

A Comparative Study on the Efficacy of Tramadol and Fentanyl Added To Low Dose Bupivacaine in Subarachnoid Block for Caesarean Section

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ABSTRACT

Background: A caesarean section is the utmost communal surgical procedure. An adjuvant with a low dose of bupivacaine added to a cesarean section is a better option.

Aim of the study: It is planned to study the effect of fentanyl and tramadol added to a low dose of bupivacaine on subarachnoid blockade in caesarean section.

Place and duration: In the Anesthesia and Obstetrics and Gynecology department of Khyber Teaching Hospital, Peshawar and Arif Memorial Teaching Hospital, Lahore for six-months duration from July 2021 to December 2021.

Methods: 90 patients were randomized into three groups, 30 pregnant females in each group. Group A received 0.5% bupivacaine 7.5 mg (one and a half ml), 5% dextrose in 0.5 ml water and total of 2 ml, group B 0.5% bupivacaine 5 mg, fentanyl 50 µg, total 2 ml. In group C, 0.5% bupivacaine was used together with 50 mg of tramadol, and a total of 2 ml was used for spinal anesthesia. The height of the sensory block was evaluated by the method of pinprick and the quality of the motor block by the Bromage scale. The effective duration of analgesia was recorded when patients requested the 1st dose of analgesia. The APGAR score was documented at one and five minutes after the baby was born.

Results: In group A; mean duration of blockade was 118.50 ± 23.60; It was 168.00 ± 30.21 mints in Group B and 215.00 ± 26.51 mints in C Group, which was significant between the three groups (P = 0.01). The systolic blood pressure has mean change among the three groups after 3, 4, 5, 6, 8, 9, 10, 20 and 30 min was significant after SAB, and the diastolic blood pressure mean change after SAB was significant at 2, 3, 8, 9, 10, 20 minutes and the p-value were 0.021, 0.037, 0.059, 0.032, 0.042, 0.065, respectively. Hypotension developed in 9 cases of A group; 10 patients of B Group and 6 in the C group. There was one case pruritus in group A; group B has 7 patients with itching and no group C has no case of itching. The measurement of VAS after SAB was significant between groups. There was also a significant variance in VLAS among the groups in the first hour (P = 0.00049), the 2nd hr. (P = 0.007), and the 3rd hr. (P = 0.001) after SAB, and the interaction between the groups was significant (P = 0.001).

Conclusion: The combination of bupivacaine and tramadol may be a better option as an intrathecal anesthetic compared to 0.5% bupivacaine in 0.5 ml of 5% dextrose or 0.5% bupivacaine in combination with fentanyl.

Keywords: SAB, Bupivacaine, Fentanyl and Tramadol

INTRODUCTION

Obstetric anesthesia is a difficult but satisfying subspecialty of anaesthesia and its inclusive reception and practice of regional block for delivery has convert obstetric anesthesia an important portion of most anesthetic practices¹⁻². Cesarean section is the common indication for anesthesia in pregnant women. Local anesthesia has become the technique of choice for Caesarean section as GA is related with increased mortality in mothers³. Hyperbaric bupivacaine is frequently cast-off local anesthesia in Caesarean section for subarachnoid block. Various methods have been tried to increase the spinal anesthesia quality during C-section, including injecting high doses of local anaesthetics, making hyperbaric local anesthetic solutions, adding epinephrine, morphine or fentanyl to local anaesthetics. Adding a supplement (opioid or non-opioid) reduced the bupivacaine dose and ensured stability of cardiovascular system⁴⁻⁵. As part of 'augmentation strategies', in addition to subarachnoid blockade, extensive range of non-opioids and opioids are given to prolong the superiority of anesthesia and the duration of anesthesia in the postoperative period⁶. A lipophilic opioid named Fentanyl has quick initiation of action succeeding administration of intrathecal block. Therefore, it is appropriate as an intrathecal block for per-operative anesthesia and as well lengthens the analgesic effect in the post-operative duration. Tramadol, a pseudo-opioid intrathecal drug, binds to the opiate receptor in the spinal cord⁷. The analgesic effect of the combination of bupivacaine and tramadol shows a rapid onset and less degree of motor blockade⁸. The main problems with opioids eliminated by tramadol use are respiratory depression, urinary retention, itching, and dose limitation. Tramadol is a synthetic analgesic because it has an opioid and non-opioid mechanism of

action and can induce analgesia with less respiratory depression, sedation, gastrointestinal congestion and the potential for abuse⁹⁻¹⁰. Effects on ventilation and cardiovascular system at the therapeutic doses are clinically insignificant. One study shows that intrathecal tramadol has a dose-dependent inhibitory effect on both sensory (A6, C) and motor transmission in the spinal cord¹¹. Epidural tramadol has been shown to reduce the need for post-operative pain relief. However, its effect on post-operative analgesia following intrathecal administration has not yet been investigated¹². The effect of intrathecal administration of tramadol on pain control after TURP was investigated¹³. There are no published reports comparing the efficacy of bupivacaine fentanyl and tramadol bupivacaine in IT caesarean section. Therefore, plan of this study is to determine the effect of fentanyl and tramadol added to a low dose of bupivacaine on subarachnoid blockade in caesarean section.

METHODS

This prospective randomized study was held in the Anesthesia and Obstetrics and Gynecology department of Khyber Teaching Hospital, Peshawar and Arif Memorial Teaching Hospital, Lahore for six-months duration from July 2021 to December 2021. The study included 90 patients of class I and II according to ASA who underwent cesarean section with the consent of the hospital ethics committee and written informed consent. People with contraindications to regional anesthesia were not included. 90 patients were randomized into three groups, 30 pregnant females in each group. Group A received 0.5% bupivacaine 7.5 mg (one and a half ml), 5% dextrose in 0.5 ml water and total of 2 ml, group B 0.5% bupivacaine 5 mg, fentanyl 50 µg, total 2 ml. In group C,

0.5% bupivacaine was used together with 50 mg of tramadol, and a total of 2 ml was used for spinal anesthesia. After the patient arrived in the operating room, the baseline parameters (blood pressure, heart rate, Spo₂, respiratory rate) were recorded and the procedure of anesthesia was explained to the patient again. 18 gauge iv cannula was placed in a peripheral vein. All pregnant women were preloaded with 20 ml of Hartmann's solution per kg for 10 minutes prior to spinal block. Using all aseptic precautions, a 27-gauge Quincke needle was used for giving spinal anesthesia in the left lateral decubitus position, and the mothers were placed in a supine position immediately after spinal injection with left displacement of uterus. All patients received O₂ support with a face mask. The blood pressure, Spo₂ and heart rate were documented immediately after spinal anesthesia. Heart rate, blood pressure, respiratory rate, and Spo₂ were recorded every three minutes for the 1st twenty minutes, at 5-minute intervals for the rest of the surgery, and then at 30-minute intervals until patient complain of pain. The side effects such as itching and discomfort, vomiting, nausea, chills, chest pain, anxiety were recorded for up to 24 hours. Hypotension was definite as a drop in systolic blood pressure of less than 20% from standard managed with an intravenous bolus of fluids and ephedrine as needed. The height of the sensory block was evaluated by the method of pinprick and the quality of the motor block by the Bromage scale. The anesthesia quality was evaluated on the basis of the motor block quality (Bromage scale, onset time) and the sensory block quality (blockage level, onset time) and the frequency of side effects by interviewing the patient and rated on Verbal rating Scale (VRS). It was classified as excellent / good / fair / bad depending on the quality of the anesthesia. The effective duration of analgesia was recorded when patients requested the 1st dose of analgesia. The APGAR score was documented at one and five minutes after the baby was born. Values are expressed as mean ± SD. The analysis was accomplished by means of Chi-square test, one-way and two-way ANOVA and Student's t-test (unpaired). Less than 0.05 of P-value was measured significant.

RESULTS

There was no statistically significant difference between the three groups in mean age, weight, height, and gestational age.

Table-1: shows the Demographic features of the patients

| Variables | Group –A (n=30) | Group –B (n=30) | Group –C (n=30) | P- value |
|--------------------------|--------------------|--------------------|--------------------|-------------|
| Age (yr) | 31.10±6.81 | 32.54±7.05 | 30.55±13.60 | 0.670 |
| Height (cm) | 151.51±4.10 | 152.90±1.85 | 149.59 ± 12.10 | 0.230 |
| Weight (kg) | 57.55±19.82 | 55.10±12.22 | 56.86±16.39 | 0.950 |
| Duration of Pregnancy | 39.20±0.917 | 37.90±7.3 | 38.50±2.1 | 0.119 |

In group A; mean duration of blockade was 118.50 ± 23.60; It was 168.00 ± 30.21 mints in Group B and 215.00 ± 26.51 mints in C Group, which was significant between the three groups (P = 0.01). The systolic blood pressure has mean change among the three groups after 3, 4, 5, 6, 8, 9, 10, 20 and 30 min was significant after SAB, and the diastolic blood pressure mean change after SAB was significant at 2, 3, 8, 9, 10, 20 minutes and the p-value were 0.021, 0.037, 0.059, 0.032, 0.042, 0.065, respectively. Hypotension developed in 7 cases of A group; 9 patients of B Group and 4 in the C group.

Table 2: Showing Incidence of hypotension

| Group | Number | Yes | No | x 2 | P-value |
|-------|--------|-----|----|------|---------|
| A | 30 | 9 | 21 | 2.90 | 0.221 |
| B | 30 | 10 | 20 | | |
| C | 30 | 6 | 24 | | |

Hypotension developed in 9 cases of A group; 10 patients of B Group and 6 in the C group. There was one case pruritus in group A; group B has 7 patients with itching and no group C has no case of itching. The measurement of VAS after SAB was

significant between groups. There was also a significant variance in VLAS among the groups in the first hour (P = 0.00049), the 2nd hr. (P = 0.007), and the 3rd hr. (P = 0.001) after SAB, and the interaction between the groups was significant (P = 0.001).

Table 3: Showing Incidence of itching

| Group | Number | Yes | No | x 2 | P-value |
|-------|--------|-----|----|-------|---------|
| A | 30 | 1 | 21 | 14.20 | 0.002 |
| B | 30 | 7 | 20 | | |
| C | 30 | 0 | 24 | | |

Table 3: shows the duration of block in minutes among the studied groups.

| Group | Number | Mean± SD |
|-------|--------|----------------|
| A | 30 | 118.50 ± 23.60 |
| B | 30 | 168.00 ± 30.21 |
| C | 30 | 215.00 ± 26.51 |
| f | 64.50 | |
| P | 0.001 | |

The visual linear analogue scale (VLAS) was used for assessment of Quality of analgesia. The data are presented in Table V.

There was also a significant variance in VLAS among the groups in the first hour (P = 0.005), the 2nd hr. (P = 0.002), and the 3rd hr. (P = 0.003) after SAB, and the interaction between the groups was significant (P = 0.001).

Table 4: Showing analysis of intensity of pain by VLAS

| Group | First hour | Second hour | Third hour | F | P |
|-------|------------|-------------|------------|-------|-------|
| A | 22.10 | 19.20 | 13.10 | 12.25 | 0.005 |
| B | 1.41±2.10 | 6.21±3.08 | 3.51±5.60 | 41.90 | 0.002 |
| C | 1.29±2.01 | 5.88±3.52 | 1.62±6.08 | 38.01 | 0.003 |

DISCUSSION

As general anesthesia (G / A) is associated with high maternal mortality, regional anesthesia has become the technique of choice. Maintaining awareness and early postoperative analgesia are considered to be the advantages of regional anesthesia¹⁴. The only reason limiting the choice of spinal anesthesia for C-section is the possibility of neonatal depression due to severe hypotension following spinal anesthesia¹⁵. Various methods have been tried to improve the quality of regional anesthesia and reduce its complications, such as adding epinephrine, morphine or fentanyl to a hyperbaric bupivacaine solution¹⁶. Moreover, the apparent synergistic effect between the two types of agents reduces the dosage requirements and provides excellent analgesic effects with few maternal side effects and little or no neonatal depression¹⁷. Fentanyl is a unique drug that can be used intrathecally, binds to opioid receptors and, when combined with a low dose of bupivacaine, provides adequate analgesia and reduces the need for large amounts of local anesthetic in its absence. Tramadol may reduce the respiratory depressant effects of commonly used intrathecal opioids¹⁸. Jones et al used 37.5 mg of fentanyl and bupivacaine with no negative effects on the new-born. Reyburn et al in 2016 administered up to 600 µg of fentanyl to pregnant women during labor without any harmful effects on the new-born. The main problems with opioids eliminated by tramadol use are respiratory depression, urinary retention, itching, and dose limitation¹⁹⁻²⁰. Tramadol, a pseudo-opioid intrathecal drug, binds to the receptors of opioid in the spinal cord. The analgesic effect of the combination of bupivacaine and tramadol shows a rapid onset and less degree of motor blockade²¹. When examining the neurochemical profile of tramadol, it was found that, unlike morphine, it also inhibits the uptake of noradrenaline (Ki = 0.79 micro-M) and serotonin (0.99 micro-M). Effects on ventilation and cardiovascular system at the therapeutic doses are clinically insignificant²². One study shows that intrathecal tramadol has a dose-dependent inhibitory effect on both sensory (AS, C) and motor transmission in the spinal cord. This result indicates that tramadol exerts dose-dependent central nerve blockade. Bupivacaine is a widely used long-acting local anesthetic without

tachyphylaxis²³. Like regular bupivacaine, it is unpredictable in terms of dose requirements and blockade of pain fiber conduction in the proposed surgical field. Petersen et al. reported that patients who received 7.5-10 mg and 10-12.5 mg of 0.5% bupivacaine hyperbaric solution developed a similar range of sensory block above T3, but the usage of high bupivacaine doses result in a lower frequency of moderate to severe pain in viscera²⁴.

In this prospective, experimental, randomized and blinded study, the benefits of a lower incidence of motor block; Equally effective anesthesia for surgery can be achieved with a combination of dextrose or bupivacaine and fentanyl, or a combination of bupivacaine-tramadol at lower doses of bupivacaine. There was no unnecessary respiratory depression in either the mother or the new-born. Vaughan et al. According to the 2019 result, the result showed that itching occurred in some of the 62 patients who required treatment. There were two cases of nausea and vomiting that did not require treatment²⁵.

CONCLUSION

The combination of bupivacaine and tramadol may be a better option as an intrathecal anesthetic compared to 0.5% bupivacaine in 0.5 ml of 5% dextrose or 0.5% bupivacaine in combination with fentanyl.

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