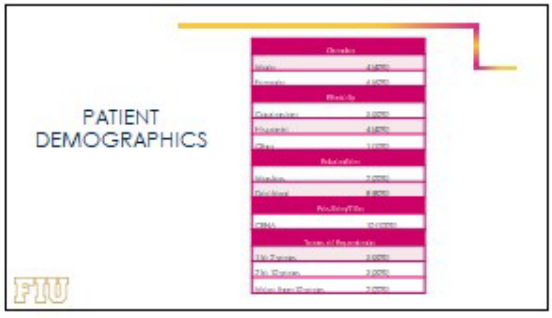
PATIENT DEMOGRAPHICS
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RESULTS: PRE-EDUCATION
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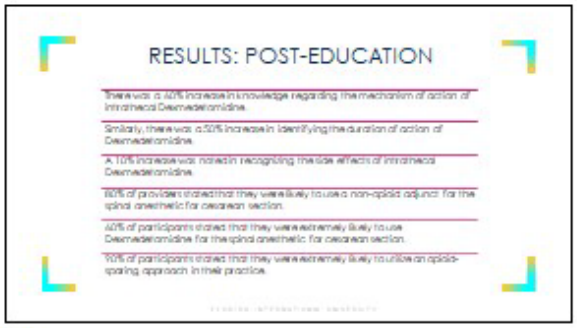
RESULTS: POST-EDUCATION
There was a 40% increase in knowledge regarding the mechanism of action of Intrathecal Dexmedetomidine.
Similarly, there was a 50% increase in identifying the duration of action of Dexmedetomidine.
A 10% increase was noted in recognizing the side effects of intrathecal Dexmedetomidine.
80% of providers stated that they were likely to use a non-opioid adjunct for the spinal anesthetic for cesarean section.
60% of participants stated that they were extremely likely to use Dexmedetomidine for the spinal anesthetic for cesarean section.
70% of participants stated that they were extremely likely to utilize an opioid-sparing approach in their practice.

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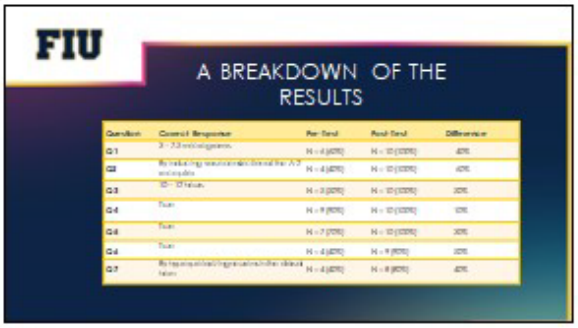
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A BREAKDOWN OF THE RESULTS
Question
Correct Response
Pre-Test
Post-Test
Difference

14


SUMMARY OF RESULTS
The data demonstrates a gap in provider knowledge regarding the use of Intrathecal Dexmedetomidine for cesarean section
Provider knowledge increased significantly as evidenced by the results of the post-test survey.
The post-test data also demonstrates a profound increase in providers' desire to expand Intrathecal Dexmedetomidine use in obstetrical anesthesia.
The data extrapolated from the post-education survey demonstrates a considerable improvement in both provider knowledge on the topic and desire to utilize Intrathecal Dexmedetomidine for cesarean section.
Such data underscores the implicit magnitude of the impact of provider education on influencing anesthetic practice.
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DISCUSSION
The United States continues to experience a significant opioid epidemic, which invariably has impacted the delivery of healthcare.
While much attention has been given to the opioid epidemic in general, its effect on the obstetric population has certainly been overlooked.
Unfortunately, drug abuse among parturients has become more common.
Drug abuse creates a plethora of issues regarding patient care for this population, including high risk pregnancies, increased instances of preterm births, the presence of congenital defects, and poor newborn health.
Parturient opioid abuse is ubiquitous; however, its widespread effects on maternal and fetal health is clearly understated.
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DISCUSSION
It is pivotal to underscore the importance of not only the opioid epidemic and its effect on healthcare practice, but the effect on the opioid epidemic on this population.
This DNP capstone project aims to elucidate the use of an opioid-sparing technique in obstetrical anesthesia.
Specifically, this project intends to propose a practice change whereby Intrathecal Dexmedetomidine becomes accepted as a neuraxial adjunct for spinal anesthesia for cesarean delivery.
Current data unequivocally demonstrates that Intrathecal Dexmedetomidine can provide adequate neuraxial blockade and analgesia for cesarean section while sparing opioid usage.
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CONCLUSION
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IN SUMMARY
- Dexmedetomidine is a potent analgesic and its role in regional anesthesia and pain management has grown in recent years.
- When administered intrathecally, Dexmedetomidine improves the quality of neuraxial blockade.
- Intrathecal Dexmedetomidine is an effective non-opioid adjuvant that has a promising future in the field of obstetric anesthesia.
- The evidence presented in this evidence-based capstone project demonstrates that Dexmedetomidine is effective, safe, and lacks the negative side effects of opioids.
- In summary, Dexmedetomidine provides adense sensory and motor block for cesarean section, in addition to satisfactory perioperative analgesia, as measured by patients' perception of pain.

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ACKNOWLEDGMENTS
A special thank you to the Florida International University Department of Nurse Anesthesiology faculty, the providers at Miami Beach Anesthesiology Associates who participated in the study, and the authors of the source material used for this project
- all of whom made this doctoral capstone project possible.

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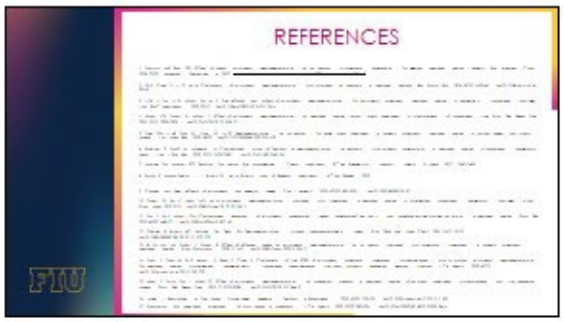
REFERENCES
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