Original Article

Comparative Evaluation of Intrathecal Fentanyl with Different Doses of Bupivacaine on Caesarean Patients Attended in a Tertiary Care Hospital

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ABSTRACT

Introduction: *The selection of anesthesia for cesarean section is determined by numerous factors, including the indication for operative delivery, its urgency, and patient and obstetrician preference and skill of anesthetists. Spinal opioid therapy is one option for managing pain following surgery.* ***Objective:*** *This study sought to characterize the cytological features of testicular aspirates from patients with azoospermia and identify those with mature spermatozoa suitable for assisted fertilization.* ***Methods & Materials:*** *This cross-sectional comparative study was carried out at the department of Anesthesiology and ICU in Kurmitola General Hospital (KGH), Dhaka, Bangladesh during December, 2023 to May, 2024. A total of 60 pregnant caesarean cases aged (18-40) years were enrolled in this study. The pregnant caesarean cases were divided into three groups with 20 cases in each group Subarachnoid block with 0.5% hyperbaric bupivacaine 10 mg and fentanyl 25 µg was administered to patients in Group A. Subarachnoid block with 0.5% hyperbaric bupivacaine (12.5 mg) and fentanyl (25 µg) was administered to patients in Group B. Subarachnoid block with 0.5% hyperbaric bupivacaine (15 mg) and fentanyl (25 µg) was administered to patients in Group C. With the aid of the Statistical Package for Social Sciences, the collected data were examined (SPSS). Unpaired t tests were performed to compare the groups mean where $p<0.05$ considered as the level of significance.* ***Results:*** *Effective analgesia duration (the interval between the start of sufficient analgesia and the*

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initial request for analgesia) was 115.00±19.11 minutes in group A, 126.25±16.29 minutes in group B, and 131.75±10.70 minutes in group C, respectively. Incidence of pruritis was more as compared to other side effects in all the three groups (20%, 30% and 20% respectively). ***Conclusion:*** *This study investigated that the combination of fentanyl 25µg with 0.5% hyperbaric bupivacaine 15 mg is more useful, acceptable clinically and superior in terms of characteristics of sensory and motor block, duration of analgesia and greater haemodynamic stability as compared to other two combinations.*

Keywords: *Comparative, Evaluation, Intrathecal, Fentanyl, Different, Doses, Bupivacaine, Caesarean, patients.*

INTRODUCTION

The choice of anesthesia for cesarean sections depends on several factors, including the reason for the procedure, its urgency, and the preferences of both the patient and the obstetrician, as well as the expertise of the anesthesiologist. Regional anesthesia offers numerous advantages, such as reducing fetal exposure to potentially sedating medications and lowering the risk of maternal pulmonary aspiration[1]. An option for managing postoperative pain includes using spinal opioids. However, spinal anesthesia, commonly employed for cesarean sections, presents risks like hypotension and post-dural puncture headaches, primarily associated with hyperbaric bupivacaine at doses of 10 to 15 mg with or without fentanyl at 10 to 25 micrograms[2]. Pregnancy-related physiological and anatomical changes affect how spinal anesthesia behaves, with pregnant women generally needing less local anesthetic than non-pregnant individuals to achieve the same effect[3]. Nonetheless, they face an increased risk of local anesthetic toxicity due to factors like enhanced tissue penetration, reduced plasma protein binding, and heightened sensitivity to cardiac effects of local anesthetics[4]. Adjustments in dosage can lead to hemodynamic instability, potentially increasing risks for both mother and baby[5]. Studies indicate that the hypotension associated with spinal anesthesia is linked to the increased sympathetic block caused by higher local anesthetic doses[6,7]. Among local anesthetics, hyperbaric bupivacaine is preferred for its potency, slow onset (5-8 minutes), and prolonged duration. Combining bupivacaine with fentanyl has been shown to reduce hypotension[8]. Intrathecal opioids added to bupivacaine improve surgical analgesia by acting on spinal cord opioid receptors, allowing for lower doses of local anesthetic and minimizing side effects while prolonging postoperative pain relief[9]. Fentanyl, a synthetic opioid, is favored for its potency, rapid onset, and quick redistribution in the body, which decreases drug concentration in the plasma[10]. This study aimed to compare the efficacy of intrathecal fentanyl in various doses of bupivacaine for cesarean section patients treated at a tertiary care hospital.

OBJECTIVE

To compare and determine the efficacy of intrathecal fentanyl with different doses of bupivacaine on caesarean patients attended in a tertiary care hospital**.**

MATERIALS & METHODS

This was a cross-sectional comparative study conducted at the department of Anesthesiology and ICU in Kurmitola General Hospital, Dhaka, Bangladesh during December, 2023 to May, 2024. Written informed consent was taken and a total of 60 pregnant caesarean cases aged (18-40) years were enrolled in this study. The pregnant caesarean cases were divided into three groups with 20 cases in each group. Baseline systolic blood pressure (SBP), diastolic blood pressure (DBP), and pulse rate were recorded in the supine position with a wedge placed under the right buttock. Patients were randomly divided into two groups of 40 participants each, with Group A, Group B and Group C. Group A patients were given subarachnoid block with 0.5% hyperbaric bupivacaine 10 mg, fentanyl 25 µg. Group B patients were given subarachnoid block with 0.5% hyperbaric bupivacaine 12.5 mg, fentanyl 25 µg. Group C patients were given subarachnoid block with 0.5% hyperbaric bupivacaine 15 mg, fentanyl 25 µg.. Under sterile conditions, a lumbar puncture was performed using a 25-gauge spinal needle at the L4-5 interspace. Following the clear flow of cerebrospinal fluid, each group received a specific drug administered slowly over 20 seconds. Patients were immediately positioned supine, with a wedge under the right buttock to prevent supine hypotension syndrome. Five liters of oxygen per minute were given using a face mask. Systolic and diastolic blood pressure, as well as maternal heart rate, were monitored every 2 minutes for the first 30 minutes, and subsequently every 5 minutes intraoperative. A decrease in systolic blood pressure of 25% from baseline was defined as hypotension and treated with 5 mg ephedrine as needed. Vasopressor usage was recorded. Sensory block level was evaluated by bilateral loss of cold sensation at 2 minutes and confirmed by pinprick assessment. Sensory block quality was rated on a descriptive scale (good, satisfactory, poor). Motor block degree was assessed using the modified Bromage scale. Intraoperative pain was assessed using a visual analog scale (VAS, 0-10 cm, where 0 = no pain, 10 = worst possible pain). Postoperative pain was also evaluated using the VAS scale. Duration of effective analgesia was measured from intrathecal injection to a VAS score > 4. There were reports of side effects include shivering, pruritus, nausea, and vomiting. Duration of regression of sensory block by two segments was recorded. Apgar scores of newborns were documented at 1 minute and 5 minutes. Results were presented as mean ± standard deviation or number (%) and compared using unpaired t-tests for continuous variables and chi-square tests for categorical data. The collected data were analyzed using Statistical Package for Social Sciences (SPSS). Unpaired t tests were performed to compare the groups mean where $p<0.05$ considered as the level of significance.

Inclusion Criteria:

1. Age: (18-40) years.
2. Physical status 1 or 2 for ASA
3. Regular profile of coagulation
4. Patient/Relative willing to give written, informed consent.

Exclusion Criteria:

1. Age below 18 years and above 40 years
2. Patients who were discharged against medical advice were referred cases.
3. ASA 3 or 4 and patients with heart conditions, as well as complicated

pregnancy conditions like placenta previa and fetal distress.
4. Patient or family member unwilling to provide verbal, written, and informed consent.

RESULTS

Table I shows the baseline characteristics of the study patients .In group A the mean age of the study patients was observed to be (30±6.20) years followed by group B (29 ±5.10) years, group C (28±5.00) years. The mean height of the patients of group A was observed to be (158.30±5.40) cm, followed by group B (157.88±39) and group C (160.98±5.10) cm. The mean weight of the patients of group A was observed to be (66.80±5.13) Kg and followed by group B (65.40±5.56) Kg and Group C (68.05±6.17) Kg. The mean heart rate of the patients of group A was observed to be (82.50±8.80) bpm and followed group B (84.80±12.63) bpm and group C (88.35±11.80) bpm. The mean systolic BP of the patients of group A was measured (132.70±13.30) mmHg and followed group B (131.50±18.29) mmHg and group C (128.10±14.53) mmHg. The mean diastolic BP level of the patients of group A was measured (80.30±7.52) mmHg and followed by group B (81.40±7.82) mmHg and group C (77.80±9.40) mmHg. The mean duration of surgery of group A was observed (60.00±5.38) minutes and followed by group B (58.50±4.15) minutes and group C (59.00±2.71) minutes.

Table I: Baseline characteristics of the study patients (*n*=60).

Group	Age (Years) Mean ±SD	Height(cm) Mean ± SD	Weight (KG) Mean ±SD	Heart rate (bpm) Mean ±SD	Systolic BP (mmHg) Mean ±SD	Diastolic BP (mmHg) Mean ±SD	Duration of surgery (minutes) Mean ±SD
A	30±6.20	158.30±5.40	66.80±5.13	82.50±8.80	132.70±13.30	80.30±7.52	60.00±5.38
B	29 ±5.10	157.88±39	65.40±5.56	84.80±12.63	131.50±18.29	81.40±7.82	58.50±4.15
C	28±5.00	160.98±5.10	68.05±6.17	88.35±11.80	128.10±14.53	77.80±9.40	59.00±2.71

Table II shows the onset of adequate analgesia and achievement of maximum upper level of sensory block was comparable in all the three groups. However, time taken to achieve maximum upper level of sensory block was more in group A (12.00±01minutes) as compared to group C (10..20±02 minutes) which was statistically significant($p<0.05$) but there was no significant difference between group A and B($P>0.05$). Duration of sensory block was prolonged in group C (139.50±16.06 minutes) as compared to group A (130.00±18.45 minutes) which

was statistically significant (p<0.05). However there was no statistically significant variation was seen in group A and B (P>0.05).

Table II: Sensory block characteristics of the study patients (*n*=60).

Group	Time take to achieve maximum sensory block (in minutes)	Inter group comparison	*p*-value	Duration of sensory block (in minutes)	Inter group Comparison	*p*-value
	Mean ±SD			Mean ±SD		
A	12.00±01	A v/s B	0.345	130.00±18.45	A v/s B	0.667
B	11.50±1.10	A v/s C	0.231	131.50±19.60	A v/s C	0.073
C	10.20±02	B v/s C	0.453	139.50±15.06	B v/s C	0.041

Table III shows motor block characteristics of the study patients. In inter group comparison of motor block characteristics. In Group A, 20 patients exhibited a Bromage scale of 1, compared to 3 patients each in Groups B and C. Conversely, a Bromage scale of 3 was observed in only 3 patients in Group A, 9 patients in Group B, and a maximum of 11 patients in Group C. The difference was statistically significant thus indicating a significantly higher intensity motor block in group C patients. On statistical comparison, group B and C (126.25±16.29 minutes) and (131.75±10.70 minutes respectively) had significant prolonged duration of motor block than group A (115.00±19.11 minutes) as shown in this table. The mean time to request for first analgesia was 115.00±19.11minutes, 126.25±16.29 minutes and 131.75±10.70 minutes for group A, B and C respectively and was comparable. Duration of effective analgesia (time from the onset of adequate analgesia to the time of first request of analgesia) 115.00±19.11was minutes, 126.25±16.29 minutes and 131.75±10.70 minutes in group A, B and C respectively. No statistical difference was seen amongst the three groups. On inter group comparison of intraoperative heart rate between group A, B and C, decrease was gradual and comparable at all-time intervals.

Table III Motor block characteristics of the study patients (*n*=60).

Group	Bromage scale of motor				Duration (in minutes) Mean ±SD	Inter group comparison	*p*-value
	0	1	2	3			
A	2	9	6	3	115.00±19.11	A v/s B	0.430
B	0	3	8	9	126.25±16.29	A v/s C	0.001
C	1	3	5	11	131.75±10.70	B v/s C	0.308

The fall of intra operative systolic blood pressure in group B was significant at 20 minutes ($p < 0.05$) as compared to group A. In group A and C, the fall in group C at 10 minutes and onwards till 40 minutes was statistically significant. In group B and C, the fall was gradual and comparable at all-time intervals. Groups A and B showed a similar and gradual decline in intraoperative diastolic blood pressure. During the 90-minute mark, there was a statistically significant decrease in intraoperative diastolic blood pressure in groups A and C, whereas in groups B and C, the decline was statistically significant from 30 minutes to 70 minutes. In all three groups, there was no instance of respiratory depression or a notable fluctuation in oxygen saturation. In case of inter group comparison of post-operative heamodynamics, systolic blood pressure remained comparable at all-time intervals but statistically significant in group A and C at 0 to 30 minutes, while diastolic blood pressure in group A and C, group B and C was statistically significant at 0 to 150 minutes. Hypotension, shivering, nausea, pruritis, and sedation were noted in every group. The prevalence of pruritis was higher in all three groups (20%, 30%, and 20%, respectively) than in other adverse effects, and very few patients needed to have injections of hydrocortisone and chlorphenaramine administered to them.

DISCUSSION

Anesthesia-related complications contribute to 5.2% of maternal deaths[11]. The risk of mortality under general anesthesia is 16 times higher compared to regional anesthesia[12]. Spinal anesthesia is preferred for elective cesarean sections due to its simplicity, cost-effectiveness, rapid onset of anesthesia, and complete muscle relaxation. It is highly efficient, requires lower drug doses, causes minimal neonatal depression, and has a lower incidence of aspiration pneumonia. However, it provides a fixed duration of anesthesia, less control over block height, and may lead to post-dural puncture headache and hypotension[13,14]. This hypotension can increase maternal morbidity, nausea, vomiting, and affect neonatal well-being by reducing utero-placental blood flow[15]. Reducing the amount of local anesthetic used and supplementing with opioids, which together improve sensory block without raising sympathetic block during cesarean sections, are two ways to lessen these effects[16].This present study evaluated the effects of combination of fentanyl 25 µg with three different doses of 0.5% hyperbaric bupivacaine (10, 12.5 and 15 mg) in spinal anesthesia amongst three groups and compared the onset and level of sensory block along with cardiovascular variables intraoperatively and sensory as well as motor block along with duration of analgesia postoperatively. This study investigated that time taken to achieve maximum upper level of sensory block was more in group A (12.00±01minutes) as compared to group C (10..20±02 minutes) which was statistically significant($p<0.05$) but there was no significant difference between group A and B($P>0.05$). Duration of sensory block was prolonged in group C (139.50±16.06 minutes) as compared to group A (130.00±18.45 minutes) which was statistically significant ($p<0.05$). However there was no statistically significant variation was seen in group A and B ($P>0.05$). Similar observation was found in another study by Sharan R et al, (2018)[17]. In that study, they observed

time taken to achieve maximum upper level of sensory block was more in group A (14.00±4.35 minutes) as compared to group C (12.00±3.75 minutes), but there was no significant difference between group A and B and group B and C. Duration of sensory block was prolonged in group C 139.50±16.05 minutes) as compared to group A (129.00±18.32 minutes). In inter group comparison of motor block characteristics, this study revealed that bromage scale of 1 was shown by 20 patients of group A and 3 patients each in group B and C, whereas bromage scale of 3 was shown by only 3 patients in group A, 9 in group B and maximum 11 in group C. The difference was statistically significant thus indicating a significantly higher intensity motor block in group C patients. On statistical comparison, group B and C (126.25±16.29 minutes) and (131.75±10.70 minutes respectively) had significant prolonged duration of motor block than group A (115.00±19.11 minutes) and the the mean time to request for first analgesia was 115.00±19.11minutes, 126.25±16.29 minutes and 131.75±10.70 minutes for group A, B and C respectively and was comparable. Duration of effective analgesia (time from the onset of adequate analgesia to the time of first request of analgesia) 115.00±19.11was minutes, 126.25±16.29 minutes and 131.75±10.70 minutes in group A, B and C respectively. No statistical difference was seen amongst the three groups. These findings are almost similar to another study by Verma KR et al (2022)[18]. This current study observed Sedation, pruritis, nausea, shivering, hypotension were observed in all the groups. Incidence of pruritis was more as compared to other side effects in all the three groups (20%, 30% and 20% respectively) and very few patients required management in form of chlorphenaramine and hydrocortisone injections. Almost similar side effects were also found in some other studies[19-21].

Conclusion:

This study investigated that the combination of fentanyl 25µg with 0.5% hyperbaric bupivacaine 15 mg is more useful, acceptable clinically and superior in terms of characteristics of sensory and motor block, duration of analgesia and greater haemodynamic stability as compared to other two combinations in caesarean section. The synergistic analgesic effect of fentanyl with 15 mg bupivacaine helped in attaining better quality of analgesia along with excellent recovery profiles.

Limitations Of the Study:

This was a single centre study with a purposive sample size with limited data over a short study period. So, the results of this study may not reflect the whole country.

Recommendations:

A multicentre study is recommended on a national scale to justify the results of this study so that the data could be a great use to the practioners, clinicians and policymakers.

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