Research Paper

Investigating Patients' Satisfaction With Patient-controlled Analgesia Versus Intrathecal Opioid Injection After Cesarean Section

Abbas Moallemy[1], Farnoosh Frahini Esfahany[1], Fereydoon Fekrat[1], Alireza Abdollazadeh Baghaei[1,2 *]

1. Anesthesiology, Critical Care and Pain Management Research Center, Hormozgan University of Medical Sciences, Bandar Abbas, Iran.
2. Shahid Mohammadi Hospital, Payambar Azam Training and Medical Center, Hormozgan University of Medical Sciences, Bandar Abbas, Iran.

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Citation Moallemy A, Frahini Esfahany F, Fekrat F, Abdollazadeh Baghaei A. Investigating Patients' Satisfaction With Patient-controlled Analgesia Versus Intrathecal Opioid Injection After Cesarean Section. Hormozgan Medical Journal. 2024; 28(1):49-54. http://dx.doi.org/10.32598/hmj.28.1.10

http://dx.doi.org/10.32598/hmj.28.1.10

Article info:
Received: 06 Nov 2023
Accepted: 22 Dec 2023
Available Online: 01 Jan 2024

Keywords:
Cesarean section, Patient-controlled analgesia, Intrathecal injection

ABSTRACT

Background: This study compares patients' satisfaction with patient-controlled analgesia versus intrathecal opioid injection after cesarean section in Shariati and Khalij Fars hospitals in Bandar Abbas City, Iran, from 2016 to 2017.

Methods: This double-blind, randomized clinical trial included 60 women with term pregnancies scheduled for elective cesarean section in Shariati and Khalij Fars hospitals in Bandar Abbas City, Iran, from 2017 to 2018. The patients were randomized into two groups: One group received patient-controlled analgesia (PCA), and the other group received intrathecal opioid injection. A numerical rating scale was used to assess pain and patient satisfaction. The patients also reported nausea, vomiting, and pruritus. The data were analyzed using the SPSS software, version 25.

Results: Nausea and or vomiting did not differ significantly between the groups (P=0.46). The highest frequency of pruritus was observed in the PCA group at 1 (P=0.44), 4 (P=1.00), and 24 (P=0.24) h after surgery. Patient satisfaction was higher in the intrathecal opioid group (9.23±1.22) compared to the PCA group (8.84±1.22); however, the difference between groups was not statistically significant (P=0.08).

Discussion: The results of the current study showed that despite the novelty of PCA, this method is not superior to conventional methods such as intrathecal opioid injection for pain relief. Also, patient satisfaction was lower with PCA compared to intrathecal opioids.

*** Corresponding Author:**
Alireza Abdollazadeh Baghaei, Assistant Professor.
Address: *Anesthesiology, Critical Care and Pain Management Research Center, Hormozgan University of Medical Sciences, Bandar Abbas, Iran.*
Tel: *+98 (912) 4958623*
E-mail: *Bagha_ar@yahoo.com*

[DOI: 10.32598/hmj.28.1.10]

Introduction

Cesarean section (C-section) is one of the most common significant surgeries worldwide [1]. Similar to any other surgery, pain is a common complaint of patients after a C-section, which results from tissue injury. The method of choice for anesthesia in C-sections is based on the emergency of the surgery and the patient's preference. General anesthesia is preferred when fetal distress leads to emergency C-sections because this way, anesthesia is rapidly induced, and there is a lower probability of hypotension. Neuraxial analgesia is chosen in case of elective C-section and when the mother is aware and awake. In addition, neuraxial analgesia reduces maternal pulmonary aspiration; therefore, the anesthesiologist should select a method that is the safest and most convenient for the mother while having the lowest fetal depression. Treatment methods for post-operative pain include systemic analgesia using opioids and non-opioids and regional analgesia [2].

Various analgesics are injected (muscular/subcutaneous) to alleviate pain after a C-section, among which opioids, such as pethidine, morphine, and methadone, are the most common. However, this method has been associated with complications, including respiratory depression, nausea, vomiting, dizziness, and fatigue. Recently, this method has gained widespread acceptance because it allows patients to control their pain. Patient-controlled analgesia (PCA) has the following parameters: 1) The bolus dose, 2) Lock-out interval, and 3) continuous injection. Multiple studies have been conducted to compare the efficacy of the methods above [3].

Another strategy to reduce post-operative pain is the intrathecal or epidural injection of opioids. This method has been used in other countries for four decades. Medications used in this strategy include fentanyl, sufentanil, alfentanil, morphine, diamorphine, hydromorphine, meperidine, and methadone [4].

Due to the inconsistent results of the previous studies in terms of pain control and complications of PCA and intrathecal opioid injection and given that PCA is a new method of pain control while having limited use because of its high cost, this study compares the two methods after C-section regarding maternal satisfaction and analgesia onset and duration to reach the superior approach.

Materials and Methods

Participants and study design

This double-blind, randomized clinical trial was conducted from 2017 to 2018 in Shariati and Khalij Fars hospitals in Bandar Abbas City, Iran. The patient and the anesthesiology resident responsible for data collection were blinded to the groupings. The target population was all pregnant women undergoing elective C-sections in these hospitals.

The sample size was calculated as 60 based on the formula for comparing means in two groups. The inclusion criterion was informed consent to participate in the study. Patients with insufficient block levels or the use of other anesthetics were excluded from the study.

After placing the patient on the operation table and initiating standard monitoring, such as non-invasive blood pressure cuff, electrocardiography, and pulse oximetry, baseline hemodynamic parameters, including systolic and diastolic blood pressure, mean arterial pressure, heart rate, and oxygen saturation, were measured and recorded. All patients received 10 mL/kg of the Ringer's solution. Then, in the sitting position and under aseptic conditions, spinal anesthesia was induced by an expert anesthesiologist with a disposable 25-gauge Quincke needle using the midline method at the L3-L4 or L4-L5 level. After visualizing the cerebrospinal fluid, 12 mg bupivacaine 0.5% was prepared in a 3-mL solution and used as a local anesthetic under sterile conditions. This solution contained 20 mg of pethidine in the first group and no other drug but normal saline in the second group. The patient was kept in a 15-degree left lateral tilt until reaching a T4-T6 block level. The pinprick test evaluated the block level within 5 min of the injection. In case of decreased systolic blood pressure <90 mm Hg during anesthesia, it was treated with 5 mg ephedrine. At the end of the operation, when the block level reached C10, a PCA pump containing morphine at 1 mg/h was set up in the recovery only for the second group.

Before surgery, the study was explained to the selected patients, and they were asked to assess their pain using a numerical rating scale (NRS) and report nausea and or vomiting at regular intervals. Also, the patients were reminded that, if desired, they could discontinue their participation at any time. The NRS ranges from 0 to 10, with 0 indicating no pain and 10 indicating the worst pain. Accordingly, higher scores indicated worse pain. Patient satisfaction was also based on their pain using NRS, with 0 showing no satisfaction with pain control,

[DOI: 10.32598/hmj.28.1.10]

4 and 5 poor satisfaction, 6 and 7 moderate satisfaction, and 8, 9, and 10 complete satisfaction [5]. The patients received a diclofenac suppository in case of pain >3.

After awakening in the recovery and then at 1, 4, and 24 h in the ward, all patients were evaluated in terms of satisfaction, pain, vital signs, and potential drug side effects, including pruritus, nausea, vomiting, and respiratory depression (respiratory rate <10/min) by the anesthesiology resident who was blinded to the grouping of the patients.

Data analysis

We used the SPSS software, version 25 (Armonk, NY: IBM Corp., USA) for data analysis. The Fisher exact test was used to compare the frequency of complications (nausea, vomiting, pruritus, pain score, and additional analgesic requirement). In addition, the Mann-Whitney and chi-squared tests were utilized to compare patient satisfaction, and the independent t-test to compare means between groups. Meanwhile, P<0.05 were considered statistically significant.

Results

The demographic and anthropometric features of the pregnant women aged 18-46 years evaluated in this study are demonstrated in Table 1. The mean age of the participants was 28.24±7.44 years in the intrathecal opioid group and 25.33±3.14 years in the PCA pump group, and there was no statistically significant difference regarding age between the two groups (P=0.10). The participants' mean weight was 70.83±9.88 kg in the intrathecal group and 69.03±7.37 kg in the PCA group, with no statistically significant difference (P=0.19). The mean height was 155.76±7.92 cm in the intrathecal opioid group, significantly lower than 164.43±4.50 cm in the PCA group (P<0.001). The mean body mass index (BMI) was significantly higher in the intrathecal opioid group compared to the PCA group (P<0.001). The significant effect of height and BMI as confounders has been controlled in the following analyses.

Nausea and or vomiting are significant post-operative complications, especially after C-section. According to Table 2, these complications occurred in none of the patients from the PCA pump group. Also, no significant difference was observed between groups at 1 h (P=0.10), 4 h (P=0.69), and 24 h (P=0.46) after surgery. Over 24 h, the Friedman test showed no significant difference in the intrathecal opioid (P=1.00) and PCA pump (P=0.36) groups.

Based on Table 3, the highest frequency of pruritus was observed in the PCA pump group, which was not significantly different from the intrathecal group at 1 h (P=0.44), 4 h (P=1.00), and 24 h (P=0.24) after surgery. Over time, pruritus decreased significantly in the intrathecal opioid (P=0.002) and PCA (P<0.001) groups.

The patient satisfaction results showed that the mean score was 9.23±1.22 in the intrathecal opioid group, which was non-significantly higher than 8.84±1.22 in the PCA group (P=0.08) (Table 4 and Figure 1).

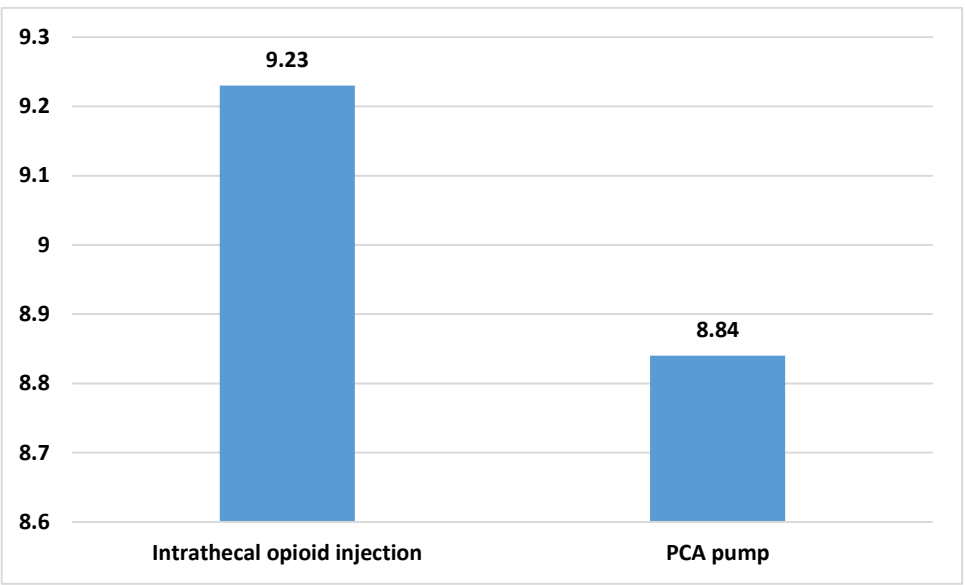

Figure 1. The mean patient satisfaction scores in the two study groups

[DOI: 10.32598/hmj.28.1.10]

Table 1. Comparison of demographic and anthropometric features between groups

Variables	Mean±SD		P*
	Intrathecal Opioid	PCA Pump	
Age (y)	28.24±7.44	25.33±3.14	0.10
Weight (kg)	70.83±9.88	69.03±7.37	0.19
Height (cm)	155.76±7.92	164.43±4.50	<0.001†
BMI (kg/m²)	29.16±3.29	25.59±3.18	<0.001

Abbreviations: SD: Standard deviation; BMI: Body mass index; PCA: Patient-controlled analgesia.

*Mann-Whitney test, †Independent t-test.

Table 2. Comparison of nausea and or vomiting between groups

Time	No. (%)		P*
	Intrathecal Opioid	PCA Pump	
At 1 h	2(3.6)	0(0.0)	0.10
At 2 h	1(1.9)	0(0.0)	0.69
At 24 h	1(2.0)	0(0.0)	0.46
P†	1.00	0.36	

Abbreviations: N: Number; PCA: Patient-controlled analgesia.

*Fisher exact test, †Friedman test.

Table 3. Comparison of pruritus between groups

Time	No. (%)		P*
	Intrathecal Opioid	PCA Pump	
At 1 h	6(10.5)	9(15.8)	0.44†
At 2 h	0(0.0)	1(1.8)	1.00
At 24 h	0(0.0)	3(5.4)	0.24
P‡	0.002	<0.001	

N: Number; PCA: Patient-controlled analgesia.

*Fisher exact test, †Chi-squared test, ‡Friedman test.

Table 4. Comparison of patient satisfaction between groups

Variable	Mean±SD		P*
	Intrathecal Opioid	PCA Pump	
Patient satisfaction	9.23±1.22	8.84±1.22	0.08

SD: Standard deviation; PCA: Patient-controlled analgesia.

*Mann-Whitney test.

[DOI: 10.32598/hmj.28.1.10]

Discussion

The current study was a prospective, double-blind, randomized clinical trial conducted in Shariati and Khalij Fars hospitals in Bandar Abbas City, Iran, from 2017 to 2018. The target population was all pregnant women undergoing elective C-sections in these hospitals, who were randomized into the PCA pump and intrathecal opioid injection groups.

Regarding the demographic and anthropometric features, aside from height and BMI, there was no significant difference between groups, which was consistent with the findings of Ghahiri et al. [6] and Kara et al. [7].

One of the crucial complications after surgery, especially a C-section, is nausea and or vomiting. Nausea and vomiting occur due to the stimulation of chemical receptors in the trigger zone. Opioids, such as pethidine, can cause nausea or vomiting by stimulating this center. In the current study, nausea and or vomiting occurred more frequently with intrathecal opioids compared to PCA; however, the results of the study by Ghahiri et al. were contradictory [6], while Trikoupi et al.'s findings were comparable [8]. They also reported lower nausea and or vomiting with PCA compared to intrathecal opioids [8].

Another complication assessed in the current study was the frequency of pruritus. Based on our results, the number of patients with pruritus was higher in the PCA pump group than in the intrathecal opioid group; nevertheless, the difference between groups was not statistically significant. This is contrary to the findings of Boonmak et al. [9].

Another variable evaluated in our study was patient satisfaction with the pain control method, determined by factors including pain, nausea, vomiting, and the like. Some of these items differed between groups; nonetheless, patient satisfaction was similar. However, the results of other studies were inconsistent. In the study by Pan et al., using the PCA pump led to lower patient satisfaction [5]. In contrast, in Trikoupi et al.'s study, intrathecal morphine was associated with higher satisfaction than the PCA pump [8]. On the other hand, Bayar et al. reported higher satisfaction with the PCA pump in their study [10].

Conclusion

The results of the current study showed that despite the novelty of pain control by the PCA pump method, this strategy cannot alleviate pain compared to older methods, such as intrathecal opioid injection. Moreover, patient satisfaction was lower with the PCA pump compared to intrathecal opioids, which can be due to its side effects such as nausea or vomiting and higher cost.

Ethical Considerations

Compliance with ethical guidelines

This study Was approved by the Ethic Committee of Hormozgan University of Medical Sciences (Code: IR-HUMS.REC.1395.135). Informed consent was obtained, and possible adverse effects or hazards, the purpose of the study, and types of methods and procedures were explained to all enrolled patients.

Funding

This research did not receive any grant from funding agencies in the public, commercial, or non-profit sectors.

Authors' contributions

Conceptualization, investigation, formal analysis and writing: All authors; Supervision: Abbas Moallemy, Alireza Abdollazadeh Baghaei and Fereydoon Fekrat; Project administration; Abbas Moallemy, Alireza Abdollazadeh Baghaei and Farnoosh Frahini Esfahany.

Conflict of interest

The authors declared no conflict of interest.

Acknowledgments

The authors acknowledge the medical staff of Shariati and Khalij Fars hospitals for their cooperation in gathering cases for this research.

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[DOI: 10.32598/hmj.28.1.10]