

# A Prospective Randomized Study to Compare the Hemodynamic Effects of Two Different Intrathecal Doses of Hyperbaric Bupivacaine using Buprenorphine as an Adjuvant in Patients Undergoing Caesarean Section

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## ABSTRACT

**Introduction:** Spinal anesthesia is routinely employed for caesarean sections. The major drawback of spinal anesthesia is hypotension. This study was undertaken to compare the effects of dose 10mg hyperbaric Bupivacaine versus a lower dose of 8mg hyperbaric bupivacaine with 60mcg buprenorphine on sensory, motor and hemodynamic parameters in patients undergoing caesarean section.

**Material and methods:** 70 pregnant women of term gestation, ASA grade II scheduled for elective caesarean section, were randomly allocated into two groups of 35 patients. Women in group A received 10 mg of 0.5% hyperbaric bupivacaine (2ml) while women in group B received 8 mg of 0.5% hyperbaric bupivacaine (1.6 ml), 60mcg of buprenorphine with 0.2 ml normal saline, a total of 2ml. Vital signs, sensory level, motor block, pain score and side-effects were noted until the patient complained of pain. Sensory parameters were not evaluated after rescue analgesia was given while motor parameters were monitored until complete motor recovery was present.

**Result:** While group A took longer to achieve highest level of sensory analgesia; group B took longer for 2 segment sensory regression of block and also had a prolonged duration of sensory analgesia. Moreover, group B patients had a faster recovery from motor block and better hemodynamic parameters like lesser incidence of hypotension and tachycardia. On the other hand, patients in group A had higher incidence of hypotension, thus, had higher vasopressor requirement. No change in time of onset of motor block or the quality of block was observed between two groups.

**Conclusion:** We conclude that reducing the dose of bupivacaine to 8mg and adding buprenorphine 60mcg gives adequate anesthesia in cesarean section with good hemodynamic stability, early motor recovery, early discharge, minimal side effects with good maternal satisfaction and fetal well-being.

**Keywords:** Spinal Anesthesia; Hyperbaric Bupivacaine; Caesarean Section; Intra Operative Hypotension; Intrathecal Buprenorphine.

## INTRODUCTION

Regional anesthesia is a major factor in patient safety during Caesarean delivery.<sup>1</sup> Although various factors influence the appropriate sensory nerve block for surgical anesthesia, the local anesthetic dose is the main determinant of its success.<sup>2</sup> Anesthesia textbooks recommend bupivacaine in a dose of 12 to 15 mg.<sup>3,4</sup> However, the use of this dose range has been associated with increased incidence of maternal arterial hypotension of 69% to 80%, resulting in maternal

and neonatal morbidity.<sup>5</sup> Maternal hypotension may lead to reduction in utero-placental perfusion resulting in fetal acid-base abnormalities. Studies have produced dissimilar findings with doses ranging from 5mg to 20mg.<sup>6,7</sup>

The use of a lower dose aims to decrease maternal side effects (hypotension, intra-operative nausea/vomiting), reduce the time to discharge from the post anesthesia care unit and to lessen use of vasopressor drugs.<sup>6</sup> Administration of excessively low doses of bupivacaine may decrease the episodes of low blood pressure but also increase the risk of intra-operative pain<sup>6</sup> and may, thus, increase the need of conversion to general anesthesia. Narcotics have been used in combination with local anesthetics in subarachnoid block for intra and postoperative analgesia in caesarean section.

Lanz et al<sup>8</sup> demonstrated that buprenorphine, a mu receptor agonist with low intrinsic activity, is compatible with CSF and can be administered safely in the subarachnoid space.<sup>9</sup> Intrathecal buprenorphine is a suitable drug for postoperative analgesia after caesarean section with no effects on neonatal APGAR scores.<sup>10</sup> Large doses of intrathecal bupivacaine were associated with severe hypotension and delayed recovery of motor block.<sup>11</sup>

Studies show that despite crystalloid preloading and ephedrine 20 mg given prophylactically by the intra muscular route, hypotension occurred in more than 50% of the patients, regardless of the baricity used.<sup>12</sup>

## MATERIAL AND METHODS

This study included 70 patients posted for elective caesarean section, randomly divided in two groups of 35 patients each. All were term gestation (38weeks to 40 weeks), height

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between 158cm – 165 cm, weight between 55kg to 65 kg and did not have any associated medical Co-morbidity. Standard ASA fasting guidelines were followed.

Patients not giving consent, having any medical problem, allergic to any drug used in the study or having active infection at injection site were excluded from study.

A detailed pre-anesthetic evaluation was done. Written informed consent was taken and relevant laboratory investigations were done for all patients. Patients were explained about the procedure, study and details of the VAS score, pre-operatively. In the operation theatre, an intravenous line was inserted; monitoring included ECG, blood pressure and saturation by pulse oximeter. Baseline vital parameters were noted like heart rate, respiratory rate, peripheral oxygen saturation and systolic blood pressure. Preloading was done with 15ml/kg Ringer's lactate solution. Spinal anesthesia was administered in the left-lateral position in L3-L4 or L4-L5 interspace using a 27G Quincke's spinal needle under all aseptic precautions. Patients were either given 0.5% hyperbaric bupivacaine 10 mg alone or 0.5% hyperbaric bupivacaine 8 mg with 60 mcg buprenorphine and 0.2ml saline. Once free flow of CSF was achieved, the drugs were injected slowly over 10sec. Sensory block was assessed by pin prick method. Operation was allowed to commence when a level of T6 was achieved. All patients received oxygen supplementation (4 liters per minute) via Hudson mask. After delivery of the baby, all parturients received oxytocin 15IU by continuous infusion. The attending pediatrician assessed the neonatal APGAR scores at 1 & 5 minutes after delivery of the baby.

All the patients were assessed for:

1. Time of onset of sensory analgesia up to T10 (TOSA T10) dermatome assessed by pinprick method.
2. Time taken to achieve highest level of sensory analgesia (TTAHLA) assessed by pinprick method.
3. Quality of sensory blockade assessed by pinprick method.
  - a. Time of two segment regression (TTSR)
  - b. Time of sensory regression to L1 (TSR to L1)
  - c. Total duration of sensory analgesia (after spinal injection till patient demands rescue analgesia) (TDSA)
4. Quality of motor blockade was assessed using the modified Bromage score
  - a. Time of onset of motor blockade (TOMB)
  - b. Quality of motor blockade in Bromage Scale (QMBBS)
  - c. Duration of motor blockade - time interval from the onset of motor blockade to complete recovery

(Bromage 0) (TCMR)

Intra-operatively, pulse rate, systolic blood pressure and saturation were monitored every 2 minutes for first 10minutes; every 15minutes upto 1 hour and every 30 minutes thereafter till the sensory block regressed to L1. Any side effects like nausea, vomiting, pruritus, respiratory depression or prolonged sedation were noted. Pain was evaluated using a standard 10 cm visual analogue scale with 0 corresponding to no pain and 10 corresponding to the worst possible pain. The results obtained were presented in a tabulated manner and the corresponding P value was calculated. P value<0.05 was considered statistically significant. Alterations in the hemodynamic parameters such as hypotension and bradycardia were treated with injection Mephentermine in incremental doses of 3mg i.v. bolus and injection Atropine 0.6mg i.v. bolus, respectively. Rescue analgesia was given in the form of injection Diclofenac 75 mg i.v. was given when VAS score was greater than 4. Thereafter, the patient was not monitored for pain while monitoring for motor effects was continued until total motor recovery.

For the purpose of this study, hypotension was defined as systolic BP less than 100mmHg or fall in systolic BP more than 20% from the baseline, whichever occurred first.

## STATISTICAL ANALYSIS

The inter-group comparison of categorical variables was done using Chi-square test / Fisher's exact probability test. The statistical significance of inter-group difference of mean of continuous variables was tested using independent sample 't' test. The entire data was entered and cleaned in MS Excel before its statistical analysis. The p-values less than 0.05 were considered to be statistically significant. The entire data is statistically analyzed using Statistical Package for Social Sciences (SPSS version 15.0, Inc. Chicago, USA) for MS Windows.

## RESULT

There was no statistically significant difference between the two groups in demographic data i.e. age, gender, weight, height and ASA status.

The average pulse rate was significantly higher in Group A compared to Group B with a P value < 0.05 (graph 1).

The average systolic BP at 4-min, 6-min, 8-min, 10-min, 30-min, 45-min, 90-min after anaesthesia was significantly higher in Group B compared to Group A with a P value < 0.05 (graph 2).

The average 1 minute and 5 minutes APGAR scores did not differ significantly between the two groups; P value > 0.05 (graph 3).

A significantly higher number of parturients in Group A had

Fall in BP	Group A		Group B		P-value (Group A v Group B)
	n	%	n	%	
No	13	37.1	24	68.6	0.008**
Yes	22	62.9	11	31.4	
Total	35	100.0	35	100.0	

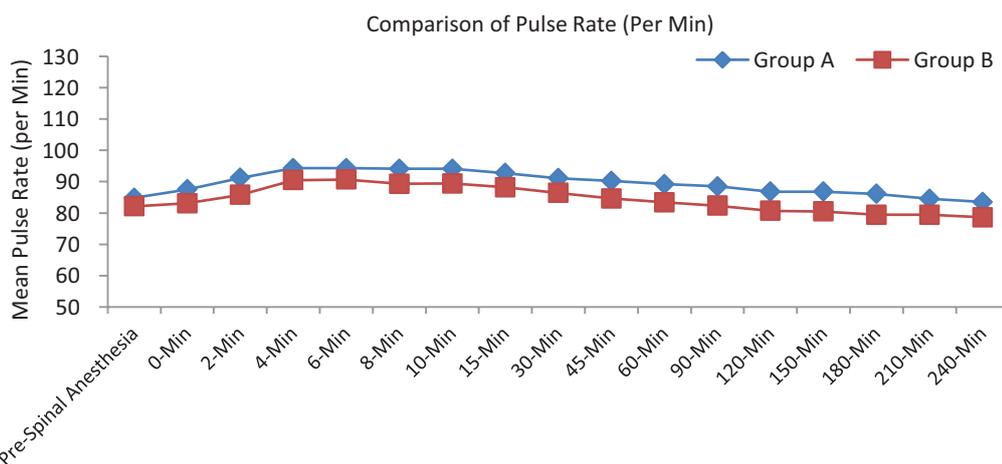
Table-1: Fall in blood pressure in each group

Sensory Effects (Minutes)	Group A [Bupivacaine (2mL)] (n=35)		Group B [Bupivacaine (1.6mL) + Buprenorphine + Saline] (n=35)		P-value (Group A v Group B)
	Mean	SD	Mean	SD	
TOSA to T10 (mins)	2.67	0.68	2.79	0.70	0.482 <sup>NS</sup>
TTAHLA (mins)	7.71	2.28	5.00	1.08	0.001 <sup>***</sup>
TTSR (mins)	91.63	7.56	97.31	10.24	0.010 <sup>**</sup>
TSR to L1 (mins)	130.31	8.22	134.77	8.39	0.028 <sup>*</sup>
TDSA (mins)	164.86	14.03	226.94	47.35	0.001 <sup>***</sup>

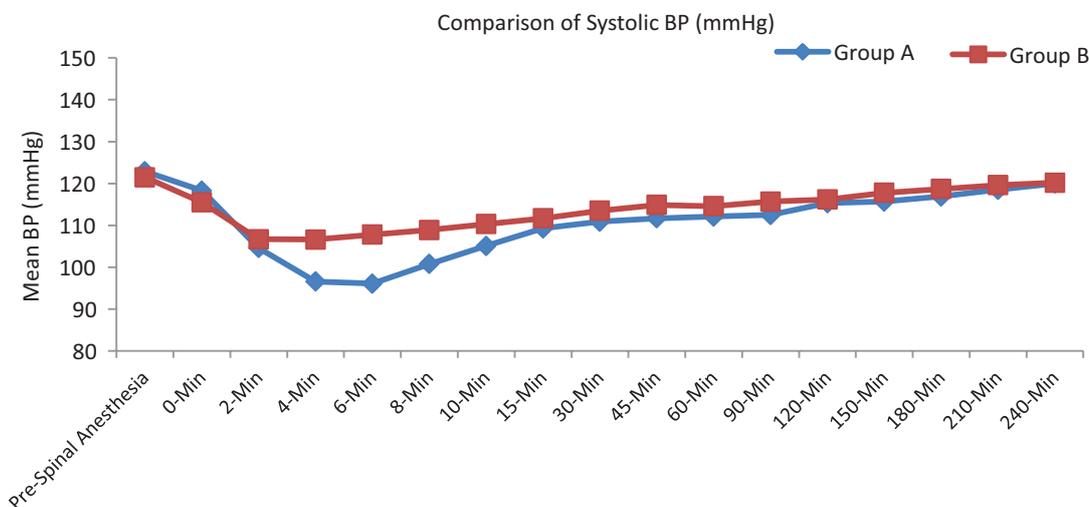
**Table-2:** Inter-group comparison of duration of sensory effects. Time of onset of sensory analgesia up to T10 (TOSA T10), time taken to achieve highest level of sensory analgesia (TTAHLA), time of two segment regression (TTSR), time of sensory regression to L1 (TSR to L1), total duration of sensory analgesia (TDSA).

Motor Effects (Minutes)	Group A [Bupivacaine (2mL)] (n=35)		Group B [Bupivacaine (1.6mL) + Buprenorphine + Saline] (n=35)		P-value (Group A v Group B)
	Mean	SD	Mean	SD	
TOMB (mins)	2.40	0.69	2.77	0.91	0.059 <sup>NS</sup>
QMBBS	3.00	0.00	3.00	0.00	0.999 <sup>NS</sup>
TCMR (mins)	131.80	11.77	94.00	12.76	0.001 <sup>***</sup>

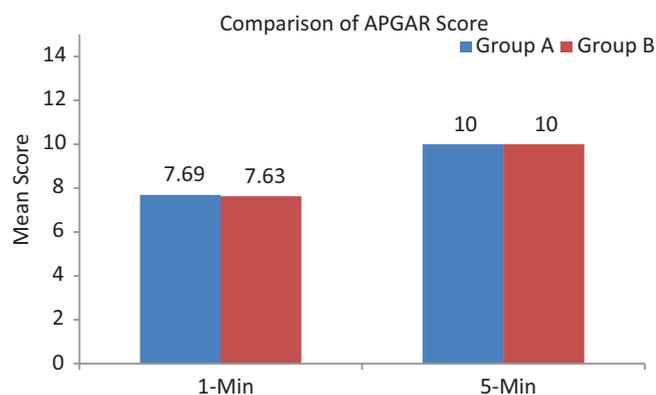
**Table-3:** The inter-group comparison of duration of motor effects. Time of onset of motor blockade (TOMB), quality of motor blockade in Bromage Scale (QMBBS), duration of motor blockade - time interval from the onset of motor blockade to complete recovery (Bromage 0) (TCMR)



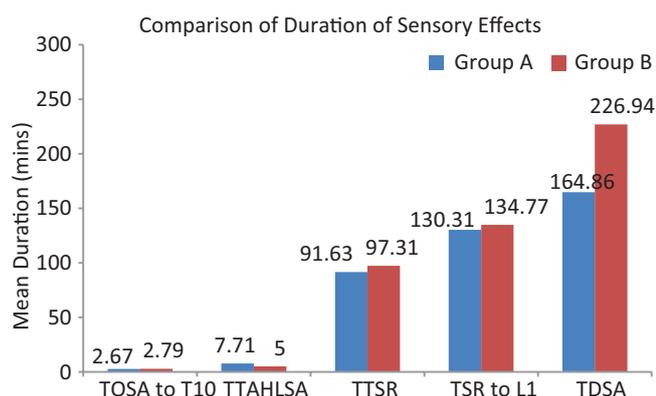
**Graph-1:** The inter-group comparison of pulse rate at different time intervals.



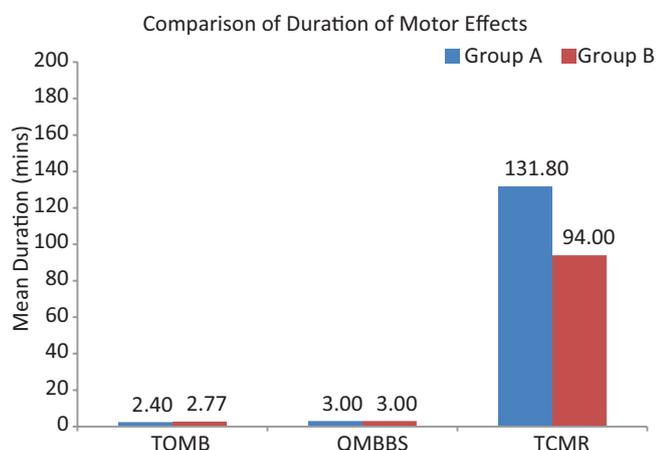
**Graph-2:** The inter-group comparison of systolic BP at different time intervals.



**Graph-3:** Inter-group comparison of APGAR score.



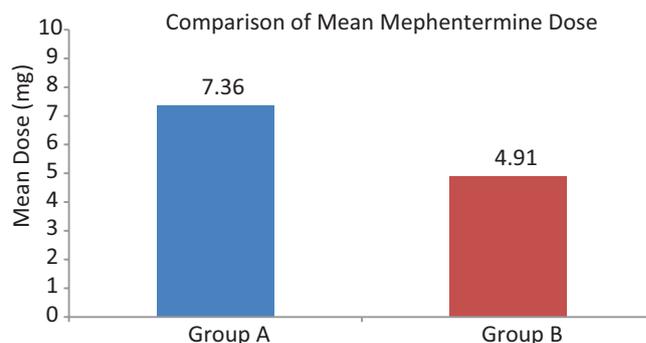
**Graph-4:** Inter-group comparison of duration of sensory effects. Time of onset of sensory analgesia up to T10 (TOSA T10), time taken to achieve highest level of sensory analgesia (TTAHLA), time of two segment regression (TTSR), time of sensory regression to L1 (TSR to L1), total duration of sensory analgesia (TDSA).



**Graph-5:** The inter-group comparison of duration of Motor effects. Time of onset of motor blockade (TOMB), quality of motor blockade in Bromage Scale (QMBBS), duration of motor blockade - time interval from the onset of motor blockade to complete recovery (Bromage 0) (TCMR)

fall in blood pressure compared to the parturients in Group B with a P value < 0.01 (Table 1).

The mean time of onset of sensory analgesia up to T10 (TOSA to T10) did not differ significantly between two intervention groups (P-value>0.05). The mean time taken to achieve highest level of sensory analgesia (TTAHLA) was



**Graph-6:** Inter-group comparison of amount of mephenetermine required.

significantly longer in Group A compared to Group B. On the other hand, the mean time for two segment regression (TTSR), mean time for regression to L1 (TSR to L1) and the duration of analgesia were significantly longer in Group B compared to Group A (table 2, graph 4).

The mean time of onset of motor blockade (TOMB) and quality of motor blockade in Bromage Scale (QMBBS) did not differ significantly between the two groups. The distribution of mean time for complete motor recovery (TCMR) is significantly higher in Group A compared to Group B (table 3, graph 5).

Vasopressor requirement was significantly higher in Group A compared to Group B; P-value < 0.01 (Graph 6).

## DISCUSSION

The advantages of spinal anesthesia include simplicity, easier to perform and has definitive end point. It is ideal in situations where rapid onset of action and profound motor blockade is required. In addition, it may also help to prevent complications due to polypharmacy, nausea, vomiting, deep vein thrombosis associated with delayed immobilization following general anesthesia. Opioid added to local anesthetic for spinal anesthesia were first introduced into clinical practice in 1979 with intrathecal Morphine as a forerunner. The use of neuraxial opioids has gained popularity over the last few years. They augment the analgesia produced by local anesthetics through direct binding with specific spinal receptors.

In the study by Rashmi Pal et al<sup>13</sup>, they used 15mg bupivacaine with either 75 mcg buprenorphine or 25 mcg fentanyl and found no change in onset of sensory analgesia with addition of either opioid.

Sunil Dixit et al.<sup>14</sup> used fentanyl as an adjuvant while Shashikala T et al.<sup>15</sup> used 60 mcg buprenorphine as an adjuvant in spinal anesthesia. Both studies concluded that that the onset of analgesia was significantly faster with the addition of an opioid.

Our findings are in concordance with the study done by Shashikala T.<sup>15</sup> in which the mean time taken to achieve the highest level of sensory was significantly quicker in the buprenorphine group.

With regards to time for two segment regressions and time to regression of sensory block to L1, our results were supported by the study done by Shashikala T et al<sup>15</sup>, both of which were

prolonged after the addition of an opioid to bupivacaine.

The present study was supported by study by Sunil Dixit.<sup>14</sup> which showed prolonged duration of analgesia when buprenorphine was added to bupivacaine.

Similar findings of prolonged pain free interval with use of opioid fentanyl were seen in the studies by Rabiee SM.<sup>16</sup> and Shashikala T.<sup>15</sup>

In concordance with the findings of Shashikala T et al.<sup>15</sup>, we found no difference in time to onset of motor blockade with the addition of an opioid.

Leo S et al.<sup>17</sup> found no difference in time taken for maximal motor block when bupivacaine dose was reduced from 9 mg to 7 mg. In our study, buprenorphine was used as an adjuvant in the group receiving lower doses of bupivacaine, even then there was no difference in onset time of maximal motor block.

In contrast to our study in which the quality of motor blockade was not affected by reducing the dose of local anesthetic; M. S. Mebazaa.<sup>18</sup> found that reducing the dose of bupivacaine from 10mg to 7.5mg leads to a statistically significant difference in the quality of motor blockade.

Our findings were supported by M. S. Mebazaa.<sup>18</sup>, who found that the time to recovery of motor block was delayed with increase in dose of bupivacaine and this difference was statistically significant ( $p < 0.001$ ). Similarly, Shashikala T.<sup>15</sup> Bryson GL.<sup>19</sup> PÖPPING Daniel M.<sup>20</sup> suggested early motor recovery by reducing the dose of bupivacaine.

Also, our study was supported by the findings of Leo S.<sup>17</sup> who concluded that episodes of hypotension were significantly lesser when the dose of bupivacaine was reduced from 9 mg to 7 mg in caesarean sections. These findings are also in concordance with the studies of Ben David B Miller.<sup>6</sup>, M. S. Mebazaa.<sup>18</sup>, Kajal Jain.<sup>21</sup>. On the contrary, studies done by Bryson GL.<sup>19</sup>, Turhanoglu S.<sup>23</sup> found no significant decrease in episodes of hypotension with reduction in dosage of local anesthetics.

Study by Kajal Jain.<sup>21</sup> found no difference in heart rate by reducing bupivacaine dose from 10 mg to 7.5mg and by adding fentanyl 20mcg intrathecally.

In terms of change in pulse rate, our findings are unique since we found higher pulse rate in group receiving 10mg bupivacain.

Similar to the findings of Nagata E.<sup>24</sup>, we found no significant difference in APGAR score with two different doses of bupivacaine. In addition, no difference in APGAR score was noted by Shaloo Ipe.<sup>22</sup> and Sunil Dixit.<sup>14</sup> when buprenorphine was used intrathecally. Furthermore, Ben David B Miller.<sup>6</sup>, Shashikala T.<sup>15</sup> M. S. Mebazaa.<sup>18</sup>, Rabiee SM.<sup>16</sup> used fentanyl intrathecally and found no episodes of neonatal respiratory depression. However, Kajal Jain et al.<sup>21</sup> found that two neonates showed APGAR less than 7 and required intubation when Fentanyl was used intrathecally.

The present study findings were supported by Shaloo Ipe.<sup>22</sup> were buprenorphine was used intrathecally 150mcg and epidurally 150 mcg or 300mcg and no significant difference in sedation, nausea, vomiting and shivering either due to changing dose of bupivacaine or addition of buprenorphine.

While study by Sunil Dixit.<sup>14</sup> Study by Rabiee SM.<sup>16</sup> which used buprenorphine intrathecally, drowsiness was seen with 60mcg buprenorphine which was contrary to our findings.

The present study found that the dose of vasopressor mephentermine required was significantly lower in 8mg bupivacain group. The present study was supported by studies like Turhanoglu S.<sup>23</sup>, M. S. Mebazaa.<sup>18</sup> which found that significantly less dose of vasopressor are required when dose of bupivacaine is reduced for spinal anesthesia. The present study was not supported by study of Bryson GL.<sup>19</sup> who found no significant difference in requirement of vasopressor drug in either study group (isobaric bupivacaine 4.5mg) or control group (10mg isobaric bupivacaine). The difference between present study and Bryson GL.<sup>19</sup> may be due to difference in dose and baricity of bupivacaine.

## CONCLUSION

We conclude that bupivacaine 8mg with 60mcg of buprenorphine can be safely be used in elective cesarean section patients with no added co morbidities. This combination provides good intra-operative anesthesia, reduces incidence of hypotension, reduces vasopressor requirement and provides good post-operative analgesia. We also conclude that 60mcg buprenorphine does not cause any significant side effects like nausea, vomiting, itching in parturients and this dose is also safe for babies as confirmed with APGAR score.

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