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A Retrospective Study on the Use of Rescue Pain Medication in Patients Who Receive Transabdominal Plane Blocks Post Caesarean Sections

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Abstract

Background and Review of Literature: Caesarean sections are one of the most performed procedures in the operating room. Managing pain for these patients is vital to ensure a positive birthing experience for mothers and facilitating bonding post-surgery. Regional anesthesia, specifically transabdominal plane (TAP) blocks, have shown to improve pain perception and reduce the need for opioid pain medications.

Purpose: This DNP project was designed to validate that performing TAP blocks on patients who have a caesarean section reduce the need for rescue pain medications. Reducing the need for these medications negates the side effects they have and promotes a positive birthing experience.

Methods: This DNP project will be retrospective chart review on patients who required a caesarean section and the use of rescue opioid medications. Charts will be reviewed in a 4-week period in the Spring of 2023 at a Midwest community hospital.

Implementation Plan/Procedure: Charts reviewed will be divided into two groups who received a caesarean section. Group 1 will be those who did not receive a TAP block. Group 2 will be those who did receive a TAP block. Both groups' charts will be reviewed for use of rescue medications and compared to one another using a Chi-Square Test.

Implications/Conclusions: This study concluded that there was no statistical reduction in the use of rescue opioid pain medications in the 24 hours following a caesarean section when a TAP block was performed.

Keywords: TAP BLOCK, OPIOID USE, CAESAREAN SECTION

A Retrospective Study on the Use of Rescue Pain Medication in Patients Who Receive Transabdominal Plane Blocks Post Caesarean Sections

This project was submitted to the faculty of Marian University Leighton School of Nursing as a partial fulfillment of degree requirements for the Doctor of Nursing Practice, Certified Registered Nurse Anesthetist track. The development of anesthetic procedures, specifically regional anesthesia, has grown vastly in the last 20 years. With advances in technology related to ultrasound, medication preparation, and techniques used, regional anesthesia has become much safer and easier to perform. However, many providers choose not to perform regional adjuncts to their anesthetics due to a multitude of reasons including time constraints, lack of knowledge, misleading information, and many others. Regional anesthesia has a place in many areas of surgical populations, to help minimize and/or negate opioid use for post operative pain. Obstetrics is one population where the utilization of regional anesthesia is lacking, specifically in women undergoing caesarean sections.

Cesarean sections represented eight percent of all operating room procedures and were the most frequent operating room procedure in 2018 (McDermott & Liang, 2021). On top of this statistic, cesarean deliveries account for 32% of all births in the North America, which equilibrates to 1.2 million deliveries via cesarean per year (Betran et al, 2016). Implementing regional block into a protocol into this population could affect millions via reduced use of rescue pain medications (roxycodone) and benefit patient satisfaction levels in a hospital system.

Background

A commonly provided anesthetic for a patient undergoing a cesarean section includes spinal anesthesia. As of 2017, more than 60% of women in the US receive some type of neuraxial procedure during their labor (Meng & Smiley, 2017). For cesarean sections

specifically, a spinal needle is inserted into the subarachnoid space, and after confirming placement with positive cerebral spinal fluid flow through the needle, a provider's preferential mixture of local anesthetics, opioids, and other medications are injected. This solution can provide adequate pain relief for the procedure while allowing the mother to be conscious during the birth. The benefit of a spinal anesthetic, depending on the local anesthetic and addition of other medications, is it has a low duration of action. The drawback is the same as the benefit, the spinal anesthesia duration of action is quick and provides comfort during the procedure, but once it wears off the mother will experience pain if no other intervention is made.

There are many ways of treating post operative pain for this population. In the clinical setting, it is not uncommon for post partem women who have had a caesarean section to not receive regional anesthesia. However, it is not best practice for them to receive a regional anesthetic block either. For this population, the regional anesthesia provided to the patients is called a transabdominal plane block, otherwise known as a "TAP" block. This type of block is performed via bilateral injections of local anesthetic into the facial plane between the internal oblique muscle and the transversus abdominis muscle. This areas skin and muscle nerve supply is through spinal nerves which originated for the T6 to L2 spinal levels (Meng & Smiley, 2017). It is important to note that this type of anesthetic does not provide visceral coverage. The benefits of local anesthetic include providing pain relief with minimal side effects. While opioids can treat post operative cesarean pain, they also cause pruritus (itching), drowsiness, constipation, nausea/vomiting, and respiratory depression (Sadiq et. al., 2022). These side effects can decrease the patient's satisfaction with their hospital stay and reduce the quality of bonding time with their new child.

A study that occurred in Oslo University Hospital in Norway concluded that at the 24-hour mark post caesarean section, incidence of a pain score of ≥4 was 68% of the included participant (Bjørnstad & Ræder, 2020). In this same study, the median dose of oxycodone for 56% of the participants was 40 milligrams within that same 24 hour period (Bjornstad & Raeder, 2020). The National Institute of Health suggests dosing oxycodone five to fifteen milligrams every four to six hours meaning while 40 milligrams is within the dosing guidelines, it is still at the higher end (Sadiq et. al., 2022).

There is little information that can validate the implementation of TAP blocks into best practice methods for post operative caesarean section pain. While traditionally, a pain score is used to gage the pain level one is in, this can be subjective based on the healthcare professional asking, and each patient's response can vary widely. Therefore, the use of rescue medication to judge pain level is used as a common variable to access the adequacy of pain relief after the TAP block in comparison to those who do not receive the block.

Problem Statement

This project sought to validate that regional anesthesia, specifically the TAP block, in the obstetric population who underwent caesarean sections reduced the use of rescue pain medications in the 24-hour period after the procedure. This retrospective review of patients took place at a community hospital in the Midwest region of the United States and was conducted during a four-week period in the Spring of 2023. Standard practice was a TAP block is suggested on an as needed basis per patient undergoing a caesarean section, however, there is not much to support it is validity to patients from the anesthesia provider. Furthermore, this data could be used to implement the use of TAP blocks at other facilities. Data gathered from this project will support the confidence of patients in anesthesia providers who perform the TAP blocks.

Implementation of this data during consent to the block will allow patients to make a more informed decision regarding the choice of receiving the TAP block.

Needs Assessment & Gap Analysis

Beacon Memorial hospital delivers more babies than any other hospital in the Beacon Hospital System at an average of 400 babies per year (Beacon, 2022). That is an average of one to two babies delivered per day. Current practice at the site is to utilize TAP blocks on an as needed basis for every caesarean section performed, however there is little evidence that can be provided to patients to support the use of them. Utilizing data collected through a retrospective review at Beacon Memorial Hospital, this project will be able to validate the use of TAP blocks with factual statistics for patients considering the procedure to assist with post-operative pain.

Review of Literature

A review of literature was performed to address the population, intervention, comparison, and outcomes (PICO) question of, "This project seeks to validate if regional anesthesia, specifically the TAP block, in the obstetric population who undergo caesarean sections reduces the use of rescue pain medications in comparison with spinal anesthesia alone in the 24-hour period after the procedure". Databases including CINAHL, PubMed, Medline – Ebsco were used for article collection. Search criteria for the review of literature included phrases and the following keywords in combination: *TAP block, transabdominal plane, cesarean, cesarean section, post.* Search criteria included articles published within the last five years, availability of the article in the English language, human subject involvement, and full texts. For the article to be included in the review of literature, the article must demonstrate the use of regional anesthesia, specifically TAP block or a variation, and rating of pain after cesarean section. Articles that did not meet these described criteria were omitted for the review of literature.

This search elicited 29 articles related to the PICO question, of which 14 were duplicates. 15 articles were reviewed, and five articles were omitted for no relevance to the PICO question. Refer to Appendix A for the full literature review matrix.

TAP Blocks with Spinal Anesthesia

TAP blocks have been associated as an adjunct to spinal anesthesia and in many cases with a shown reduction in postoperative caesarean section rescue opioid pain medication requirement (Habib et al, 2021; Jadon et al., 2018; Nedeljkovic et al., 2020; Staker et al., 2018). With the use of TAP blocks in conjuncture with spinal anesthesia has added benefits of reduced pruritus, more favorable safety profile, and better overall pain relief on post operative day one (Aga et al., 2021; Habib et al, 2021; Nedeljkovic et al., 2020). The use of TAP blocks has been shown a 59% reduction in the use of rescue pain medication in the first 24 hours in one study in comparison with spinal anesthesia alone (Staker et al., 2018). With the majority of studies showing a reduction in rescue pain medication, Yu et al. (2021) and Borys et al. (2019) observed little benefit of TAP blocks when compared to a multimodal oral analgesic regimen. Another study showed the use of intrathecal morphine in a spinal in comparison with a spinal with local anesthetic and TAP blocks were clinically similar with pain relief in the post operative period (Kwikiriza et al., 2019).

Anesthesia without TAP Blocks

Spinal anesthesia solely is associated with increase postoperative opioid use in those patients undergoing caesarean sections (Nedeljkovic et al., 2020). Nedeljkovic et al. (2020) observed that those who did not receive TAP blocks required 51.6% more opioids in the 72 hours post caesarean sections. In one study involved the use of epidural for post operative pain management, it was shown that that epidural group required less opioids in the 24 hour post

operative period than those who received a spinal anesthetic with TAP blocks (Canakci et al., 2018).

Theorical Framework

The Symptom Management Theory (SMT) helps organize relevant concepts for research and practice in the form of a nursing framework (Bender et. al., 2018). The SMT is used to eliminate or minimize the extent of an issue or problem in health whether it be physical, mental, or social functioning. There are three components to SMT that include symptom experience, symptom management strategies, and outcomes (Bender et. al., 2018).

The change that is being made in the illness or symptom is the most important part of the theory. Symptom experience is how the patient conceptualizes their understanding of their symptoms. This experience is measured from their baseline normal to the introduction of the new stimulus, which in this project would be their pain following a caesarean section (Bender et. al., 2018). Symptom management strategies includes any intervention made to alter one's perception to the stimulus, delay its onset, or negate the symptom experiences entirely. In the case of this project, it would be the implementation of the transabdominal plane (TAP) block to intervene to prevent and/or minimize the symptom experience for the patient. The last component to this theorical framework is the outcome. Symptom outcomes should be clear and measurable (Bender et. al., 2018). This project will compare the symptom experience between two groups, both having a caesarean section, with one group having the intervention of symptom management strategy of receiving a TAP blocks. The outcome will assess the differences in pain perception within the first 24 hours post procedure, and the amount of rescue pain medication needed.

Project Aims, Objectives, and Expected Outcomes

The purpose for this project was to validate that TAP blocks performed on post cesarean section patients reduces the need for rescue pain medication within the first 24 hours. This data could be used at other locations to implement a post cesarean section protocol to help with post operative pain without the use of additional narcotics.

The main objective for how this project was to achieve the aim through the data collected by anesthesia personal at Beacon Memorial Hospital. Data collected includes use of rescue pain medication, pain level, overall experience, and if the patient has issue with mobilization. The primary variable that was used was the use of rescue pain medication for those who received TAP blocks in comparison to those who did not receive one. The efficacy of TAP blocks was determined through this data and used to either prove or disprove the use of them in this patient population.

Project Design and Methods

The idea behind this scholarly project was to validate that TAP blocks for caesarean sections reduce the use to opioids in the parturient population. This validation will allow providers to have credible data to support the use of TAP blocks when presenting the anesthetic plan to the patients. The project has identified two groups, TAP block recipients and those who opt out and compare the need for rescue pain medication in the 24-hour period after a caesarean section.

Project Site and Population

The location for this retrospective review is an obstetric and neonatal level 3 perinatal hospital with an average of 400 births per year (Beacon, 2022). The hospital is a public facility in the Midwest region of the United States. The community is made up of multiple ethnicities and has a wide range of socioeconomic patients.

The population for this project is women who have received a scheduled caesarean section from March 1, 2023, to March 31, 2022. The exclusion criteria for this project are emergent situations, and those who are unable to provide consent for the procedure.

Measurement Instruments

For this retrospective study, a tool has been developed to summarize the data into quantitative data. This tool can be referred to in Appendix B. The tool summarizes the data collected from patients. The quantitative data that will be complied into the spread sheet includes the following parameters: did the patient receive a TAP block in addition to spinal anesthesia, and did the patient require additional rescue medication in the first 24 post operatively.

This tool has been developed to compare the two groups of those who did receive TAP blocks and those who did not. The parameter of if the patient required rescue pain medication was used to objectively view the efficacy of the TAP blocks and if they reduce opioid consumption post operatively.

Data Collection Procedures

Upon approval from Beacon Health's Institutional Review Board (IRB), this project divided the participants into two groups: those who received TAP blocks with spinal anesthesia and those who solely received spinal anesthesia for caesarean section. The data was collected for both groups of those who required rescue pain medication in the first 24 hour post caesarean section. Using this objective data to evaluate pain, the project either invalidate or validate whether TAP blocks reduce the number of opioids needed. This data will in turn be used to help providers explaining their anesthetic plan to patients in the future.

Ethical Considerations

Internal Review Board (IRB) approval was obtained prior to initiating this DNP project. The project notified both Marian University's IRB of the project, and Beacon Health's IRB and received exemption status from both, see Appendix C. No personal data was collected for the project. There will be no demographics, or identifiable traits that would identify any participants. All information acquired for this project was stored on an encrypted password protected computer that only the facilitator of the project had access too. An addition, a password was added to the Microsoft Excel file. Information will be stored for two years after completion of this project, and then destroyed.

Results

Participants

A total of 40 patients electronic medical records (EMR) were reviewed and used in this study. 20 patients were placed in and met requirements for the control group, while the remaining 20 were placed into the experimental group. The experimental group were those who received a spinal anesthetic without narcotic and the addition of a TAP block for post operative pain. The TAP block consisted of a total of 60 mL of 0.5 percent bupivacaine, spilt equally bilaterally. Both groups EMR were reviewed 24 hours post operatively to evaluate use of opioid pain medication.

Post Operative Rescue Medication Use

To determine if TAP blocks are effective in reducing the consumption of post operative rescue pain medication, the experimental group was compared to the control group. A Chi-Square Test was utilized to evaluate if there was a statistical difference between the groups. It was concluded that there was not a statistical difference in the reduction of opioid rescue pain medication 24 hours post operatively for those who received a TAP block. The Chi-Square Test

of Independence established a P value of 0.1138462, meaning there was a lack of statistical significance between the two groups.

Discussion

This DNP project sought to find if the addition of a TAP block would reduce the use of rescue pain medication in the 24 hour period post operatively after a caesarean section. The project consisted of two groups, an experimental group who received a TAP block in place of added narcotic to the spinal anesthetic. The control group solely received a spinal anesthetic with narcotics. The study concluded that there was not a statistical difference between the two groups, implying that TAP blocks do not reduce the need for rescue opioid pain medications in the 24 hours after a caesarean section.

The results of the study did not correlate with previous studies such as Jadon et al. (2018). This study showed a reduction in the use of opioids post operatively. The limitation of these studies were the omission of if the patients were on any kind of multimodal pain regiments. A limitation of this study was the sample size. If this study could be repeated at an institution where TAP blocks were used in higher volume, it would be interesting to see the correlation with the addition of them. Another limitation of the study was the retrospective review of charts. The investigator had to rely on other providers charting and there was a question of standardization between providers. A prospective study with an increased sample size would be ideal with more precise regulations over the experimental group.

Conclusion

In conclusion, this study found that there was no additional benefit with the addition of TAP blocks in conjunction with spinal anesthesia in reducing the need for rescue pain medication in the following 24 hours after a caesarean section. Additional studies are needed to

evaluate the effectiveness of TAP blocks and their place in the obstetric population with regards to improving the birthing experience.

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Appendix A

Literature Review Matrix

Citation	**Research Design & Level of Evidence**	**Population / Sample size n=x**	**Major Variables**	**Instruments / Data collection**	**Results**
Aga, A., Abrar, M., Ashebir, Z., Seifu, A., Zewdu, D., & Teshome, D. (2021). The use of perineural dexamethasone and transverse abdominal plane block for postoperative analgesia in cesarean section operations under spinal anesthesia: an observational study. *BMC anesthesiology*, *21*(1), 292. https://doi.org/10.1186/s12871-021-01513-4	Prospective	Patients undergoing elective cesarean section with spinal anesthesia. Sample size = 58	TAP blocks with dexamethasone and bupivacaine and TAP blocks with bupivacaine	The primary outcomes are the period for the first request of postoperative pain relief medication and the numerical rating scale (NRS) pain intensity scores at 2, 6, 12, and 24 h after surgery. The secondary outcomes are comparing the 24-h tramadol and diclofenac analgesic requirements and the incidences of side effects on postoperative day one	An additive agent of perineural dexamethasone at a dose of 8 mg during bilateral TAP block for elective CS operation under spinal anesthesia provided better pain relief on postoperative day 1.
Borys, M., Potręć-Studzińska, B., Wiech, M., Piwowarczyk, P., Sysiak-Sławecka, J., Rypulak, E., Gęca, T., Kwaśniewska, A., & Czuczwar, M. (2019). Transversus abdominis plane block and quadratus lumborum block did not reduce the incidence or severity of chronic postsurgical pain following cesarean section: a prospective, observational study. *Anaesthesiology intensive therapy*, *51*(4), 257–261. https://doi.org/10.5114/ait.2019.88071	Prospective, observational study	Women with singleton pregnancies above 18 years old, greater than 36 weeks, and undergoing cesarean section under spinal. Sample size = 233	TAP block, quadratus lumborum block	The patients received either TAP block or QLB as the primary analgesia technique following cesarean section. The control group consisted of patients without any postsurgical plane block. The incidence and characteristics of chronic pain were evaluated using the Neuropathic Pain	Chronic postsurgical pain is highly prevalent following cesarean section. The studied plane blocks did not reduce the incidence or severity of CPSP after cesarean section when compared to the standard analgesic regimen.

				Symptom Inventory at the first, third, and sixth months after surgery.	
Canakci, E., Gultekin, A., Cebeci, Z., Hanedan, B., & Kilinc, A. (2018). The Analgesic Efficacy of Transverse Abdominis Plane Block versus Epidural Block after Caesarean Delivery: Which One Is Effective? TAP Block? Epidural Block?. *Pain research & management*. https://doi.org/10.1155/2018/3562701	Randomized Control	Patients in the ASA I-II risk group, undergone an elective C-section, were randomly assigned to the study. Sample Size = 80	Epidural group and TAP block with spinal group	The amount (mg) of total analgesics received by the patients in the first 24 hours of the postoperative period	The epidural anesthesia is still the golden standard to achieve a post caesarean analgesia. Epidural anesthesia is a considerably effective method in controlling the postoperative pain.
Habib, A. S., Nedeljkovic, S. S., Horn, J. L., Smiley, R. M., Kett, A. G., Vallejo, M. C., Song, J., Scranton, R., & Bao, X. (2021). Randomized trial of transversus abdominis plane block with liposomal bupivacaine after cesarean delivery with or without intrathecal morphine. *Journal of clinical anesthesia*, *75*, 110527. https://doi.org/10.1016/j.jclinane.2021.110527	Randomized Control	Women with term pregnancy of 37 to 42 weeks scheduled for elective CD under spinal anesthesia. Sample Size = 153	Tap block with liposomal bupivacaine, intrathecal morphine, and tap block plus intrathecal morphine	The LB and LB + ITM groups were compared with the ITM group for all efficacy outcomes. Postsurgical opioid consumption in morphine milligram equivalents through 72 h was compared by assessing noninferiority before testing superiority. Postsurgical pruritus severity was assessed on an 11-point numerical rating scale.	LB TAP block with or without ITM resulted in statistically noninferior postsurgical opioid consumption through 72 h, reduced pruritus, and favorable safety compared with ITM in women undergoing CD.
Jadon, A., Jain, P., Chakraborty, S., Motaka, M., Parida, S. S., Sinha, N., Agrawal, A., & Pati, A. K. (2018). Role of ultrasound guided transversus abdominis plane block as a component of multimodal analgesic regimen for lower segment caesarean section: a randomized double blind clinical study. *BMC anesthesiology*, *18*(1), 53. https://doi.org/10.1186/s12871-018-0512-x	Randomized double blind clinical study	Patients undergoing caesarean delivery. Sample size = 139	TAP block with 0.375% ropivacaine group, TAP block with 20 ml saline	All the subjects received a standard spinal anesthetic and diclofenac was administered for post-operative pain. Breakthrough pain was treated with tramadol. Post-operatively, all the subjects were assessed at 0, 2, 4, 6, 8, 10, 12,	TAP block reduces pain, prolongs the duration of analgesia and decreases supplemental opioid consumption when used for multimodal analgesia for pain relief after caesarean section

				18 & 24 h. The primary outcome was the time to first analgesic request	
Kwikiriza, A., Kiwanuka, J. K., Firth, P. G., Hoeft, M. A., Modest, V. E., & Ttendo, S. S. (2019). The analgesic effects of intrathecal morphine in comparison with ultrasound-guided transversus abdominis plane block after caesarean section: a randomized controlled trial at a Ugandan regional referral hospital. *Anaesthesia*, *74*(2), 167–173. https://doi.org/10.1111/anae.14467	Prospective, Randomized controlled trial	Women were eligible for enrolment if they fulfilled the following inclusion criteria: between the ages of 15 and 49; receiving spinal anesthetic without sedation for an uncomplicated caesarean delivery via a low, transverse abdominal incision (Pfannenstiel); in good health, with no major medical problems (ASA status 2); and able give informed consent. Sample size = 130	Intrathecal Morphine group, TAP block group	The subjects were reviewed at 8 h, 16 h and 24 h following the placement of intrathecal morphine or TAP block by a research assistant, a qualified midwife trained in data collection.	The study found that intrathecal morphine and TAP block provided clinically similar outcomes for pain relief after caesarean section
Nedeljkovic, S. S., Kett, A., Vallejo, M. C., Horn, J. L., Carvalho, B., Bao, X., Cole, N. M., Renfro, L., Gadsden, J. C., Song, J., Yang, J., & Habib, A. S. (2020). Transversus Abdominis Plane Block	Randomized, Double-blind,	Women with term pregnancies undergoing	Tap block with liposomal bupivacaine plus	The primary end point was total postsurgical opioid consumption through 72 hours. Pain	TAP block using LB plus bupivacaine HCl as part of a multimodal analgesia protocol incorporating

With Liposomal Bupivacaine for Pain After Cesarean Delivery in a Multicenter, Randomized, Double-Blind, Controlled Trial. *Anesthesia and analgesia*, *131*(6), 1830–1839. https://doi.org/10.1213/ANE.0000000000005075	controlled trial	elective cesarean delivery under spinal anesthesia Sample Size = 186	bupivacaine HCI, and tap block with bupivacaine HCI alone	intensity was measured using a visual analog scale	intrathecal morphine resulted in reduced opioid consumption after cesarean delivery
Staker, J. J., Liu, D., Church, R., Carlson, D. J., Panahkhahi, M., Lim, A., & LeCong, T. (2018). A triple-blind, placebo-controlled randomized trial of the ilioinguinal-transversus abdominis plane (I-TAP) nerve block for elective caesarean section. *Anaesthesia*, *73*(5), 594–602. https://doi.org/10.1111/anae.14222	Triple blind, controlled randomized trial	We recruited women ≥ 18 years and ≥ 65 kg who were scheduled for elective caesarean section with spinal anesthesia between February and July 2016. Sample size = 100	I-TAP group, control group	The primary outcome was total fentanyl consumption at 24 h.	This trial demonstrated that the addition of the I-TAP block to a multi-modal analgesic regimen resulted in a 59% reduction in total PCA fentanyl dose over the first 24 h after elective caesarean section
Yu, Y., Gao, S., Yuen, V. M., Choi, S. W., & Xu, X. (2021). The analgesic efficacy of ultrasound-guided transversus abdominis plane (TAP) block combined with oral multimodal analgesia in comparison with oral multimodal analgesia after caesarean delivery: a randomized controlled trial. *BMC anesthesiology*, *21*(1), 7. https://doi.org/10.1186/s12871-020-01223-3	Randomized Control Trail	Parturient who were scheduled for elective caesarean delivery under spinal anesthesia Sample Size = 159	Placebo vs TAP block group	All the parturient were evaluated for pain or related complications in the first 24 h after surgery. The primary outcome is the percentage of parturient who required oxycodone as a rescue analgesia.	Bilateral single-shot of TAP blocks confer little additional benefit when a multimodal oral analgesic regimen is used for pain control after caesarean section under spinal anesthesia.

Appendix B

Data Collection Tool

Patient	Type of Anesthesia	Received TAP Block?	Required Rescue Pain Medication within 24 hours?
Patient A	General	Yes	No
Patient B	Spinal	Yes	No
Patient C	Spinal	No	Yes
Patient D	Spinal	Yes	No

Appendix C

IRB Approval

MARIAN UNIVERSITY
Indianapolis

Institutional Review Board

DATE:	05-02-2023
TO:	Nicholas Ramey & Dr. Derrianne Monteiro
FROM:	Institutional Review Board
RE:	S23.165
TITLE:	A Retrospective Study on the Use of Rescue Pain Medication in Patients Who Receive Transabdominal Plane Blocks Post Caesarean Sections
SUBMISSION TYPE:	New Project
ACTION:	Determination of EXEMPT Status
DECISION DATE:	05-02-2023

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

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

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

Amanda C. Egan, Ph.D.
Chair, Marian University Institutional Review Board

BEACON HEALTH SYSTEM

Institutional Review Board
600 East Boulevard Elkhart, Indiana 46514
FWA 00029724 IORG 0005215 IRB 00003842

April 14, 2023

Nicholas Ramey
6045 Winthrop Ave
Indianapolis, IN 46220
Nramey936@marian.edu

RE: A Retrospective Study on the Use of Rescue Pain Medication in Patients Who Receive Transabdominal Pain Blocks Post Caesarean section

Dear Nicholas,

The following documents were received:

- Application – Research Review
- Project Protocol
- CV – Investigator – Nicholas Ramey
- Human Research Protections Training – Nicholas Ramey
- Conflict of Interest Disclosure Attestation

I have reviewed the protocol entitled: **A Retrospective Study on the Use of Rescue Pain Medication in Patients Who Receive Transabdominal Pain Blocks Post Caesarean section**

This protocol involves the retrospective chart review of female patients, greater than or equal to 18 years of age, who have undergone caesarean section. The incidence of rescue pain medication received will be compared between patients who received a transabdominal plane block (TAP block) and those who did not. There will be no patient identifiers used during data collection. The data collected will be recorded in such a manner that the identity of the human subjects cannot be readily ascertained.

This research qualifies for exemption from IRB review.
Category 4
Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable bio specimens, if at least one of the following criteria is met:

- The identifiable private information or identifiable bio specimens are publicly available;
- **Information, which may include information about bio specimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects**

This protocol presents no more than minimal risk to the research participants. The data collected will be kept in a secure location with adequate protections for privacy and confidentiality.

This protocol complies with 45 CFR 46 subpart B – additional protections for pregnant women, human fetuses, and neonates.

If the study scope, data collection or review process change, a protocol amendment must be submitted to the IRB for review.

Under HIPAA regulations, only the necessary information required to complete the research project should be accessed in the EMR. **Beacon Heath Information Management department may require an account disclosure be filed for medical records access. If you are accessing the patient's electronic medical record, you should contact Celeste Michelle Holden (574) 523-3320 for directions on how to accomplish this.**

The Beacon Human Research Protections Office is interested in seeing the final fruits of your hard work. Please email completed manuscript or publication resulting from this research to irbbeacon@beaconhealthsystem.org.

The Beacon Institutional Review Board complies with the FDA and OHRP requirements for IRBs.

If you have any questions please call me at 574-523-3437 or Betty McKinney at 574-296-6505.

Respectfully yours,

Darra Savick, Pharm.D., R.Ph.
Chairperson
Institutional Review Board

DNP FINAL RAMEY

Final Audit Report 2023-05-08

Created:	2023-05-08
By:	Nicholas Ramey (nickoramey@gmail.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAmWzKeTMTqBC3CQghudWO90jcF0e2y3Ym

"DNP FINAL RAMEY" History

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Signer dmonteiro@marian.edu entered name at signing as Dr. Derrianne Monteiro
2023-05-08 - 8:26:38 PM GMT

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