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Comparative study between intrathecal bupivacaine versus intrathecal bupivacaine and fentanyl in elective caesarean sections

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Abstract---Background: Intrathecal administration of adjuvant drugs have been used increasingly for increasing the onset, duration and quality of analgesia. This study was designed to compare the efficacy of intrathecal hyperbaric bupivacaine with that of intrathecal hyperbaric bupivacaine with fentanyl for patients undergoing elective caesarean sections. Materials & methods: 50 aged between 15 to 30 years, whose weight is 45 to 80 kg, belonging to ASA class I and II, scheduled for elective caesarean sections were selected and randomized into 2 groups. Group B received 9mg of hyperbaric bupivacaine 0.5% and group BF received 9mg of hyperbaric bupivacaine 0.5% with 10mcg of fentanyl. The onset of analgesia, onset of motor blockade, the duration of sensory blockade, the duration motor blockade, the quality of blockade, duration of analgesia, Intrathecal Injection to delivery time, APGAR SCORE of neonates, hemodynamic parameters of parturient and side effects were recorded. Results: There was significant difference between the two groups in the meantime to onset of sensory anaesthesia (group BF 3.28±0.73mins, group B 3.84±1.06mins; p value=0.009). The onset of motor blockade was similar in both the groups. Excellent block was achieved in 80% patients in group B compared to 100% of patients in group BF. There was significant difference in mean duration of motor blockade between the groups (Group BF 136.8±9, Group B 110.40±4.31; p value=0.0000). The mean duration of analgesia was 180.4±1.09mins in group BF and 124.8±5.49mins in group B, which was statistically significant (p= 0.0001). The Intrathecal Injection to delivery time, APGAR SCORE of neonate were same in both the groups. Hemodynamic parameters were stable in both the groups.

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Side effects observed in both the groups were minimal and easily treatable. Conclusion: Addition of fentanyl 10mcg to intrathecal hyperbaric bupivacaine 0.5%(9mg) hastens onset of analgesia prolongs the duration of sensory block, duration of motor block, total duration of analgesia and improves the quality of block with minimal side effects.

Keywords---fentanyl, bupivacaine, intrathecal.

Introduction

Type of anaesthesia for caesarean section depends on the indication for the operation, the degree of urgency, the desires of the patient and the judgement of anaesthesiologist. Caesarean section can be done under general anaesthesia or regional anaesthesia, each of the technique having its own merits and demerits. General anaesthesia for caesarean section of late is becoming obsolete for various reasons. Recently regional anaesthesia is gaining popularity due to absence or minimal biochemical and metabolic changes. Epidural or spinal anaesthesia can be used for caesarean section. Spinal anaesthesia has many advantages over epidural anaesthesia. Spinal anaesthesia consists of temporary interruption of nerve transmission within the subarachnoid space produced by injection of a local anaesthetic solution into cerebrospinal fluid. Subarachnoid block allows the patient to remain awake, minimizes or completely avoids the problem associated with airway management. The technique is easier to perform[1]. Spinal block uses a small dose of anaesthetic and offers a rapid onset of action, gives reliable surgical analgesia and good muscle relaxation allowing the surgical incision to be made sooner and producing a shorter total operating room time.[2] It produces more profound block than epidural anaesthesia and the need for supplementary intravenous analgesics and anxiolytics is decreased. Because the dose of local anaesthetic used with spinal anaesthesia is small, there is little chance of maternal toxicity and very minimal placental transfer of drug to fetus.

Safe practice of spinal anaesthesia includes properly selecting and preparing the patient, accessing the cerebrospinal fluid, administering appropriate anaesthetic drugs and adjuvants, managing physiologic side effects and overseeing the patient throughout the procedure as well as in the early recovery period. The provision of effective anaesthesia during the procedure and postoperative analgesia is still evolving and getting fine-tuned in the specialty of anaesthesia. One of the primary aims of anaesthesia is to provide analgesia during the surgical procedure. However, a patient problem with pain does not end with surgical procedures. Pain during postoperative period is a cause of concern not only for the patient but also for the surgeon and the anaesthesiologists. Spinal anaesthesia with hyperbaric bupivacaine 0.5% is a popular method. The advantages of subarachnoid block are sometimes offset by a relatively short duration of action and complaints of postoperative pain when it wears off. There is a need for increasing the duration of analgesia without increasing the duration of motor blockade, thus prolonging postoperative analgesia, reducing postoperative analgesic requirements, facilitating early

ambulation, thereby resulting in early discharge of the patient. In order to do that, number of adjuvants have been added to spinal anaesthetics. The addition of opioid, fentanyl to hyperbaric bupivacaine hydrochloride has been suggested as one such method to accomplish these goals. Therefore, this study is designed to compare the analgesic effects of intrathecal hyperbaric bupivacaine with fentanyl and intrathecal hyperbaric bupivacaine alone in patients undergoing elective caesarean sections,

Aims and Objectives

The study is aimed at comparing the efficacy of 9mg of intrathecal hyperbaric bupivacaine 0.5% and a combination of 9mg of intrathecal hyperbaric bupivacaine 0.5% and fentanyl 10mcg in patients undergoing elective caesarean sections.

Materials and Methods

50 patients undergoing elective caesarean sections under spinal anaesthesia at Fathima Institute of Medical Sciences, Kadapa, Andhra Pradesh, were included in the study. The study was undertaken in the Department of Anaesthesiology during the period of 2019-2021. The study was carried out after obtaining the approval of the hospital ethics committee.

Inclusion criteria

- Patients aged between 15 and 30 years.
- Patients weighing 45-80 kg.
- Patents belonging to ASA grade I and II.
- Patients scheduled for elective caesarean sections.

Exclusion criteria

- Any contraindication to regional anaesthesia.
- Pregnancy induced hypertension.
- Severe anaemia.
- Eclamptic patients.
- Patients with coagulation abnormalities.
- Maternal haemorrhage.
- Labouring parturient.
- Foetal distress.

Method

50 patients were randomly divided into 2 groups, 25 each.

- GROUP I:
  25 patients received 9mg of hyperbaric bupivacaine 0.5% within a single shot intrathecally and these patients were named as group B.
- GROUP II:

25 patients received 9mg of hyperbaric bupivacaine 0.5% with Fentanyl 10mcg in a single shot intrathecally and these patients were named as group BF.

Statistical analysis

Student t test was used to test the significance of mean values between the two groups. Chi square test was used to test the significance of proportions. The statistical software namely EPI INFO was used for the analysis of data. Microsoft Word and Excel were used to generate graphs, tables and master chart.

Results

A comparative study consisting of 2 groups with 25 patients in group B (Bupivacaine) and 25 patients in group BF (Bupivacaine with Fentanyl) is undertaken to evaluate the effect of drugs on the onset of analgesia, onset of motor blockade, quality of block, duration of motor blockade, duration of analgesia and haemodynamic. Any significant adverse effects were also noted.

Table 1
Showing distribution of Age & weight

Age in years	GROUP-B	GROUP-BF
15-20	5	6
21-25	19	14
26-30	1	5
MEAN + SD	22.20 + 2.00	22.52 + 2.94
Weight in Kgs	GROUP-B	GROUP-BF
45-50	6	5
51-55	12	14
56-60	4	5
61-65	3	1
MEAN + SD	53.40+0.54	53.52+4.273

The above table shows the age and weight distribution among the two groups. Both the groups were comparable with respect to age and weight distribution. P value of age is 0.1725 (nonsignificant). P value of weight is 0.7159 (nonsignificant).

Table 2
Showing Onset of sensory block in minutes

TIME IN MINUTES	GROUP-B	GROUP-BF
0-1	0	0
1-2	3	4
2-3	7	10
3-4	6	11
4-5	9	0
5-6	0	0

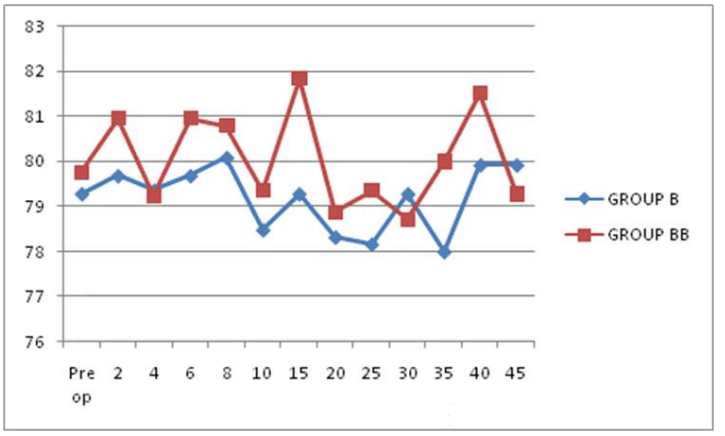
MEAN + SD	3.840 + 1.068	3.280 + 0.737

The above table shows onset of sensory analgesia in both groups in minutes. In group B, the mean onset of analgesia is 3.840 + 1.068 minutes. In group BF, the mean onset of analgesia is 3.280 + 0.737 minutes. The difference in mean onset of sensory analgesia between the two groups is highly statistically significant as p value is 0.009.

Table 3
Onset of motor block in minutes

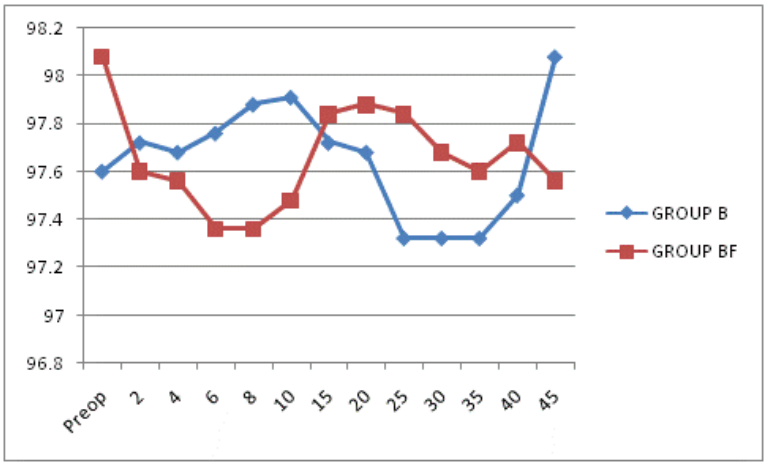
TIME IN MINUTES	GROUP-B	GROUP-BF
0-1	0	0
1-2	0	0
2-3	3	0
3-4	7	10
4-5	6	11
5-6	9	4
MEAN + SD	4.84 + 1.068	4.760 + 0.723

Table 3 shows mean onset of motor blockade of both groups in minutes. The mean onset of motor blockade in group B is 4.84 + 1.068 minutes and 4.760 + 0.723 minutes in group BF. The difference in mean onset of motor blockade between the two groups is statistically not significant as p value is 0.074.



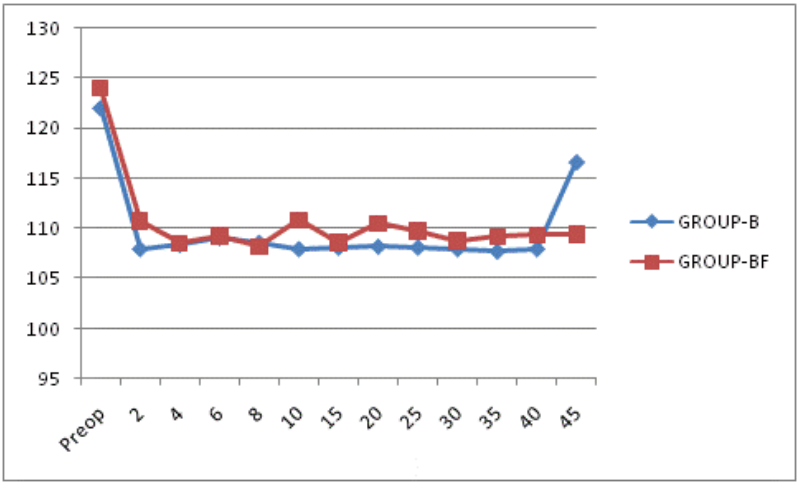
Graph 1. showing Heart rate of patients in both the groups

Graph 1 shows heart rate at various intervals in both the groups. There is no significant variation in the heart rate in the two groups.



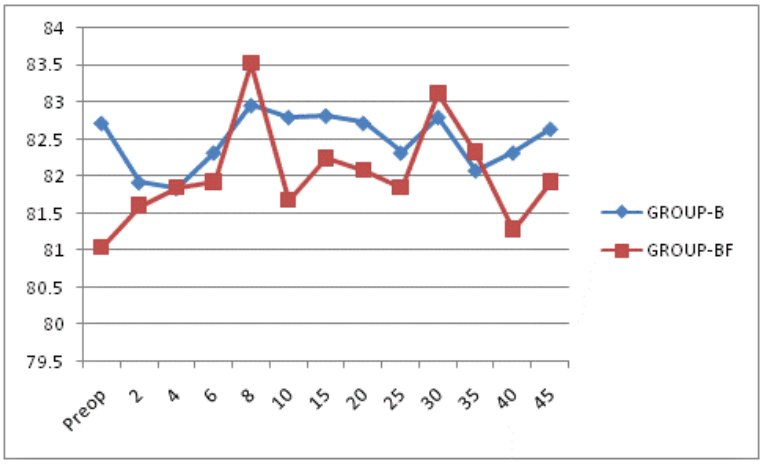
Graph 2. SpO2 of patients in both the groups

The above graph shows SpO2 at various intervals in both the groups. There is no significant variation in the SpO2 in the two groups.



Graph 3. Systolic BP of patients in both the groups(mmHg)

The above graph shows systolic BP at various intervals in both the groups. There is no significant variation in the systolic BP in the two groups.



Graph 4. Diastolic BP of patients in both the groups(mmHg)

The above graphs shows Diastolic BP at various intervals in both the groups. There is no significant variation in the diastolic BP in the two groups.

Discussion

The results of the present clinical study are discussed under the following headings: The patients studied across the groups did not vary much with respect to age and weight.

Onset of analgesia

There is a close relationship between lipid solubility and onset of analgesia. Fentanyl being a highly lipid soluble opioid has faster onset of action. In the present study, the mean time taken for the onset of analgesia in group B was 3.840 + 1.068 minutes compared to
3.280 + 0.737minutes in group BF. The difference in the mean onset of analgesia between the two groups was statistically significant.

Onset and duration of motor blockade

In our present study the onset of motor blockade in group B and group BF was 4.84+1.068min and 4.68±0.723min respectively. The difference in the mean onset of analgesia between the two groups was statistically not significant. Dahlgren et al (1993) in their study concluded that addition of fentanyl to hyperbaric bupivacaine resulted in similar times for onset of motor block in two groups[3]. So the present study results are correlating with above study results.

Quality of block

All the patients (100%) in group BF had excellent block compared to 80% of patients in group B. Hunt Co et al (1989), in their study concluded that addition of fentanyl 6.25-50mcg to 10.5mg hyperbaric bupivacaine in spinal anaesthesia reduced the intraoperative need for supplement IV analgesics from 67% to 0%

during caesarean section[4]. So the present study results are correlating with above study results.

Duration of sensory block

In our present study the duration of sensory blockade in group B and group BF was 120.80+7.594min and 125.60±5.831min respectively. The difference in the mean duration of sensory block between the two groups was statistically significant. Dahlgren et al(1997) in their study concluded that addition of fentanyl to hyperbaric bupivacaine resulted in prolongation of duration of sensory anaesthesia in caesarean section[5]. Dahl JB et al(1999) in their study concluded that addition of morphine, fentanyl, sufentanil and fentanyl to hyperbaric bupivacaine resulted in prolongation of duration of sensory anaesthesia in caesarean section[6]. So the present study results are correlating with above study results.

Duration of motor block

In our present study the duration of motor blockade in group B and group BF was 110. 80+4.311min and 136.8±9min respectively. The difference in the mean duration of motor block between the two groups was statistically significant. Bogra et al (2005) in their study concluded that addition of fentanyl to hyperbaric bupivacaine resulted in prolongation of duration of motor block in caesarean section[7]. So the present study results are correlating with above study.

Total duration of analgesia

In our study the duration of analgesia was significantly prolonged in bupivacaine with Fentanyl group (180.4±1.098 min) compared to bupivacaine group (124.8±5.492min). Dahl JB et al (1999) in their study concluded that addition of morphine, fentanyl, sufentanil and fentanyl to hyperbaric bupivacaine resulted in prolongation of duration of sensory anaesthesia in cesarean section. Fentanyl group had median total duration of analgesia 4 hrs(range 2-13). Dahlgren et al (1997) in their study concluded that addition of fentanyl to hyperbaric bupivacaine resulted in prolongation of duration of sensory anaesthesia in cesarean section. Ben. David et al[8] and H. Singh et al[9] in their studies observed that total sensory recovery time was prolonged up to 140 minutes and 146 minutes in Fentanyl groups. Catherin O. Hunt et al[10] and Varrasi et al[11] found that intrathecal Fentanyl increases mean duration of postoperative analgesia. Addition of opioid to low dose of Bupivacaine is expected to provide good surgical anesthesia and extended period of analgesia[12,9,13].

Idowu OA, Sanusi AA, Eyelade OR[14] from Department of Anaesthesia, University College Hospital, Ibadan, Oyo State, Nigeria studied addition of 25 microg of fentanyl to 2.5 mls of 0.5% hyperbaric bupivacaine intrathecally on sixty healthy women of American Society of Anaesthesiologist (ASA) physical status I scheduled for elective Caesarean section at the UCH, Ibadan. Patients were randomized to group B, n=30 and group FB, n=30. Maternal heart rate, blood pressure, respiratory rate, sensory level, motor block, pain score (NRS) and side effects were observed every 2 minutes for first 15 minutes, then at 5 minutes interval for the

remainder of the operation. Thereafter at 30 minutes interval until the first complaint of pain and concluded that complete analgesia (time from injection of intrathecal drug to first report of pain) lasted longer in group FB (240 +/- 29 minutes) than group B (99 +/- 12 minutes) with a p-value of 0.002. The duration of effective analgesia (time from injection of intrathecal drug to first request for analgesic) in group FB (276 +/- 26 minutes) while group B was (121 +/- 10 minutes) with a p-value of 0.001. Both were statistically significant.

Siddik-Sayyid SM, Aouad MT, Jalbout MI, Zalaket MI, Berzina CE, Baraka AS[15] from Department of Anesthesiology, Medical Center, American University of Beirut, Beirut, Lebanon. Forty-eight healthy parturients scheduled for elective cesarean delivery were randomly allocated to receive intrathecally either 12 mg of hyperbaric bupivacaine plus 12.5 microg of fentanyl (n = 23) or bupivacaine alone (n = 25). In the latter group, IV 12.5 microg of fentanyl was administered immediately after spinal anesthesia. We compared the amount of IV fentanyl required for supplementation of the spinal anesthesia during surgery, the intraoperative visual analog scale, the time to the first request for postoperative analgesia, and the incidence of adverse effects. Additional IV fentanyl supplementation amounting to a mean of 32 +/- 35 microg was required in the IV Fentanyl group, whereas no supple- mentation was required in the Intrathecal Fentanyl group (P = 0.009). The time to the first request for postoperative analgesia was significantly longer in the Intrathecal Fentanyl group than in the IV Fentanyl group (159 +/- 39 min versus 119 +/- 44 min; P = 0.003). The incidence of systolic blood pressure <90 mm Hg and the ephedrine requirements were significantly higher in the IV Fentanyl group as compared with the Intrathecal Fentanyl group (P = 0.01). Also, intraoperative nausea and vomiting occurred less frequently in the Intrathecal Fentanyl group compared with the IV Fentanyl group (8 of 23 vs 17 of 25; P = 0.02) and concluded that Supplementation of spinal bupivacaine anesthesia for cesarean delivery with intrathecal fentanyl provides a better quality of anesthesia and is associated with a decreased incidence of side effects as compared with supplementation with the same dose of IV fentanyl.

Intrathecal Injection to Delivery Interval in minutes

Intrathecal Injection to Delivery Interval is same in two groups. Dahlgren et al (1997) in their study concluded that addition of fentanyl to bupivacaine for cesarean section does not result in prolongation of intrathecal injection to delivery interval[5]. The present study results are correlating with above study results.

Apgar Score

In the present study APGAR scores at 1 minute and 5 minutes are same in two groups. Dahlgren et al (1997) in their study reported that APGAR SCORE was same in all patients who received fentanyl and placebo. Bogra et al(2005) in their study concluded that addition of fentanyl to bupivacaine for cesarean section didn't result in low APGAR scores[7]. The present study results are correlating with above study results.

Hemodynamic parameters

The hemodynamic parameters of our patients were found to be stable throughout the intraoperative period. In group BB and group B, the mean heart rate, SpO2, SBP, DBP were comparable with no significant difference between the groups. Kristiina S et al[16] in their study found no incidence of bradycardia during intra operative period. Their finding correlates with our study results. Catherin O. Hunt et at[10] in 1987 evaluated the effect of different doses of intrathecal Fentanyl with Bupivacaine 10 mg and found no significant changes in hemodynamic status.

Side effects

The side effects observed were minimal and easily treatable in both the groups. In bupivacaine with fentanyl group the side effects were nausea, vomiting, hypotension, and in bupivacaine group nausea and hypotension were the side effects.

Conclusion

We conclude that onset of analgesia was significantly hastened by addition of fentanyl to bupivacaine. The onset of motor blockade was not significantly altered with the addition of fentanyl to bupivacaine. The duration of sensory blockade, motor blockade, Duration of analgesia was significantly prolonged with addition of fentanyl to bupivacaine. Quality of postoperative analgesia was excellent with addition of fentanyl to bupivacaine. Hemodynamic parameters were stable in both the groups. Side effects observed were minimal and easily treatable in both the groups. With all the above observations we conclude that addition of fentanyl to intrathecal bupivacaine provides faster onset of analgesia, prolonged duration of analgesia, excellent quality of analgesia with minimal side effects compared to intrathecal bupivacaine alone for elective caesarean sections.

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