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# ORIGINAL ARTICLE

## COMPARATIVE EVALUATION OF INTRATHECAL BUPIVACAINE-FENTANYL AND BUPIVACAINE-SUFENTANIL FOR CAESAREAN SECTION

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**ABSTRACT: BACKGROUND:** Addition of lipophilic opioids like Fentanyl and Sufentanil to local anaesthetic for spinal anaesthesia has shown to prolong the duration of analgesia. This study was carried out to study (a) Comparison of effect of Fentanyl and Sufentanil added to Bupivacaine on onset and duration of anaesthesia in Cesarean Section. (b) To compare the quality and duration of analgesia between the two opioids and (c) To compare the effect on neonatal outcome. **METHODS:** 50 parturients of ASA grade 1 and 2 undergoing Cesarean Section were randomized into two groups of 25 each. Group F received 2.5 ml 0.5% Bupivacaine heavy + inj. Fentanyl 0.25 ml (12.5 mcg) and Group S received 2.5 ml 0.5% Bupivacaine heavy + inj. Sufentanil 0.1 ml (5 mcg) intrathecally. Onset of sensory and motor blockade was noted in all the patients. Haemodynamic parameters were recorded every 5 minutes for first 30 minutes and then every 15 minutes till the completion of surgery. Duration of sensory and motor sensory blockade was observed post operatively. **RESULT:** Both the groups were stable haemodynamically. Both the groups were comparable regarding the duration of sensory and motor block, but the total duration of effective analgesia was significantly longer in Sufentanil group. Pruritus was significant side effect in Sufentanil group. Neither the mother nor the neonate had respiratory depression. **CONCLUSION:** Addition of Sufentanyl to intrathecal bupivacaine provides longer duration of analgesia as compared to intrathecal fentanyl-bupivacaine. However, the incidence of pruritus was greater in Sufentanyl group.

**KEYWORDS:** Intrathecal, Cesarean Section, Bupivacaine heavy, Fentanyl, Sufentanil.

**INTRODUCTION:** Labour pain is excruciating and a significant contributor of stress and anxiety. Painful uterine contractions cause maternal hyperventilation and increased catecholamine concentration resulting in maternal fetal hypoxemia.[1]

An ideal labour analgesic technique should provide adequate and satisfactory analgesia without any motor blockade or adverse maternal and fetal effects.

The basic aim of spinal anaesthesia is to provide adequate pain relief with no deleterious effect on the patients. Caesarean delivery leaves the mother in significant pain postoperatively. After Caesarean delivery the need for analgesia must be weighed against the needs for mother and baby to be alert and able to interact with each other as soon as possible.

Spinal anaesthesia has increasingly become the technique of choice for caesarean delivery. It has the advantage of simplicity of technique, rapid onset of action and reliability in producing uniform sensory and motor blockade when compared to epidural anaesthesia. Its main disadvantage relates to its limited duration of action and hence absence of long lasting postoperative analgesia.

To deal with the problem of limited duration of action and improve the quality of analgesia both intra-operatively and postoperatively intrathecal opioids have been tried as adjunct to Bupivacaine.

DOI: 10.14260/jemds/2014/2826



The quality of analgesia is excellent when highly lipid soluble Opioids are added. Addition of opioids to local anesthetics reduces its requirement by synergistic effect of opioids receptors in the spinal cord. This reduces the chances of haemodynamic perturbation.[2]

Fentanyl, a short acting lipophilic Opioid was given intrathecally along with local anaesthetic by Belzarena and coworker in 1992.[3]

Fentanyl is a lipophilic molecule similar to Meperidine, which is more readily eliminated from CSF then hydrophilic drugs like Morphine. The use of intrathecal Fentanyl, lipophilic Opioids and Bupivacaine for caesarean delivery was described by Hunt (1989).[4]

Recently there has been increased interest in using even more lipophilic Opioids, Sufentanil in combination with Bupivacaine for caesarean delivery (Braga et al. 2003).[5]

The addition of Fentanyl and Sufentanil to Bupivacaine for spinal anaesthesia has shown improved intra operative analgesia and significantly prolonged the duration of effective and complete analgesia compared with Bupivacaine alone.

**METHODS:** A randomized study was carried out on 50 healthy full term parturients of ASA grade I and II, undergoing elective and emergency caesarean section after obtaining clearance from the institutional ethics committee. Parturients with medical disorder, infection at the site of injection, coagulopathy and other bleeding diathesis, severe hypovolemia, patients with fetal compromise, preeclampsia and eclampsia, any respiratory diseases, preexisting neurological deficit were excluded from the study. After obtaining informed written consent, Parturients were randomly allocated by a computer generated table of random numbers into 2 groups of 25 each.

Informed consent was obtained from all patients followed by their preanaesthetic checkup where detailed history was taken, patient was physically examined and relevant routine investigations were carried out.

Preoperatively all patients were administered 500ml of ringer lactate and received inj. ranitidine 50mg iv and inj. ondensatron 4mg iv and monitor were connected, baseline reading recorded. Subjects were randomly allocated to two groups of 25 each.

Under all aseptic precautions, subarachnoid block was given in lateral decubitus position via midline approach in L3-L4 interspinous space with Quinckes spinal needle 25 G. After confirmation of free flow of cerebrospinal fluid, the drugs was injected slowly intrathecally. Patient in Group F received 2.5 ml 0.5% Bupivacaine heavy + inj. Fentanyl 0.25 ml (12.5 mcg) intrathecally and Group S received 2.5 ml 0.5% Bupivacaine heavy + inj. Sufentanil 0.1 ml (5 mcg) intrathecally.

The patient was immediately turned supine after subarachnoid block and the uterus was displaced to the left using a wedge. All patients were given supplemental oxygen.

The level of sensory blockade was assessed by pin prick method. The time for sensory blockade to attain T6 level was recorded.

Intra-operatively, patients were monitored for pulse, blood pressure and respiratory rate and SPO2 every 5minutes for first 30minutes and then every 15minutes till the completion of surgery. Motor blockade was assessed by modified Bromage Scale.

Side effects such as Pruritus (rated as none, minimal, moderate and severe),[6] hypotension (fall of more than 20% from baseline systolic reading.) motor blockade, nausea/vomiting, respiratory depression or bradycardia (heart rate<60) were noted.

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Duration of motor and sensory blockade was observed postoperatively. Effective analgesia time defined as the time to request for the first dose of analgesia by patient was assessed. Time of rescue analgesia was noted in all patients. The Parturients were monitored for 2hrs following procedure. They were questioned after 24hrs about their views on the procedure and the satisfaction, enquiry about the symptoms related to postdural puncture headache (PDPH) was made.

**Statistical Analysis:** Data were analyzed using software version SPSS. Demographic data were analyzed using analysis of variance. Unpaired t-test and chi-square tests were used where appropriate. Sample size of 50 with 25 Parturients in each group was determined with power of study of 80%. Data were expressed as mean±SD, standard tests of significance were applied to determine the p value. $P < 0.05$ was considered significant.

**RESULTS:** There was no significant difference between the groups with respect to maternal demographic characteristics, parity (Table-I). The level of sensory blockade was assessed using pinprick method and sensory level of T6 deemed necessary to be included in the study. The time to reach T6 sensory level, highest sensory block attained and time to regress to T12 was recorded.

The time to achieve T6 sensory level was faster in Sufentanil group (2.46±0.357) as compared to Fentanyl group (2.60±0.456) but the difference is not significant ($p>0.05$).The highest level of thoracic dermatomes in group F was (5.72±0.458), and in group S was (5.60±0.50), which is comparable in both the groups. ($p>0.05$) (Table II). The highest sensory level attained was T5-T6 in all patients.

The time of Regression of sensory level up to T12 in Sufentanil group (98.21±26.294) and Fentanyl group (97.81±30.594) ($p<0.05$) is comparable.

The duration of effective analgesia (Time to request for the first dose of analgesia by patients) was significantly longer in Sufentanil group (368.4±46.384) as compared to Fentanyl group (214.6±26.057) ($p<0.05$) (Table-III).

The onset of grade 0 motor blockage was faster in Sufentanil group (2.46±0.320 min) than Fentanyl group (2.54±0.462mins) but not significant ($p>0.05$).

The mean duration of grade 0 Bromage scale (no movement of feet and limbs) was comparable in both Sufentanil and Fentanyl group (127.6±17.380) (128.4±17.720) ($p>0.05$) (Table-IV).

We observed that there was a fall in pulse rate after 10minutes of spinal anesthesia in both Fentanyl (93.60±6.618 to 82.93±4.730/ min) group and in Sufentanil group (99.21±6.324 to 82.82±3.055/ min) (Table-V). There was no statistical difference in the mean pulse rate between groups. There was also a fall in blood pressure after 10minutes induction in Fentanyl (118.4±7.461 to 115.2±5.830 mmHg) group and in Sufentanil (116.81±6.377 to 112±6.782 mmHg) group (Table-VI).

There is no statistical difference in mean systolic blood pressure between groups F and S ($p>0.05$). However, the fall in pulse and blood pressure was not more than 20% from baseline and none of the patients required any treatment for the same. None of the patients had respiratory depression.

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At 120minutes, patients were assessed for oxygen saturation. No significant difference was found in both the groups. None of the patients in Fentanyl and Sufentanil group required rescue analgesia at 120minutes.

Neonatal neurobehavioral assessment was done by Apgar score at 1 and 5minutes after delivery. All neonates had Apgar score of 9/10 at 1 minute ($p>0.05$) and 10/10 at 5mins. None of the neonates had respiratory depression (Table-VII).

The patients were observed for intraoperative and postoperative complications. 1/25 (4%) of patients in Fentanyl group had nausea and vomiting while none of the patients had nausea, vomiting in Sufentanil group. Pruritus was the significant side effect in Sufentanil group (12/25) as compared to Fentanyl group (03/25). Shivering was seen in 2/25 patients in Fentanyl group and 1/25 patients in Sufentanil group. No occurrence of Bradycardia, Hypotension and respiratory depression was observed. (Table-VIII).None of the Parturients from either group had symptoms suggestive of PDPH.

| Characteristics | Group S (n=30) | Group F (n=30) |
|---|---|---|
| Mean age (years) | 23.46 | 22.02 |
| Mean weight (kg) | 58.18 | 59.60 |
| Mean height (cm) | 152.48 | 154.24 |
| Parity (%)<br>Primipara<br>Multipara | <br>62.33<br>37.66 | <br>66.66<br>33.33 |

TABLE I: Material demographics characteristics

| Time interval | Group F N=25 Mean ± SD | Group S N=25 Mean ± SD |
|---|---|---|
| Time to T6 (minutes) | 2.60±0.456 | 2.46±0.351 |
| Highest sensory level (Thoracic Dermatome) | 5.72±0.458 | 5.60±0.50 |

TABLE II: ONSET OF SENSORY BLOCK

| Time interval (Minutes) | Group F (n=25) Mean ± SD | Group S (n=25) Mean ± SD |
|---|---|---|
| Time to regression to T12 dermatome | 97.81±30.594 | 98.21±26.294 |
| Duration of effective analgesia | 214.6±26.057 | 368.4±46.384 |

TABLE III: Regression of sensory level and duration of analgesia

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| Time interval (Minutes) | Group F (n=25) Mean ± SD | Group S (n=5) Mean ± SD |
|---|---|---|
| Onset of grade O motor block | 2.54±0.462 | 2.46±0.320 |
| Total duration of grade O motor block | 128.4±17.720 | 127.6±17.387 |

TABLE IV: COMPARISON OF MEAN TIME FOR MOTOR BLOCK

| Time interval (minutes) | Group F (Per minutes) Mean ± SD | Group S (Per minutes) Mean ± SD |
|---|---|---|
| Baseline | 93.60±6.618 | 99.21±6.324 |
| 5 | 96.80±7.023 | 100.64±7.804 |
| 10 | 94.08±7.578 | 94.88±6.110 |
| 15 | 92.80±7.350 | 93.44±6.096 |
| 20 | 88.81±8.317 | 90.24±4.772 |
| 25 | 81.92±4.995 | 86.72±3.203 |
| 30 | 85.21±4.898 | 85.76±2.602 |
| 45 | 83.68±4.607 | 82.08±30290 |
| 60 | 82.96±4.730 | 82.82±3.055 |
| 120 | 82.48±4.174 | 86.81±3.885 |

TABLE V: Mean pulse rate at different time interval

| Time Interval (minutes) | Group–F (Per minuets) Mean ± SD | Group S (Per minutes) Mean ± SD |
|---|---|---|
| Baseline | 118.4±7.461 | 116.81±6.377 |
| 5 | 109.6±10.77 | 113.21±9.073 |
| 10 | 104.8±8.225 | 104.82±8.717 |
| 15 | 105.6±7.681 | 105.21±6.454 |
| 20 | 106.8±5.567 | 107.23±5.567 |
| 25 | 108.4±5.537 | 108.00±6.633 |
| 30 | 112.11±5.773 | 109.63±8.020 |
| 45 | 113.2±5.567 | 111.23±8.225 |
| 60 | 113.2±5.567 | 112.00±6137 |
| 120 | 115.6±5.830 | 112.32±6.782 |

TABLE VI: Mean systolic blood pressure at different time interval

DOI: 10.14260/jemds/2014/2826



| | 1 min Mean ± SD | 5 min Mean ± SD |
|---|---|---|
| Group – F | 9.16±0.374 | 10.00±0.00 |
| Group – S | 9.08±0.276 | 10.00±0.00 |

TABLE VII: Neonatal Apgar score in two groups

| Complications | Group F (n=25) | | Group S (n=25) | |
|---|---|---|---|---|
| | No | % | No | % |
| Nausea/Vomiting | 01 | 4% | 0 | 0% |
| Pruritus | 3 | 12% | 12 | 48% |
| Shivering | 2 | 8% | 1 | 4% |
| Respiratory Depression | 0 | 0% | 0 | 0% |
| Hypotension | 0 | 0% | 0 | 0% |
| Bradycardia | 0 | 0% | 0 | 0% |

TABLE VIII: Intra/postoperative complications

**DISCUSSION:** Effective pain control is essential for optimum care of patients in the postoperative period. The remarkable increase in the analgesic efficacy provided by intrathecal and epidural opioids has greatly improved the management of post-surgical, obstetric and chronic pains.

Highly lipid – soluble synthetic opioids such as Sufentanil and Fentanyl are being increasingly used along with local anaesthetic agents such as Bupivacaine to provide excellent relief of pain unlike hydrophilic opioids (morphine) or intermediate lipid-soluble opioids (Meperidine) which have longer residency time in CSF and associated with cephaled migration. So there is a risk of delayed respiratory depression 12-14 hours after the last dose and they have fairly segmental analgesic profiles.

Lignocaine has rapid onset but short duration of action, whereas Bupivacaine has slow onset and longer duration of action. As bupivacaine provides longer postoperative analgesia, so we opted for intrathecal Bupivacaine in our study. We used 12.5mg of hyperbaric Bupivacaine to provide subarachnoid block. This study was undertaken with the idea of providing an effective intraoperative and postoperative analgesia and to evaluate characteristics of subarachnoid block with Bupivacaine when Fentanyl and Sufentanil are used as adjuvant.

Quality of analgesia was found to be comparable in both groups in our study. Addition of opioids to intrathecal Bupivacaine prolongs duration of analgesia compared with either drug used alone evidence suggests that Bupivacaine increase the binding of morphine to opioids receptors, especially the highly dense kappa receptors, as the result of an associated conformational change in opioids receptors.[7]

In our study, we have used 12.5 mg Bupivacaine as used by used by Hilda and colleagues (1984).[8] this dose was adequate to achieve the sensory level of T4 in all the patients. This is in contrast with studies done by Bruce Ben David et al. (2002)[9] and Jaishri Bangra et al. (2005)[10] who have used low dose Bupivacaine with Fentanyl as an adjunct. Many studies have demonstrated anti-nociceptive synergism between intrathecal opioids and local anaesthetics. Patients undergoing

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cesarean section may benefit from the co-administration of local anaesthesia and opioids agent because of improved intraoperative comfort in post-operative requirement for additional analgesia.

However these advantages need to be balanced against problems such as Pruritus, nausea, sedation and respiratory depression.

While comparing the various doses of intrathecal Fentanyl along with Bupivacaine In a study in 1989, Hunt O Catherine et al. concluded that optimum dose of Fentanyl was 6.25g because higher doses did not increase the duration of analgesia significantly.

A. De. Fe. De Assuncao Braga and colleagues (2003)[5] used varying doses of Sufentanil (2.5g, 5g, 7.5g) with Bupivacaine in caesarean section, they observed that intrathecal 5g and 7.5g Sufentanil increased the duration of effective analgesia compared with 2.5g Sufentanil but the incidence of Pruritus increased when doses of 7.5g was used.

The advantage of subarachnoid opioids is low doses provides adequate and lower duration of analgesia with minimal side effects. Also >12.5g Fentanyl might provide greater analgesia efficacy, but the incidence of side effects like respiratory depression and Pruritus also increase.

Hence 5g Sufentanil and 12.5g Fentanyl intrathecally is an apparently optimum dose to provide good clinical effects with minimal side effects.

A study conducted by Jaishod Bogra et al. (2005)[10] on synergistic effect of intrathecal Fentanyl and Bupivacaine in caesarean section observed that onset of sensory blockade to T6 thoracic dermatome was faster with increasing doses of Bupivacaine alone or combination with Fentanyl. In our study, the mean time of onset of sensory block at T6 is comparable in both 6the Fentanyl (12.5g) and Sufentanil (5g) groups. Although it is little faster in Sufentanil group but the difference is not statistically significant. This result is contrast with the studies done by Braga et al. (2003) and Bogra et al. (2005). In their studies, the onset time of sensory block at T6 is significantly shorter in Sufentanil group.

This is due to high lipid solubility of Fentanyl and Sufentanil. The mean higher sensory level attained was 5.72±0.458 in Fentanyl group and 5.60±0.50 in Sufentanil group. The difference was not statistically significant.

The mean time of onset of motor blockade was 2.54+0.462 is Fentanyl group and 2.46+0.320 in Sufentanil group, mean time for motor block was less in Sufentanil group as compared to Fentanyl group but difference is not significant.

Also the mean duration of grade 0 motor blocks was 128.4±17.720 Fentanyl group and 127.4±17.387 in Sufentanil group i.e. comparable in both the groups. Contrasting results were observed but Dirk Meningier et al. (2003)[11] in their study on effect of intrathecal Sufentanil, Fentanyl and placebo added to mepivacaine 2% for caesarean section. They observed that the time from intrathecal injection to motor block bromage scale 1 was significantly shorter when Fentanyl 5g and sectioned 2.5g was added to mepivacaine.

We observed that duration of analgesia provided by intrathecal Sufentanil and Bupivacaine was 366.5±4.384mins as compared with 214.6±26.057 mins by Fentanyl group. This difference was statistically significant. This prolonged duration of analgesia with Sufentanil could be attributed to the known superiority of Sufentanil over Fentanyl in terms of potency.[12] Parturients receiving Sufentanil required less total dose of Bupivacaine than those receiving Fentanyl.

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Duration of analgesia after intrathecal administration of opioids depend upon the agent, its lipophilicity as well as done employed. Hence in our study, intrathecal Sufentanil which is highly lipophilic in dose of 5g provided the significantly longer duration of effective analgesia as compared to Fentanyl 12.5g group.

In our study, the mean regression time to T12 sensory level was 97.81±30.594 minutes in Fentanyl group and 98.21±26.294 minutes in Sufentanil group. The mean regression time to T12 sensory level in both the groups is comparable which is in contrast with the study of Dahlgrem et al. (1997)[13] and Meiningier et al.(2003)[11], which the mean regression time to T12 sensory level is significantly prolonged in Fentanyl and Sufentanil group.

In our study, we observed that these were a fall in pulse rate often 10 minutes of intrathecal injection in Sufentanil and Fentanyl group. This was been due to relief of anxiety because of sedative effect of Fentanyl and Sufentanil. However, fall is not more than 20% and did not require any treatment.

An initial fall in blood pressure was seen in our study patients of both the group, which may be attributed to the sympathetic blockade produced by local anesthetics.

The fall was never more than 20% of preoperative value and blood pressure returned to the preoperative value with 1hour of intrathecal injection.

We did not observe any significant change in the respiratory rate and oxygen saturation in both the groups. There was no evidence of respiratory depression as well.

Our observation correlates well the studies done by Gunnar Dahlgren et al. (1997)[13] A De. F. De Assuncas Braga et al. (2003)[5] and Jaishri Bogra et al. (2005).[10] these studies did not report any incidence of respiratory depression, bradycardia and hypotension, as the doses used by them were comparable with our study. The study done by S.K.K. Nagiam et al.[14] did not report episodes of desaturation in patients because the doses of Fentanyl and Sufentanil used by them were quite high as compared to our study.

The incidence of Pruritus was the significant side effect in Sufentanil group (12/25 patients) as compared to Fentanyl group (3/25 patients) S .K. K. Ngiam (1998)[14] observed that 35% of patients in Sufentanil group and 27.8% in Fentanyl group has Pruritus.

In our study Pruritus is significantly more in Sufentanil group than Fentanyl group. However, none required any treatment except assurance. This is in contrast with study done by S.K.K. Ngiam (1998) in which both the groups has almost comparable incidence of Pruritus.

However the other side effect like nausea, vomiting is less than compared to Fentanyl group (4%). Similar findings were observed in Gunnar Dahlgren (1997)[13] that incidence of nausea and vomiting were similar in patients receiving Bupivacaine, Fentanyl and Sufentanil group. A. De. Fe. De. Assuncao et al. (2003)[5] also observed that incidence of nausea was lower in patients receiving Sufentanil as compared to placebo similar results were observed by Jaishri Bogra et al. (2005)[10] as well.

Fentanyl and Sufentanil are highly lipophilic drugs. Hence very small amount of drug remains for cephaled migration and stimulation of CTZ, so there was less incidence of nausea vomiting.

Other side effect like shivering was seen in 8% patients in Fentanyl group and 4% patients in Sufentanil group.

In our study there was no statistically significant difference in the Apgar score of neonate between two groups. All newborn were healthy and cried immediately after birth.

Similar results were observed by S.K.K. Ngian et al. and A. De. F. De. Assuncao Brago et al. The Apgar score at 1 and 5minutes were satisfactory in both Fentanyl and Sufentanil group and there was no statistically difference the two groups.

**CONCLUSION:** We conclude that use of Sufentanil and Fentanyl intrathecally achieved high patient satisfaction as well as excellent sensory and motor blockage with improved intra-operative analgesia and prolonged duration of effective analgesia without significant effect on neonate neurobehaviour. Sufentanil provided significant longer duration at labour analgesia compared with Fentanyl, intrathecal Sufentanil provides better protection against nausea and vomiting as compared to Fentanyl out cause's significant occurrence of pruritus as compared to Fentanyl.

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