Original Article

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A Comparative Study of Intrathecal 0.5% Bupivacaine and 0.5% Bupivacaine with Fentanyl in Patients Undergoing LSCS

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Abstract

This study was conducted to compare the effects of hyperbaric bupivacaine 0.5% alone versus hyperbaric bupivacaine 0.5% + fentanyl 25mcg in spinal anaesthesia in patients undergoing LSCS.

Objective: A prospective randomised comparative study, conducted to compare the onset and duration of analgesia and hemodynamic changes, side effects like nausea, vomiting, respiratory depression, shivering, pruritis, etc. if any.

Method: After institutional committee approval and obtaining written informed consent. 64 patients posted for LSCS were randomly divided into two groups with 32 patients in each group. All patients were examined before the surgery and thoroughly investigated as per institution protocol and counselled about the anaesthesia and procedure. Patients were instructed to fast for 6-8 hours before surgery. Baseline blood pressure, heart rate and oxygen saturation were recorded. Lumbar subarachnoid block was performed. After confirming free flow of CSF the drug was injected. Features assessed :The time of onset of sensory analgesia at T10 segment, maximum level of analgesia, degree of motor blockade, duration of effective analgesia, hemodynamic parameters and complications.

Results: Addition of fentanyl to bupivacaine can be safely administered in patients undergoing caesarean section without significant hemodynamic changes and adverse effects. It markedly improves intraoperative anaesthesia and significantly reduces need for postoperative analgesia. Total duration of analgesia with bupivacaine alone was 176.6 +/-31.9 mins versus 276.7+/- 31.4 mins with added fentanyl.

Conclusion: The addition of 25 micro gram of fentanyl to 2ml (10mg) of hyperbaric bupivacaine intensified and prolonged the duration of bupivacaine induced sensory block without affecting motor blockade.

Keywords: Bupivacaine; Fentanyl; Intrathecal Opoids; Obstetric Anaesthesia; Post-Operative Pain Management; Spinal Anaesthesia.

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Introduction

Surgical intervention in obstetric practice is becoming increasingly common. Intrathecal analgesia in labour has become an established technique, and various local anaesthetics and opioids have been used either alone or in combination.[1]

Spinal anaesthesia consists of the temporary interruption of nerve transmission within the subarachnoid space produced by injection of a local anaesthetic solution into subarachnoid space.

Spinal anaesthesia confers numerous advantages with smaller doses of local anaesthetic. It is simple to perform with rapid onset of action and good muscle relaxation. One main disadvantage is its limited duration of action, hence insufficient postoperative analgesia. To address this problem and to improve the quality of subarachnoid block, intrathecal Opioids are used as adjuvants to Bupivacaine. Among the manufactured narcotics, fentanyl is better due to higher potency, quicker beginning of activity and fast redistribution reducing its plasma concentration. Thus, improving the early postoperative analgesia.

So this study was undertaken to examine the effect of adding fentanyl to hyperbaric bupivacaine for spinal anaesthesia in patients undergoing elective LSCS.

Materials and Methods

Source of data: This study was carried out in the Department of Anaesthesiology, B.LD.E (Deemed to be University) Shri BM Patil Medical College, Hospital and Research Centre, Vijayapur.

Study Design: Prospective randomised comparative study

Study Period: One and half years from December 2018 to September 2020.

Sample Size: Total sample size 32+32=64

with anticipated mean difference of mean duration of analgesia between the study groups as 45.3 min and Anticipated SD as 40.1 min the minimum sample size per group was 32 With 95% power and 1% level of significance.

By using the formula:

$$n = \frac{(Z_\alpha + Z_\beta)^2 \, 2 \, SD^2}{MD^2}$$

Where Z= Z statistic at a level of significance

MD= Anticipated mean difference

SD= Anticipated Standard deviation

Hence 32 cases were included in each group.

The statistical analysis between the two groups will be compared using student's 't' test and chi-square test.

Randomization: The study population of 64 patients age and weight matched were randomly divided by computer generated slip into two groups with 32 patients in each group.

Group I received 0.5% Bupivacaine 2ml.

Group II received 0.5% Bupivacaine 2ml + Fentanyl 25 mcg.

Results were recorded using a preset performa.

Study group: After institutional committee approval and written informed consent, 64 patients posted for caesarean section were selected. A complete physical examination and routine investigations were done for all patients. Heart rate, non invasive blood pressure, Spo2 were monitored and recorded.

After taking informed consent. The cases were divided into 2 groups with 32 patients in each group by computer generated slip. Group I received Hyperbaric bupivacaine 0.5% 2ml (10mg). Group II receivedHyperbaric bupivacaine 0.5% 2ml (10mg) + fentanyl citrate (25mcg)

Inclusion criteria: Patients undergoing elective LSCS, Patients belonging to ASA grade I and II.

Exclusion criteria: Patients in whom regional anaesthesia is contraindicated, patients with foetal abnormalities, patients with known allergy to study medication, patient with history of hypertension, epilepsy, cardiac illness.

Investigations Required: Hemoglobin, total count, Platelet count, Random blood sugar, Blood Urea, Serum Creatinine, ECG, Others (if required).

Procedure: All patients were examined the day before surgery and thoroughly investigated according to institute protocol and counselled with regards to anaesthesia as well as procedure. Patient's meeting the above criteria were asked to participate in the study and informed consent was obtained. All resuscitation and monitoring equipments like bag-valve-mask system, laryngoscope, endotracheal tubes and emergency drugs were kept ready in the operation theatre for management of any adverse event.

On the day of operation, patient were taken to the operation theatre. Baseline values of blood

pressure, heart rate and oxygen saturation were recorded. Intravenous line was secured with 20G cannula and premedication i.e Inj.ondensetron 4mg given. The patients were placed in the left lateral position on the operating table. The back was cleaned with betadine and spirit.

The area draped with a sterile towel, L3 – L4 space identified and lumbar subarachnoid block was performed, using a 26 guage Quincke-Babcock spinal needle. After confirming free flow of CSF the drug was injected slowly at a rate of 0.25 ml per second.

Anaesthesia Features Assessed

- The time of onset of sensory analgesia at T10 segment. This is the time taken to achieve analgesia at T10 dermatome assessed by pin prick method.
- Maximum level of analgesia. This is the highest level of sensory block as assessed by pinprick method.
- Degree of motor blockade. Motar blockade is assessed using modified Bromage score.
- Duration of effective analgesia. This was taken as the time interval between injection of spinal drug to first reports of pain.Pain was assessed using visual analogue scale.

Rescue analgesia was given with injection diclofenac 1.5mg/kg IV infusion in 100ml normal saline and time of rescue analgesia was noted.

- Cardiovascular/hemodynamic status. After the block patient was monitored for pulse rate and blood pressure every 2 mins initially for 10 min and then every 15 min up to one hour and every 30 min thereafter, till the sensory block regresses to L1.

Bradycardia: A pulse rate of less than 60 beats per minute was considered bradycardia and it was treated with injection atropine 0.6mg IV bolus.

Hypotension: A systolic blood pressure of less than 90 mmHg or decrease in 20% below the base line systolic blood pressure was considered hypotension. It was treated with rapid infusion of IV fluids. Oxygenation via face mask, foot end elevation and injection ephedrine in incremental doses of 6mg IV bolus.

- Any complications or side effects like nausea, vomiting, respiratory depression, shivering, pruritus, etc. if any, were noted.

Results

	Group I	Group II
Mean age (years)	25.3+/-4.6	23.9 +/- 4.20
Mean weight (kgs)	52.0 +/- 1.6	51.0 +/- 2.1
Mean duration of surgery (min)	61.6 +/- 9.8	62.0 +/- 7.7
Mean time of onset of sensory analgesia (min) at T10	2.2 +/- 0.7	1.7 +/- 0.5
Mean height of analgesia (range)	T4 (T3 – T6)	T4 (T3 – T6)
Mean time for highest sensory level (min)	5.3 +/- 2	4.1 +/-1.7
Mean time for two segment regression from the highest sensory level (min)	93.8+/-15.7	129.5+/-33.1
Mean time for sensory regression to L1 from the highest sensory level	170.8+/-30.9	263.8 +/-29.6
Mean time for complete sensory recovery (min)	183.0+/- 31.9	274.5 +/-30.0
Mean time of total duration analgesia (min)	176.6+/- 31.7	276.7 +/-31.4
Mean time of onset to Grade III motor block (min)	3.0 +/-0.9	2.6 +/- 0.8
Mean time of duration of Grade III motor block (min)	112 +/- 21.3	133.3 +/-39.0
Complication: Hypotension(%)	43.8%	34.4%
Bradycardia (%)	15.6%	12.5%
Nausea and vomiting (%)	15.6%	12.5%
Shivering (%)	9.4%	6.3%
Itching (%)	0	6.3%
Respiratory depression (%)	0	0
Post dural puncture headache and neurological complication	0	0

Discussion

1. Onset of sensory analgesia was achieved in 2-3 minutes in a majority of patients in Group I and 1-2 minutes in a majority of patients in Group II which was significant ($p < 0.05$). The mean height of sensory analgesia range was T4 (T3-T6) in both the groups. The time taken to achieve the highest sensory level was 5.3 +/- 2.0 minutes in Group I and 4.1 +/- 1.7 minutes in Group II which was significant ($p<0.05$).
2. Time for two segment regression, time for sensory regression to L1 and time for complete sensory recovery was significantly prolonged in bupivacaine with fentanyl combination when compared to bupivacaine alone.

3. Time of onset to Grade III motor block was not significant (3.0 +/- 0.9 minutes in Group I and 2.6 +/- 0.8 minutes in GroupII).
4. The total duration of analgesia was significantly more in bupivacaine with fentanyl combination, i.e. 273.9 +/- 33.7 minutes when compared to bupivacaine alone group, i.e. 172 +/- 42.9 minutes.
5. The addition of fentanyl 25 mcg to bupivacaine 2 ml (10 mg) was not associated with any significant haemodynamic changes.
6. Hypotension, bradycardia, nausea-vomiting, shivering, pruritus were observed. These were significantly more in bupivacaine alone group. The incidence of hypotension (43.8%) was more in Group I compared to (34.4%) in group ll (bupivacaine and fentanyl)but it was not significant. p>0.05.
7. No cases of respiratory depression, post dural puncture headache or neurological complication were observed during 24 hours postoperativeperiod.

Conclusion

Spinal anaesthesia is the most versatile block available and is used for various surgeries on the lower half of the body. It is ideal in situations when rapid onset of action and profound motor blockade is required. The use of neuraxial opioids has gained popularity over the last few years. Administration of fentanyl intrathecally is an established method for intraoperative anaesthesia and to supplement postoperative analgesia Fentanyl is more lipid soluble than morphine. Thus it is readily eliminated from the CSF than morphine, making late respiratory depression less likely. Intrathecal use of fentanyl is advantageous due to its extremely rapid onset of action, getting desired level of analgesia and anaesthesia with minimum dosage of fentanyl as well as bupivacaine.

This study showed that fentanyl 25mcg prolongs the duration and intensity of bupivacaine induced sensory blockade block without affecting the onset and intensity of motor blockade. This suggests a potential synergism between fentanyl and bupivacaine.

We thus conclude that a combination of fentanyl and bupivacaine can be safely administered for patients who undergo caesarean section, without significant haemodynamic changes and adverse effects. It would markedly improve intraoperative anaesthesia and significantly reduce the demand for postoperative analgesic with good maternal satisfaction.

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