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Study of pain scores and need for rescue analgesia with intrathecal fentanyl as an adjuvant with 0.5% hyperbaric bupivacaine for cesarean section

Thrupthi BP[1], Nazima Y Memon[2], Niteen K Nandanwankar[3], Yennawar SD[4], Ajay L Jogdand[5], Juhi P Bagga[6]

[1]Senior Resident, Department of Anaesthesiology, Grant Medical College and JJ Group of Hospitals, Mumbai, [2]Associate Professor, Department of Anesthesiology, Government Medical College, Aurangabad, [3]Associate Professor, [4]Professor, [5]Senior Resident, Department of Anesthesiology, Government Medical College, Ambajogai, [6]Senior Resident, Department of Anesthesiology, Dr. Shankarrao, Chavan Government Medical College, Nanded, Maharashtra, India

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ABSTRACT

Background: Cesarean section contributes to the major part of surgeries taking place in any hospital now a days. Hence, improving anesthesia in cesarean section is of paramount importance. Intrathecal fentanyl can produce rapid, profound analgesia for cesarean section, early labor with minimal side effects. It also has minimal respiratory depressant effect on fetus. Present study was aimed to study pain scores and need for rescue analgesia with intrathecal fentanyl as an adjuvant with 0.5% hyperbaric bupivacaine for cesarean section. **Aims and Objectives:** Primary Objective was to evaluate intrathecal fentanyl as an adjuvant with 0.5 % hyperbaric Bupivacaine for caesarean section. The secondary objective was to compare onset and duration of sensory and motor blockade as well as to assess pain scores, analgesic requirements and side effects. **Materials and Methods:** The present study was hospital-based randomized double-blind control study conducted in pregnant women of 18–35 years age, 50–70 kg weight, ASA-II, posted for elective cesarean section. 60 patients were randomly divided into Group I (study group, n = 30, receiving 0.5 % hyperbaric bupivacaine 1.6 ml + intrathecal fentanyl 0.4 ml/20 mcg) and Group II (control group, n = 30, receiving 0.5% hyperbaric bupivacaine 1.6 ml + 0.4 ml normal saline). **Results:** The difference in mean time for onset of sensory block, onset of motor block, maximum time taken to achieve highest level of sensory analgesia, total duration of motor block, and degree of motor block was statistically insignificant. The difference in mean duration of time to sensory regression was statistically highly significant ($P < 0.0001$). VAS score was used to assess pain postoperatively initially every 5 min then every 30 min up to 5 h. VAS score in post-operative period was less in Group I and difference was statistically significant. Mean Apgar Score at 1 and 5 min were comparable in both the groups with no statistically significant difference. Diclofenac consumption was significantly decreased in Group I as compared to group II. **Conclusion:** We conclude that the 0.5% hyperbaric Bupivacaine 8 mg with Fentanyl 20 µg is safe, effective, superior for spinal anesthesia, provided more longer duration of analgesia and significantly reduced number of rescue analgesia doses in cesarean section.

Key words: Fentanyl; Hyperbaric bupivacaine; Post-operative analgesia; Spinal anesthesia

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INTRODUCTION

Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage.[1] With improvement and advancement in obstetric care cesarean section is becoming increasingly common surgical procedure and contributes to the major part of surgeries

Address for Correspondence:
Dr. Thrupthi BP, Senior Resident, Department of Anaesthesiology, Grant Medical College and JJ Group of Hospitals, Mumbai - 400 013, Maharashtra, India. **Mobile:** 7204502972. **E-mail:** thrupthibp13@gmail.com

taking place in any hospital now a days.[2] Hence, improving anesthesia in cesarean section is of paramount importance.

Spinal anesthesia is the preferred anesthesia for cesarean section being simple to perform and economical with rapid onset. It provides additional benefits such as alleviating stress response to surgery, reduced aspiration risk in pregnancy, reduced pulmonary complications, less incidence of post-operative nausea and vomiting, early ambulation, and recovery.[3] Moreover, in cases of spinal anesthesia mother can start nursing the newborn relatively early as compared to patients undergoing cesarean section under general anesthesia which will also prevent neonatal complications associated with inadequate feeding such as neonatal hypoglycemia. One of the important problems with spinal anesthesia is due to limited duration of action and to overcome this, various adjuvants are being used to improve the onset as well as duration of blockade.[4]

Hyperbaric bupivacaine 0.5% is routinely used for spinal anesthesia in cesarean section. Many drugs such as epinephrine, opioids, midazolam, neostigmine, ketamine, and alpha 2 agonist like clonidine, dexmedetomidine are used as adjuvants to facilitate early onset and prolong the duration of anesthesia.[5] The adjuvant not only shortens the duration of onset of analgesia but also prolongs the duration of local anesthetic effect. Another important use of adjuvant is that it reduces the volume of local anesthetic drug thereby reducing the adverse effects associated with use of large volume of local anesthetic drugs used for spinal anesthesia. The combined use of local anesthetic drug with adjuvant is associated with prolongation of analgesia without increase in the adverse effect of anesthetic drugs.[6]

Fentanyl is a synthetic opioid which produces excellent analgesia and had been in use for sedating patients who had been intubated for various reasons. In cases of patients undergoing surgeries under spinal anesthesia intrathecal fentanyl (maximal benefit achieved with 25 mcg) can produce rapid, profound analgesia.[7] When used as an adjuvant to other anesthetic drugs, it can be very useful for cesarean section as well as in early labor with minimal side effects. It also has minimal respiratory depressant effect on fetus. Intrathecal fentanyl added to hyperbaric bupivacaine 0.5% to provide good intraoperative analgesia, prolong anesthesia with decreased incidence of side effects.[8]

The present study was aimed to study pain scores and need for rescue analgesia with intrathecal fentanyl as an adjuvant with 0.5% hyperbaric bupivacaine for cesarean section. The effect of fentanyl used as an adjuvant on fetal safety (incidence of fetal respiratory depression) in terms of comparison of Apgar scores between the two groups were of particular interest to us.

Aims and objectives

(1) To evaluate intrathecal fentanyl as an adjuvant with 0.5 % hyperbaric Bupivacaine for caesarean section.
(2) To compare onset and duration of sensory and motor blockade as well as to assess pain scores, analgesic requirements and side effects.

MATERIALS AND METHODS

The present study was hospital-based randomized double-blind case control study conducted in Department of Anaesthesiology at Dr. Shankarrao Chavan Government Medical College Nanded India. Study duration was of 2 years (November 2018 to October 2020). Study was approved by Institutional Ethical Committee. 60 ASA Grade II patients scheduled for cesarean section under spinal anesthesia were divided using computer assisted randomization table into two groups.

Sample size calculation was calculated on the basis of pilot studies done for analyzing effects of addition of intrathecal fentanyl as an adjuvant with 0.5% hyperbaric bupivacaine for cesarean section. Keeping power (1-Beta error) at 80% and confidence interval (1-Alpha error) at 95%, the minimum sample size required in each group was 30 patients; therefore, we included 30 patients in each group.
Group I (study group) - 30 patients (n=30) receiving bupivacaine 0.5% heavy 1.6 ml+intrathecal fentanyl 0.4 ml (20 mcg) = total volume 2 ml.
Group II (control group) - 30 patients (n=30) receiving bupivacaine 0.5% heavy 1.6 ml+0.4 ml normal saline = total volume 2 ml.

Written valid Informed consent was taken from the patients for the procedure. A detailed history was taken and thorough general and systemic examination was performed. Preanesthetic check-up was done before the surgery. Patients were evaluated for any systemic diseases and laboratory investigations were recorded. Investigations such as hemogram, urine routine and microscopic examination, Kidney function test, liver function test, electrocardiograph, and blood sugar level were performed before surgery. Patients were shifted to operating room, IV access was obtained on the forearm with no.20 G IV cannula and all patients were preloaded with 10 ml/kg ringer lactate before the surgery. All patients were monitored with non-invasive blood pressure monitoring, pulse oximetry and ECG. Baseline vitals were recorded. All patients were given intravenous premedication with injection ondansetron 4 mg and Inj. Metoclopramide 10 mg.

Patients were given left lateral position and under all aseptic precautions lumbar puncture was performed with 25 G Quincke's spinal needle at L3-L4 intervertebral space. Patients

were monitored for time of onset of sensory analgesia to T10, time of onset of Grade III motor blockade, highest level of sensory analgesia, time taken for highest level of sensory analgesia, time for sensory regression, grade of motor block achieved, total duration of motor blockade, and duration of analgesia. Intraoperative maternal hemodynamic parameters were noted and compared. APGAR scores at 1 min and 5 min were recorded in neonates to know any fetal side effects. VAS score was used to assess pain postoperatively initially every 5 min then every 30 min up to 5 h.

Statistical analysis was performed with SPSS version 20. The results were compiled using suitable tables and graphs whenever necessary. Quantitative data were presented with the help of Mean and Standard Deviation. Qualitative data were presented with frequency and percentage tables. The Mann-Whitney U test was used to compare differences between two independent groups. For quantitative data, unpaired t-test was applied and for qualitative data Chi-square test was applied. P<0.05 is taken as statistically significant.

Inclusion criteria

1. Pregnant women of 18–35 years age posted for elective LSCS.
2. ASA Grade II.
3. Written and informed consent given by patient.

Exclusion criteria

1. Patients who refused consent.
2. History of allergy to local anesthetic or opioids.
3. ASA-III–V parturient.
4. Pre-existing systemic disease.
5. Pre-eclampsia or eclampsia parturient.
6. Patient with history of bleeding disorders.
7. Patient with psychiatric disorders.
8. Incomplete blockade.
9. Local infection at the site of injection.

RESULTS

In present study age, sex, weight, height, BMI, ASA grade, and duration of surgery were comparable in two groups. There was no statistically significant difference (P>0.05) among them (Table 1).

The difference in mean time for onset of sensory block, onset of motor block, maximum time taken to achieve highest level of sensory analgesia, total duration of motor block, and degree of motor block was statistically insignificant (P>0.05). Time to sensory regression was found to be 77.66±5.13 min in Group I while 42.23±2.58 min in Group II. The difference in mean duration of time to sensory regression was statistically highly significant (P<0.0001). Duration of postoperative analgesia was significantly longer in Group I (210.96±12.80) as compared with Group II (127.93±10.05). This difference was statistically highly significant (P<0.05) (Table 2).

The analysis of intra-operative parameters showed that there was no statistically significant difference (P<0.05) in Heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure and SpO_2 in both the groups at 0, 5, 10, 15, 30 and 45 min and all these hemodynamic parameters were found to be comparable in both the groups (Table 3).

VAS score was used to assess pain postoperatively initially every 5 min then every 30 min up to 5 h. When score was found more than 4, injection diclofenac sodium 75 mg was given IV as a rescue analgesic. VAS score in post-operative period was less in Group I as compared to Group II. This difference was statistically significant from 150 to 270 minutes (P<0.05) (Table 4).

Diclofenac consumption was significantly decreased in Group I as compared to Group II. The difference in total doses of inj. diclofenac was highly significant (P<0.00001) (Table 5).

Side effects in form of Nausea and vomiting, bradycardia, hypotension, and pruritus was 60%, 100% 57.14%, and 100% respectively in Group I and was 40%, 0%, 42.86%, 0% in Group II included there was no significant difference in side effects between two groups (Figure 1).

Finally, the comparison of both the groups in terms of fetal side effects as depicted by APGAR score at 1 and 5 min of birth was done. The mean APGAR score at 1 and 5 min in Group I was found to be 8.2±0.40 and 9.93±0.25, respectively. In Group II, mean APGAR score at 1 and 5 min was found to be 8.3±0.53 and 9.8±0.40. The comparison of mean APGAR scores in both the groups showed that there was no statistically significant difference in both the groups (Table 6).

Table 1: Demographic profile among various groups

Characteristics	Group I (%)	Group II (%)	P-Value
Mean age (years)	22.36±2.07	23.26±2.11	0.101 (Not Significant)
ASA Grade II	30 (100)	30 (100)	1 (Not Significant)
Weight (kg)	58.00±3.36	58.13±2.78	0.867 (Not Significant)
Height (cm)	155.1±3.25	154.23±2.64	0.2693 (Not Significant)
BMI (kg/m^2)	24.13±1.64	24.45±1.43	0.423 (Not Significant)
Duration of surgery (min)	61.43±5.92	61.2±4.82	0.867 (Not Significant)

Table 2: Mean time of onset of sensory and motor block

Parameters	Group I	Group II	P value
Onset of sensory block (sec)	157.6±18.81	161.33±13.76	0.384 (Not Significant)
Onset of motor block (sec)	330.7±22.81	333.53±21.62	0.624 (Not Significant)
mean time taken to achieve highest level of sensory analgesia (sec)	330.33±19.60	339.16±19.61	0.087 (Not Significant)
Mean time to sensory regression (min)	77.66±5.13	42.23±2.58	<0.0001 (Highly Significant)
Duration of motor block (min)	108.06±8.39	105.9±10.35	0.374 (Not Significant)
Duration of analgesia (min)	210.96±12.80	127.93±10.05	0.0001 (Highly significant)

Table 3: Comparison of intra-operative parameters

	Group I (n=30)	Group II (n=30)	P Value
Heart rate			
0 min	80.23±6.98	83.36±8.57	0.1264
5 min	77.73±7.83	76.60±8.21	0.5875
10 min	86.8±16.03	93.26±11.22	0.0760
15 min	85.66±17.38	92.50±11.38	0.0778
30 min	83.46±15.66	89.50±10.36	0.0847
45 min	82.40±14.65	87.76±9.54	0.0989
Systolic blood pressure			
0 min	80.23±6.98	83.36±8.57	0.1264
5 min	77.73±7.83	76.60±8.21	0.5875
10 min	86.8±16.03	93.26±11.22	0.0760
15 min	85.66±17.38	92.50±11.38	0.0778
30 min	83.46±15.66	89.50±10.36	0.0847
45 min	82.40±14.65	87.76±9.54	0.0989
Diastolic blood pressure			
0 min	71.40±4.70	73.73±5.72	0.0901
5 min	68.10±6.02	70.13±6.63	0.2194
10 min	61.66±5.60	63.06±5.57	0.3363
15 min	69.83±6.00	66.43±7.99	0.0674
30 min	68.93±6.17	65.13±6.58	0.0246
45 min	64.1±3.38	65.86±3.31	0.0458
Mean arterial blood pressure (mmHg)			
0 min	83.43±4.76	84.63±3.77	0.28
5 min	78.63±4.70	79.60±4.22	0.40
10 min	75.06±5.74	77.03±5.91	0.19
15 min	76.86±5.82	77.56±5.67	0.63
30 min	78.13±4.01	79.03±4.02	0.38
45 min	78.20±3.07	80.26±3.36	0.01
SpO_2 (%)			
0 min	98.9±0.88	98.83±0.68	0.7472
5 min	99.03±1.05	98.97±1.01	0.2640
10 min	98.87±0.91	98.80±1.22	0.2848
15 min	98.43±1.04	99.03±0.83	0.0175
30 min	98.5±1.33	98.86±0.88	0.217
45 min	98.43±1.00	98.56±1.30	0.6638

Table 4: Comparison of VAS score Group I and II (Mann Whitney test)

Time interval (min)	Group I (Mean VAS)	Group II (Mean VAS)	P value
0	0	0	-
5	0	0	-
10	0	0	-
15	0	0	-
20	0	0	-
30	0.164+0.349	0.172+0.236	0.9920
60	0.166+0.346	0.170+0.284	0.9920
90	0.167+0.372	0.174+0.321	0.9920
120	0.833+0.530	0.833+0.582	0.1235
150	1.7+0.534	2.50+0.169	<0.00001
180	2.36+0.614	3.26+0.628	<0.00001
210	2.93+0.639	4+0.730	<0.00001
240	3.90+0.758	4.6+0.711	<0.00001
270	4.60+0.813	5.2+0.748	<0.00001
300	5.5+0.731	5.6+0.679	0.6312

Table 5: Total doses of inj. diclofenac required in 24 h

Doses of Inj. Diclofenac	Group I (%) \	Group II (%) \	P value
1 (75 mg)	18 (60)	00 (00)	<0.00001 (Highly significant)
2 (150 mg)	12 (40)	13 (44)	
3 (225 mg)	00 (00)	17 (56)	

Table 6: Comparison of APGAR score at 1 min and 5 min in both the groups

	Group I	Group II	P Value
APGAR at 1 min	8.2±0.40	8.3±0.53	0.4128 (Not significant)
APGAR at 5 min	9.93±0.25	9.8±0.40	0.1366 (Not Significant)

DISCUSSION

As cesarean section is one of the common surgeries, its incidence has been increased in recent days. Maintaining intraoperative analgesia, hemodynamic stability, achieving adequate analgesia without causing any harm to the neonate is the main aim. To achieve that many adjuvants such as Fentanyl, buprenorphine, and tramadol have been routinely used.

Opioids are well known to improve the analgesic potency of local anesthetics. If administered intrathecally a short acting lipophilic opioid is known to augment the quality and duration of subarachnoid block. Furthermore, it decreases the dose of local anesthetic agents.[9]

Archana and Veena conducted a prospective double blind comparative study on 60 parturient. They were allocated into 2 groups of 30 each. Group I received 1.6 ml of 0.5% hyperbaric bupivacaine with 0.4 ml of preservative free fentanyl (20 mcg). Group II received 2 ml of 0.5% hyperbaric bupivacaine. They reported that the addition of Fentanyl 20 μg to hyperbaric Bupivacaine enhances the quality of intraoperative analgesia provides better hemodynamic

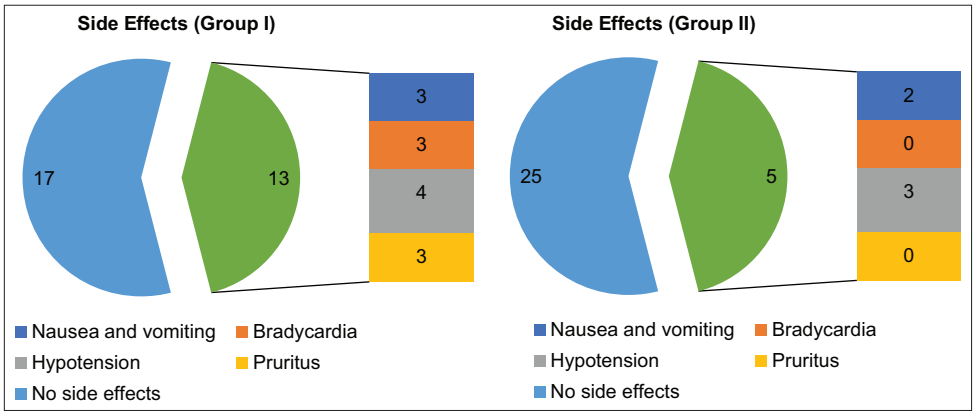

Figure 1: Side effects in Group I and II

stability and prolongs duration of post-operative analgesia without affecting newborn's clinical status.[10]

In study by Venkata et al., conducted randomized controlled prospective study comparing a low dose bupivacaine (7.5 mg) and fentanyl mixture to a conventional dose of hyperbaric bupivacaine for cesarean section (200±9.1 min vs. 143±9 min). Furthermore, quality of analgesia which was assessed by VAS was excellent in bupivacaine and fentanyl compared to bupivacaine only group. They concluded that rescue analgesics are significantly reduced by addition of intrathecal fentanyl.[11] The present study results in terms of duration of analgesia is comparable with results of above studies. Similar findings were noted by Hunt et al., and Bano et al.[12,13]

VAS score was used to assess pain postoperatively initially 5 min then every 30 min up to 5 h. VAS score in post-operative period was less in Group I as compared to Group II (Bupivacaine+Normal saline). This difference was statistically significant (P<0.05).

Biswas et al., conducted randomized double blinded study to evaluate the effects of fentanyl (12.5 mcg) on the onset and duration of hyperbaric bupivacaine induced sensory and motor block, quality of intraoperative surgical anesthesia and requirements of analgesia in early post-operative period. They showed superior analgesia during cesarean delivery and in early post-operative period (183+9 min vs. 129+9.5 min) and reduced VAS scores in patients of study group compared to control group.[14]

Yesuf et al., conducted hospital-based observational cohort study - Analgesic effect of intrathecal fentanyl as an adjuvant to spinal anesthesia in comparison with spinal anesthesia with bupivacaine only for mothers delivered by emergency cesarean section. Study showed reduced VAS scores in patients given intrathecal fentanyl, demanded for less doses of analgesics compared to study group.[15]

In our study, first rescue analgesia was given when patient has pain with VAS >4, injection. Diclofenac was administered and total dose of Diclofenac required in 24 h calculated. Inj. diclofenac (75 mg) consumption was significantly decreased in Group I as compared to Group II. Difference in total doses of inj. diclofenac was highly significant (P<0.00001).

Acharya et al., conducted a study titled effect of Low Dose Bupivacaine and Fentanyl during elective cesarean section under spinal anesthesia. It showed that reduced doses of analgesics are required in patients of study group compared to study group.[16] The present study results in terms of requirement of rescue analgesic is comparable with results of above studies.

In the present study, hypotension was observed in 13.3% of patients in group I, 10% of patients in Group II which was treated with 6 mg boluses of Mephentermine and was not significant among the groups. This result concurs with Archana and Veena.[9] study where they noticed no significant difference among Bupivacaine–Fentanyl combination groups. Similar results were found in studies done by Venkata et al.[10]

Bradycardia was noticed in 10% of patients in Group I which was treated with 0.6 mg of IV atropine. No patient in group B had significant bradycardia. Mean values of heart rate in both the groups was almost similar. This result concurs with Archana and Veena study where they noticed no significant difference among Bupivacaine-Fentanyl combination groups.[9]

Thus, from our study, it was observed that fentanyl (20 mcg) as an adjuvant to spinal bupivacaine in cesarean section reduces the dose of local anesthetic agent Bupivacaine and significantly prolongs the post-operative analgesia with no significant maternal and neonatal side effects. We also conclude that addition of 20 mcg intrathecal fentanyl to 0.5% hyperbaric bupivacaine during cesarean section significantly prolongs the duration of analgesia and significantly reduces pain score and hence reduced requirements of rescue analgesia.

Limitation of the study

The limitation of this study was a relatively small number of cases and the fact that we only included ASA Grade II cases. A larger study that also includes ASA Grade III patients would further substantiate the results of this study.

CONCLUSION

We conclude that the 0.5% hyperbaric Bupivacaine 8 mg with Fentanyl 20 μg is safe, effective, superior for spinal anesthesia, provided longer duration of analgesia and significantly reduces number of rescue analgesia doses in cesarean section and we strongly recommend its use routinely to reduce dose of local anesthetic and prolong the duration of post-operative analgesia.

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Authors Contribution:
TBP- Concept and design of the study; interpreted the results, prepared first draft of manuscript and critical revision of the manuscript; **NYM-** Statistically analyzed and interpreted; reviewed the literature and manuscript preparation; **NKN, YSD-** Design of the study, statistically analyzed and interpreted, preparation of manuscript and revision of the manuscript; **ALJ, JPB-** Concept and coordination of the overall study.

Work attributed to:
Department of Anesthesiology, Dr Shankarrao Chavan Government Medical College, Nanded, Maharashtra, India

Orcid ID:
Thrupthi BP - https://orcid.org/0000-0001-7593-3946
Nazima Y Memon - https://orcid.org/0000-0002-5584-6746
Niteen K Nandanwankar - https://orcid.org/0000-0001-6081-3677
SD Yennwar - https://orcid.org/0000-0002-4509-4050
Juhi Bagga - https://orcid.org/0000-0001-6363-0163

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