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A Comparative Study of the Efficacy of Intrathecal Plain Bupivacaine Hydrochloride and Bupivacaine Hydrochloride with Fentanyl Citrate in Lower Segment Caesarean Section

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Abstract

Background: Neuraxial administration of opioids with local anaesthetics improve the quality of intraoperative analgesia. It is also known to produce a longer duration of postoperative analgesia. The purpose of this study was to compare the efficacy of intrathecal plain bupivacaine with bupivacaine and fentanyl combination in patients who undergo a lower segment caesarean section.

Methods: A total of 100 patients were randomized into two groups of 50 each to receive either plain bupivacaine or bupivacaine with fentanyl. The hemodynamic changes, sensory and motor blockade were observed both intraoperatively and postoperatively.

Results: 10 mg of 0.5% bupivacaine with 12.5 µg fentanyl produces an effective level of the sensory blockade and maintains stable intraoperative hemodynamic parameters with decreased incidences of adverse effects like nausea and vomiting. The total duration of effective analgesia was significantly longer in the fentanyl group.

Conclusions: Intrathecal fentanyl in a dose of 12.5µg of fentanyl with bupivacaine for spinal anaesthesia in caesarean section provides good intraoperative analgesia and also significantly reduces the demand for postoperative analgesia.

Keywords: Intrathecal Fentanyl; Hyperbaric Bupivacaine; Intraoperative Analgesia; Sensory Blockade.

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Background

The number of caesarean sections has increased in recent times. Care for the parturient has thus become a great challenge and by this way has given the obstetric anaesthetist a chance to contribute better to obstetric services.[1] Historically, caesarean sections were performed by general anaesthesia[1] but the most preferred means presently is the spinal anaesthesia.[2] Spinal anaesthesia is simple to perform, economical and produces rapid onset of anaesthesia and complete muscle relaxation. It is highly efficient, requires less dose, produces very minimal neonatal depression, awake mother and lesser incidence of aspiration pneumonitis. However, it also produces a fixed duration of anaesthesia, postdural puncture, headache, hypotension and lesser control of block height.[3]

Bupivacaine is an amide-type of local anaesthetic that has slow onset (5–8 minutes) but a high potency and a long duration of action lasting from 1.5 to 2 hours. The dose of hyperbaric bupivacaine for caesarean sections is 12 to 15 mgs.[4] Lower segment caesarean sections (LSCS) involve peritoneal traction and handling of intraperitoneal organs. This may result in intraoperative visceral pain. With high doses of hyperbaric bupivacaine, the visceral pain is reduced.[5,6]

Opioids have been a choice in regional anaesthesia to improve the antinociceptive effect of local anaesthetics. Morphine and fentanyl have been commonly used intrathecally with a local anaesthetic in LSCS.[7,8] Fentanyl is one of the most common short-acting opioids used intrathecally as an adjuvant to local anaesthetic. It has synergistic effects with the local anaesthetic and improves the status of intraoperative and postoperative analgesia.[9] It is found that 10-25 mcg of fentanyl intrathecally can prolong the duration of postoperative analgesia for approximately 180 – 240 minutes.[10]

Maternal and neonatal outcomes are a vital issue during a LSCS. Thus, choosing an appropriate drug as an adjuvant with a local anaesthetic has always been a great challenge for anaesthesiologists. Hence, this study was done to compare the effect of adding fentanyl as an adjuvant to intrathecal bupivacaine against plain bupivacaine only in women who undergo a caesarean section. The primary outcome was to assess the postoperative analgesia. Our secondary outcomes were the onset of block, hemodynamic changes, and maternal complications as well as Apgar scores of neonates.

Methods

The study was started after obtaining permission from the Institutional Ethics Committee clearance. Written informed consent was obtained from all the study participants. All patients were belonging to the American Society of Anaesthesiology (ASA) grade 1 or 2 and none of them had any contraindication for spinal anaesthesia. Women with multiple pregnancies, pregnancy-induced hypertension (PIH), placenta previa, bleeding diathesis, COPD, heart diseases, and those with foetal distress were excluded from the study.

A prospective double-blind trial was performed on 100 patients who were posted for LSCS at Dr Somervell Memorial CSI Medical College Hospital, Karakonam. They were randomly allocated to receive either 1.8 ml of 0.5% hyperbaric bupivacaine hydrochloride (Group A, n=50) or 1.6 ml of 0.5 % hyperbaric bupivacaine hydrochloride with 10 micrograms (0.2 ml) fentanyl citrate (Group B, n=50). Both the groups received the drugs intrathecally and the total volume administered was 1.8 ml. In the operating room, an intravenous cannula (18G) was inserted and the patients received 20 ml /kg of Ringer's lactate solution. Pulse rate, blood pressure, rate of respiration were recorded before spinal anaesthesia. Under all aseptic precautions, lumbar puncture was performed with 25 gauge Quincke's needle in the L3-L4 space with the patient in the left lateral position. Patients were infiltrated with 2% plain lignocaine before lumbar puncture, followed by injection of drugs intrathecally as per the assignment. Immediately after the block, each patient was placed with a 10 cm wedge under the right hip.

All patients received supplementation of oxygen at 5 litres/minute via Hudson's mask. For the first 30 minutes, pulse and blood pressure were measured every 2 minutes and thereafter it was measured every 5 minutes followed by measurements at 30 minutes interval. SPo2 was monitored continuously. If the systolic blood pressure fell below 90 mm Hg, additional vasopressor support was given with an incremental dose of ephedrine. If bradycardia occurred, 0.6 mg of atropine was given intravenously. The onset and duration of sensory block and motor block were assessed. The time taken from the intrathecal injection to the highest level of sensory block was recorded. The degree of motor block was assessed using the Bromage scale. The duration of complete analgesia was assessed from the time of injection to the first report of pain. APGAR scores were also recorded at 1 and 5 minutes after delivery of the baby.

Statistical Analysis

The data was entered in Microsoft Office Excel 2007 and IBM SPSS version 21 was used for analysis. Student t-test was used to find if there was any statistically significant difference between two groups.

Results

Table 1: Baseline characteristics of the study population.

Baseline Characteristics	Group A (Bupivacaine)	Group B (Bupivacaine and Fentanyl)	P Value
Age	25.25 ± 2.92	25.15 ± 2.41	0.45
Height	151.25 ± 2.88	152.05 ± 1.65	0.29
Weight	61.50 ± 9.78	61.65 ± 6.78	0.48
APGAR Score	9 ± 0	9 ± 0	-

Table 2: Baseline hemodynamic parameters of the study population.

Hemodynamic Parameters	Group A (Bupivacaine)	Group B (Bupivacaine and Fentanyl)	P Value
HR	84.70 ± 7.12	83 ± 8.54	0.25
SBP	108.90 ± 9.00	108.70 ± 7.98	0.47
DBP	65.55 ±9.62	64.55 ±9.36	0.37
MBP	79.35 ±8.20	78.50 ±7.94	0.38
RR	16.60 ±1.46	16.80 ±1.64	0.34

Table 1 shows the demographic data of the study population. The mean age of the study population in Group A was 25.25 and it was 25.15 in Group B.

Table 3: Characteristics of sensory, motor block and regression time.

Characteristics	Group A (Bupi vacaine)	Group B (Bupivacaine and Fentanyl)	T Value	P-Value
Onset of sensory analgesia at T10 (min)	1.85 ± 0.5	1.75 ± 0.35	1.159	0.249
Time to achieve highest level of sensory analgesia (min)	6.75 ± 0.81	6.22 ± 0.72	3.458	0.0008*
Time for two segments regression	87.72 ± 15.23	112.54 ± 35.42	4.552	<0.0001*
Onset of grade III motor block	3.15 ± 0.34	2.56 ± 0.51	6.806	<0.0001*
Total duration of grade III motor block	108.89 ± 15.46	111.78 ± 29.67	0.611	0.543
Duration of complete analgesia	181.25 ±17.61	191.75 ±19.55	2.822	0.0058*

Table 4: Complications in the study population.

Complications	Group A	Group B	P Value
Hypotension	21(42%)	15 (30%)	0.2113
Bradycardia	19 (38%)	12 (24%)	0.1301
Nausea and vomiting	10 (20%)	4 (8%)	0.0373*

There was no statistically significant difference in the age groups between the study population. Similarly, there was no significant difference between the groups in terms of height and weight

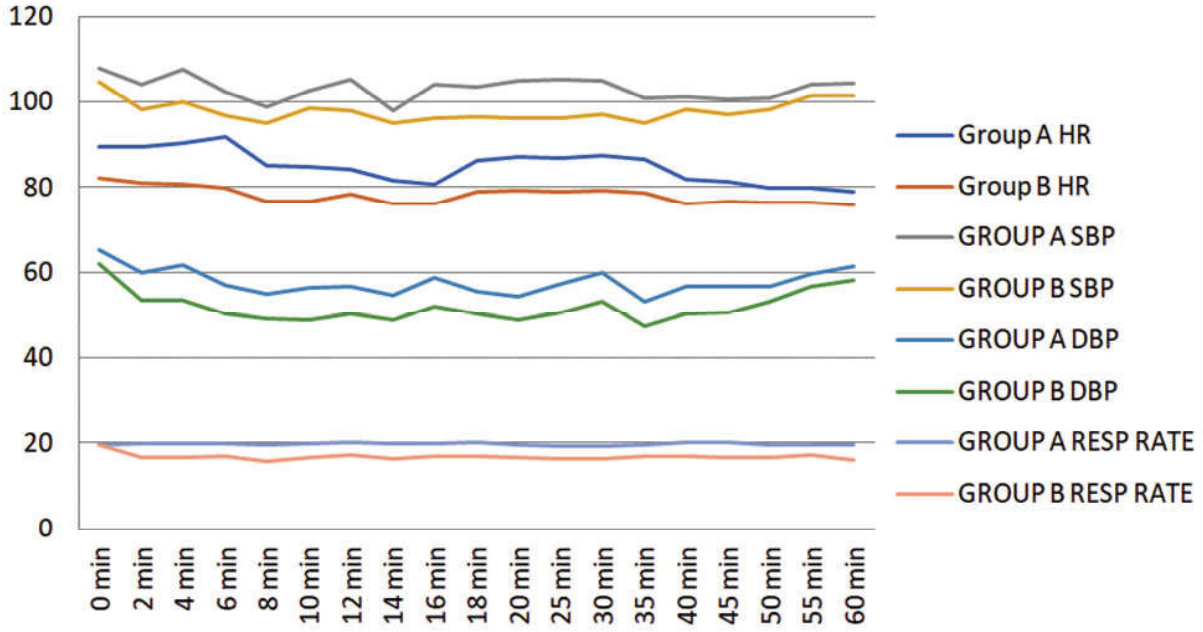

Fig. 1: Changes in hemodynamic parameters over a period of time.

of the population. Table 2 shows the baseline hemodynamic parameters in both groups. There was no statistically significant difference in hemodynamic parameters between the two groups.

The onset of sensory analgesia at T10 was compared and it was found that there was no statistically significant difference between both the groups. But time taken to achieve the highest level of sensory analgesia and for two-segment regression was significantly prolonged in the group which received bupivacaine and fentanyl.

The time taken to achieve grade 3 motor block was earlier in the group which received both bupivacaine and fentanyl when compared to the group which received only plain bupivacaine. The mean onset of motor block was 3.15 minutes in the group that received only bupivacaine, whereas it was 2.56 minutes in the group that received both fentanyl and bupivacaine. This difference was found to be statistically significant. There was no statistically significant difference in the mean total duration of the grade 3 motor block (Table 3). The quality of intraoperative surgical anaesthesia was significantly better with bupivacaine and fentanyl as no patient complained of discomfort during the intraoperative period and the total duration of analgesia was also longer in this group.

The changes in hemodynamic parameters are shown in Figure 1. Hemodynamic stability was more among the group which received bupivacaine and fentanyl when compared to the group which received only bupivacaine. In the group which received bupivacaine and fentanyl, only 15 (30%) patients required ephedrine whereas 21 (42%) patients required ephedrine in the group that received only bupivacaine. This indicates that hypotension was more common in Group A.

Hypotension, bradycardia, nausea and vomiting were the most common side effects that were noted. Nausea and vomiting (20%) were more common in the group which received plain bupivacaine and this was found to be statistically significant.

Discussion

Recently regional anaesthesia is found to be more popular among obstetric anaesthetists when compared to general anaesthesia owing to the lesser side effects. The use of neuraxial opioids has increased as they improve the quality of intraoperative analgesia produced by local anaesthetics. They tend to bind to spinal opiate receptors and thus prolong the duration of analgesia. Fentanyl and other opioids administered in the subarachnoid space act primarily on the μ receptors in the substantia gelatinosa of the dorsal horn of the spinal cord by suppressing excitatory neuropeptide release from c fibers.[11] The combination of local anaesthetic with an opioid allows for a reduction in doses of both the drugs and also the side effects associated with both.

However regional anaesthesia is not without risks. Despite the lower abdominal incision, a T4 sensory dermatome level is required to prevent referred pain from traction on the peritoneum and the uterus.[12] The type and dose of local anaesthetic used in spinal anaesthesia must include consideration of the level of anaesthesia desired, duration of surgery, postoperative analgesia and preference of the anaesthesiologist. In the present study, it was decided to compare the effects of the traditional choice of hyperbaric bupivacaine (0.5%) with a mixture of fentanyl and bupivacaine on maternal hemodynamics, level of sensory blockade and duration of complete analgesia.

Hemodynamically, Group B was found to be more stable as this group required less ephedrine to treat hypotension. These findings are consistent with the studies done by Sivevski et al.[13] and Ben David et al.[14] The mean time of onset of sensory block in group A was 1.85 minutes while it was 1.75 minutes in group B and the difference was not statistically significant. These results are concurrent with other studies done by Belzarena SD,15 Biswas BN et al.[16] and Hunt CO et al.[12] The highest sensory level was achieved at 6.75 minutes in Group A and 6.22 minutes in Group B and this difference was statistically significant. The findings are similar to a study done by Uike S et al.[17]

The reasons for rapid action in bupivacaine could be high lipid solubility and greater affinity for μ receptors.[18] The time for two-segment regression was much lesser in the bupivacaine group when compared to the group which received bupivacaine and fentany.[1] Similar findings were observed in studies conducted by Biswas et al.[16] and Benhamou D et al.[8] The onset of grade III motor block was faster with bupivacaine and fentanyl. Similar findings were found in a study done by Uike S et al.[17] The total duration of motor block and duration of complete analgesia were also much longer in the group which received bupivacaine with fentanyl. Findings in this study with respect to duration of analgesia and motor block were similar to those observed in the study conducted by Uike S et al.[17]

In the present study, it was seen that nausea and vomiting were less common in the group which received bupivacaine with fentany.[1] Similar

findings were found in the study conducted by Manullang T et al.[19] and Dahlgren G et al.[20] This reveals that the combination would allow for less antiemetic usage.

Conclusion

It can be concluded that intrathecal fentanyl as an adjuvant to intrathecal hyperbaric bupivacaine (0.5%) in a dose of 12.5 µg-provides significant prolongation of the duration of sensory block and effective analgesia with significantly decreased need for antiemetics. Thus, the use of intrathecal fentanyl in a dose of 12.5 µg will help in producing excellent quality of analgesia and prolong the duration of analgesia also with a single injection and with no adverse effect on the mother.

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