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Intrathecal Bupivacaine with Fentanyl Versus Bupivacaine Alone for Caesarean Section Under Spinal Anesthesia

Zanyar Noori Osman*

Abstract

Background and objectives: Postoperative pain might start due to the decrement effect of anesthetic drugs. Complications are reduced and recovery hastens with post-surgical pain control. The aim of this study is to evaluate the effect of spinal anesthesia by combining drugs (Bupivacaine and Fentanyl) versus Bupivacaine alone, to manage postoperative pain.

Methods: This study is a randomized clinical trial in which sixty patients, that underwent caesarean section under spinal anesthesia at The Slemani Maternity Teaching Hospital between November 2021 and March 2022. The patients were grouped into two: 30 patients in each of group (F) that received Bupivacaine 15mg(3ml) and Fentanyl 10µg, and 30 patients in the group (B) that received Bupivacaine 15mg (3ml) only. The parameters (pain at the site of surgery, pain outside the site of surgery, pruritus outside of the surgical site and pain during the return of movement) were recorded in the post-operative periods: 30 minutes,1, 1.5, 2 and 2.5 hours.

Results: We found that the intrathecal administration of Fentanyl and Bupivacaine has decreased postoperative pain compared to Bupivacaine alone. The data showed statistically significant results in all post-operative periods: 30min (F group %13, B group %83.3), 1hour (F group %13.3, B group %93.3), 1:30hour (F group %23.3, B group %93.3), 2hour (F group %33.3, B group %96.6) and 2:30hour (F group %60, B group %100).

Conclusion: Adding Fentanyl is more effective for decreasing postoperative pain compared to Bupivacaine alone.

Keywords: Bupivacaine, Caesarean Section, Fentanyl, Postoperative pain, Spinal anesthesia

Introduction

In 1991, anesthetic services substituted epidural to spinal anesthesia in elective caesarean operations. [1] Spinal anesthesia was the first regional anesthetic technique and it was in Germany in 1898 that August Bier performed the first surgery under the spinal technique. [2] This technique was briefer to perform and intraoperatively patients were more comfortable.[1] Spinal anesthesia blocks the spinal nerves using and injected anesthetics locally to the space which is called the subarachnoid.[1] Because it is relatively simple to perform, this type of anesthesia is the most nerve block procedure

* M.B.Ch.B., C.A.B.M.S., Lecturer at Kurdistan Higher Council of Medical Specialties (KHCMS) –Kurdistan–Iraq, Internist, zanyar_osman@univsul.edu.iq

commonly used in gynecological operations along with urological, orthopedic and obstetric.[3] The spinal anesthetic is usually done whilst the patient is awake.[3] Spinal anesthesia increases patient comfort, lowers the complication rate and controls pain better that intravenous anesthetics.[4] Postoperative pain may start different inflammatory, visceral or somatic reactions that leads to chronic pain if inadequately managed.[5] Pain that develops postoperatively is a type of pain that occurs acutely due to a surgical injury with an inflammation reaction and an afferent neuronal storm.[6] The incidence of this type of pain described to be as higher as 60%, and in spite of the intensive effort, it doesn't subside completely.[5] Both the patient and the surgeon are concerned about the good control and treatment of postoperative pain, because of the possible adverse effects of the physiological reactions to the pain after the surgery.[7] Inadequate pain control may result in excess death.[6] Sublimaze was the first fentanyl formulation that received approval from the Food and Drug Administration (FDA) as an intravenous agent in the 1960s.[8] It becomes the most used opioid for intraoperative analgesia.[9] Fentanyl is famous of its onset to be quick and its action to be of short duration after intrathecal administration.[10] In caesarean sections, it is commonly added to intrathecal Bupivacaine by many anesthesiologists. It improves postoperative pain reduction and the quality of anesthesia without producing major side effects as anaphylaxis and methemoglobinemia rarely occur.[11] First discovered in 1957, Bupivacaine is a local anesthetic of a powerful effect with an amino group structure different from other local anesthetics that are used. Neonatal outcomes like APGAR score, showed non-significant adverse outcomes.[12] The aim of this study is to evaluate the effect of spinal anesthesia by combining drugs (Bupivacaine and Fentanyl) or spinal anesthesia without fentanyl by using Bupivacaine only, to manage postoperative pain.

Patients and methods

This study is a randomized clinical trial in which sixty adults parturient, aged between 22 to 43 years, pregnancy equal to or above 37 weeks, with a live and single fetus, underwent caesarean section under spinal anesthesia and of physical status 1 & 2 of the American Society of Anesthesiologists, were randomly selected among parturient presented to The Slemani Maternity Teaching Hospital in between November 2021 to March 2022. The selection number is based on the scheduled caesarean sections in the hospital according to the regulations and the parturient age selection based on the largest number of pregnant admissions. The parturient grouped into two equals: First one is the case group (group F) receiving Bupivacaine 15mg(3ml) and Fentanyl 10µg, and the second group is the control group (group B) receiving Bupivacaine 15mg (3ml) only. The following characteristics were put as exclusion criteria: patient refusal, active maternal hemorrhage, infection on or near the site of the needle insertion, clinical signs of coagulopathy, pregnant women having psychiatric disorders, drug addiction, history of hypersensitivity to the study drugs and the patient that takes parenteral analgesics during this surgery. The data were reviewed depending on many questionnaires and the monitors. The questions in intra- operative include: the patient's demography (age, height, weight), receiving intra- operative analgesia or not, the size of the spinal needle, the number of trials, Bupivacaine combined with Fentanyl or not. The questions and monitors in the postoperative period include: pain at the surgical site, pain outside the surgical site, pruritus outside of the surgical site, pain after the return of movement.In the operation theatre, a two-line bore cannula was inserted before starting the procedure, when the procedure started, all the

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parameters including the size of the Spinal needle (SN).Subarachnoid anesthesia was administered with %0.5 heavy Bupivacaine 15mg(3ml) with or without fentanyl 10µg at the locations: L3-L4 / L4-L5 interspace. With a variety in several trials,[1,2,3,4], we used a spinal needle in gauges (26-27) under aseptic technique, then infusing the drug. During the postoperative period, we monitored and recorded these parameters (pain at the site of surgery, pain outside the site of surgery, pruritus outside of the surgical site, and pain during the return of movement. Then continued to monitor and record these every 30min until 2.5h. According to the numerical rating scale (NRS) (from 0 = no pain to 10 = worst pain imaginable), Pain Intensity (PI)PI was evaluated. Mild pain (score: 1-3), moderate pain (score: 4-6) and severe pain (score: 7-10). The researcher informed the patients and explained the study for them in their native languages. Ethics approval has been taken from Research Ethics Committee at Slemani Polytechnic University, Slemani, Iraq. The neonatal effect of the procedure was assessed by the in-duty pediatrician and no significant changes noted in the APGAR score. After data collections and analysis, excel spreadsheet was used for data entry then the analysis of statistics was performed by using the IBM SPSS program, version 25. Monitoring categories comparison done according to separate timings in the postoperative period. For comparing the categorical data, Fisher exact and one-way ANOVA tests were used. A p value of 0.05 were used as the significance cutoff point of statistical tests. The data is presented in tabular and diagrammatic forms to describe the variables of this study.

Results

There were 30 patients (50%) in the group B, and another 30 patients (50%) in the group F. Pain at the site of surgery, outside the site of surgery and pain during the return of movement was significantly lower in group F compared to group B, we found that the combined Fentanyl and Bupivacaine was superior in controlling pain compared to using Bupivacaine only, but significantly increase the incidence of pruritus. Demographic data were the same for all participants apart from the age as they were all female and from the Slemani City. In the 30 min post- operative period presented in Table (1). Although Bupivacaine effect lasts longer, yet during questioning parturient reported pain. Only pain at the site of surgery and outside the site of surgery shows statistically significant results.

Table (1): the observed parameters after 30 min post-operative

	Bupivacaine (30 patients)	Bupivacaine & Fentanyl (30 patients)	p value
Pain at the site of surgery	83.3%	13%	<0.0 0001
Pain outside the site of surgery	23%	6.6%	<0.0 01
Pruritus outside of surgical site	0%	16.6%	0.01
Pain during the return of movement	0%	0%	1

In the 1-hour post- operative time presented in Table (2), only pain at the site of surgery and pruritus outside of surgical site were statistically significant. We made sure that the parturient report genuine pain sensation and no other types of sensation.

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Table (2): The observed parameters after 1 Hour post-operative

	Bupivacaine (30 patients)	Bupivacaine & Fentanyl (30 patients)	p value
Pain at the site of surgery	93.3%	13.3%	<0.00001
Pain outside the site of surgery	26.6%	13.3%	0.03
Pruritus outside of surgical site	3.3%	26.6%	<0.00001
Pain during the return of movement	3.3%	0%	0.2

In the 1.5 hours postoperative time presented in Table (3), again pain at the surgical site and pruritus outside of the surgical site were statistically significant.

Table (3): The observed parameters after 1.5 Hour post-operative

	Bupivacaine (30 patients)	Bupivacaine & Fentanyl (30 patients)	p value
Pain at the site of surgery	93.3%	23.3%	<0.00001
Pain outside the site of surgery	26.6%	16.6%	0.1
Pruritus outside of surgical site	3.3%	36.6%	<0.00001
Pain during the return of movement	3.3%	0%	0.2

In the 2 hours post- operative time presented in Table (4), again pain at the site of surgery and pruritus outside of surgical site were statistically significant.

Table (4): The observed parameters after 2 Hours post-operative

	Bupivacaine (30 patients)	Bupivacaine & Fentanyl (30 patients)	p value
Pain at the site of surgery	96.6%	33.3%	<0.00001
Pain outside the site of surgery	20%	10%	0.07
Pruritus outside of surgical site	3.3%	53.3%	<0.00001
Pain during the return of movement	10%	6.6%	0.4

In the 2.5 hours post- operative presented in Table (5), pain during the return of movement shows statistically significant results along with pain at the site of surgery and pruritus outside the surgical site.

Table (5): The observed parameters after 2.5 Hours post-operative

	Bupivacaine (30 patients)	Bupivacaine & Fentanyl (30 patients)	p value
Pain at the site of surgery	100%	60%	<0.00001
Pain outside the site of surgery	10%	10%	1
Pruritus outside of surgical site	3.3%	30%	<0.00001
Pain during the return of movement	16.6%	6.6%	0.04

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Discussion

Pain is described as disturbance in both sensation and emotion experiences, determined by many factors like physiologic, sensory, affective, cognitive, sociocultural, and behavioral factors.[13] Postoperative pain mostly has properties of a nociceptive pain, that is a type of pain caused by damage to body tissue.[14] Pain after a C-section that is moderate to severe can lead to health problems, make patients uncomfortable and unhappy, slow down wound healing, delay recovery, lengthen staying in hospital, quality of life reduction, and increase the risk of chronic pain. All of these complications can have financial consequences for the health service.[13] Although postoperative pain is an expected physiological event, yet physicians and nurses must make appropriate relief of this complication by using up to date anesthetic techniques with the availability of new medications and the applying the basic knowledge regarding the postoperative pain.[14]Systemic and intrathecal administration of opioids are the most applied modalities for pain treatment postoperatively.[13] Intrathecal opioids increases the analgesia duration, but not affecting the motor or autonomic nervous systmes.[10] Fentanyl is a synthetic pharmaceutical opioid that is licensed for severe pain.[8] Pruritus after surgery is not completely understood and may have causes like drugs (including opioids).[15] The most serious adverse effect of intrathecal opioids is respiratory depression while the most common one is pruritus. Nausea, vomiting are other usually reported side-effects.[11]Results of this work is in line with other studies to indicate that the analgesic drug Fentanyl when administrated intrathecally is effective in the treatment of postoperative pain after spinal anesthesia and showed that its efficacy is significantly better than using Bupivacaine alone. This efficacy is not completely explained in the studies listed below. In our study, we found that the intrathecal administration of Fentanyl with Bupivacaine will decrease postoperative pain after spinal anesthesia in comparison to intrathecal administration containing Bupivacaine alone. The data show statistically significant results in all periods post-operative period. This result is mirrored by the following studies:In Waxler et al, one hundred patients enlisted and all were of the equal grade of (ASA) as our patients. They concluded that combination of Bupivacaine and Fentanyl leads to elimination of the visceral pain and prolong postoperative analgesia. [15]Raoji et al, included fifty subjects of ASA physical status I for caesarean section. Patients were categorized into two groups randomly, group FB and group B consisting of 25 for each group. Patients in FB were given Bupivacaine plus 25 µg fentanyl. Group B received Bupivacaine plus 0.5ml normal saline. No significant differences observed in the onset of analgesia in both groups. Group FB showed longer postoperative analgesia time than Group B. This was statistically significant.[16]In Weigl et al, two randomized parallel-groups scheduled for elective CS. Again; the Fentanyl group showed reduced opioid requirements in comparison to the controls and it was statistically significant.[17]Uppal et al. Seventeen randomized controlled clinical trials with more than thousands of participants and data used for a meta-analysis. Intra- operative analgesia decreased by adding Fentanyl to Bupivacaine. [18] In Gauchan, et al. Addition of fentanyl to intrathecal bupivacaine for caesarean section increases the duration of postoperative analgesia without increasing maternal or neonatal side effects[19].In our study, we found pruritus was more if we compare Group F to the group B. It is postulated that pruritus mostly an activation of mu-receptors for opioids that is located in the spinal cord.

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Conclusion

Combining of intrathecal Bupivacaine and Fentanyl shows more effective pain control than using Bupivacaine alone in patients undergoing caesarean section.

Disclosure:

The authors assert that they have no conflicts of interest.

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