ORIGINAL RESEARCH PAPER

Volume-7 | Issue-7 | July-2018 | PRINT ISSN No 2277 - 8179

INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

COMPARATIVE STUDY OF THE EFFECT OF INTRATHECAL FENTANYL ON THE QUALITY OF HYPERBARIC BUPIVACAINE INDUCED SUBARACHNOID BLOCK IN ADULT PATIENTS

Anesthesiology

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KEYWORDS

Introduction-
Pain management is an integral part of postoperative patient management.

It is a well-known fact that the postoperative pain management improves the outcome of patients. Many techniques are used in order to provide postoperative analgesia to the patients- Systemic, peripheral nerve catheters, patient controlled analgesia, etc. in a high turn-over setting, it becomes important to minimize errors of drug administration, yet provide controlled analgesia. Very often the drugs have been added to the subarachnoid space to prolong analgesia provided by the drugs, such as clonidine, neostigmine, tramadol, etc. We attempted to give an opioid to test the analgesia efficacy of the drug in the subarachnoid space. We hypothesized that the addition of Fentanyl does not have any effect on the duration of analgesia produced by Bupivacaine.

Method-
The trial was designed as a randomized, controlled, double blinded, single centre trial to evaluate the postoperative analgesic efficacy of 25 mic of Injection Fentanyl as an adjuvant to 0.5% Bupivacaine (heavy). After obtaining consent from the Institutional Review Board, the study was done from 2005 to 2007. 50 ASA grade II, between the age 20 to 50 years patients and I were included, who were scheduled for posted for lower extremity surgeries. Patients who were not willing or had any allergy towards local anesthetic, history of bleeding tendency were not included in the study group. Randomization was done using simple compute generated random number table. A nurse, blinded to the study, prepared the drugs and a resident doctor applied the spinal block with sufficient training in applying the spinal block. An observer who was unaware of the drugs prepared recorded the monitor readings.

The two groups were as follows-
Group I = 3 ml of 0.5% heavy Bupivacaine + 0.5 ml of Normal Saline 0.9% (N=25)

Group II = 3 ml of 0.5% heavy Bupivacaine + 0.5 ml of Fentanyl (N=25)

After seeking a written, informed consent from the patient, standard monitors (ECG, NIBP, Pulse oximetry) were applied. 20 G intravenous Cannula was applied and Ringer lactate begun. Under complete aseptic precautions, the spinal block was given in the sitting position with the drug provided. Patients were made supine soon after the procedure. Oxygen was delivered using a facemask. Sensory level testing by pin-prick method, and motor testing was done using Modified Bromage scale was done in every minute till Grade 3 was achieved on Modified Bromage scale. The following was recorded in every patient – highest level of sensory block attained, time taken to achieve. Pulse rate, SpO2, Non-Invasive Blood Pressure, Respiratory Rate, occurrence of side effect (Pruritis, Nausea, vomiting, shivering) was done in every 2 minutes, upto the first 30 minutes, and then at 15 minutes interval until the patient complained of pain/ VAS was 5/ till the requirement of rescue analgesic.

The patients were assessed for any side effects or complications in the postoperative period for 24 hrs and following complications, if any were treated with conventional methods.

Hypotension- defined as fall in the systolic blood pressure >= 30% of preoperative value/less than 90 mm Hg, treated with rapid infusion of fluids and giving Trendelenburg position.

Respiratory Depression- defined as respiratory rate < 9 breaths / min or SpO2 < 90%

Bradycardia- Pulse rate less than 60/min. Treated with incrementa doses of Injection Atropine 0.6 mg

Shivering- treated with prewarmed IV fluids, covering patient with blankets and if severe, with Injection Ondansetron 0.1 mg/kg i.v.

Nausea and vomiting- provided systolic BP > 90 mm Hg or Mean BP >65 mm Hg, injection Ondansetron was given as 0.1 mg/ kg i.v.

Pruritis - injection Chlorpheniramine maleate 10 mg iv was given

Post dural Puncture headache- good hydration and a head low position was given

Patients were shifted to the ward on meeting the following criterion-
1. Ability to lift both lower limbs
2. Systolic Blood Pressure >100 mm Hg
3. Respiratory Rate 12-20 /min
4. Heart rate between 60-120/min

Data was then analyzed using statistical package for social sciences, unpaired t- test was applied, and p values were considered statistically significant if p value <0.05

Results –
The two groups were comparable with respect to age, weight, height and gender (Table 1). The highest sensory level achieved was higher in the Fentanyl group (T6) than the control group (T8). Time taken from injection to the highest sensory level was 8.08 +_1.87 min in the control group, whereas it was 7.84 +_ 1.62 min in the Fentanyl group (Table 2). This, however, was not statistically significant. Time taken for sensory regression of to L1 from the highest sensory level was significantly more in the Fentanyl group (211.24 +_ 16.34 min) vs the control group (191.12 +_14.28 min). There was no statistically significant difference between onset of grade III motor block or duration of Grade I Motor block (min) as can be seen in the table. The total duration of analgesia was significantly longer in the Fentanyl group (262.80 +46.86 min) than the control group (212.40+ 31.13 min). (Table 2)

The number of patients experiencing Bradycardia and hypotension were more in the Fentanyl group, 28% and 20% respectively, than the control group (20% and 16%). However, it was not statistically

significant. The incidence of shivering and vomiting was significantly lower in the study group than control group. None of the patients had respiratory depression in either groups. 12 % patients experienced pruritis in the Fentanyl Group but none in the control group (Table 3).

Discussion-

Spinal Anaesthesia is a popular technique of anaesthesia for surgeries on the lower half of the body. Use of an opioid reduces the period of recumbency after spinal anaesthesia, by allowing early ambulation and results in decrease of the post-dural puncture headache and the period of hospital stay[1-3].

The addition of intrathecal fentanyl (10-25 mic) enhances intraoperative analgesia, provides several hours of postoperative analgesia without prolonging motor block or delaying discharge[4].

The spread of Fentanyl after administration into the cerebrospinal fluid into the opioid receptors or other non-specific binding sites in the spinal cord[5] and rostral migration via the cerebrospinal fluid to supraspinal sites. Because of the high lipid affinity of Fentanyl, only a very small portion of the administered dose migrates to the cervical region[5].

In our study we saw that 25 mics of Fentanyl given in the subarachnoid space prolongs the duration of sensory anaesthesia producedby Bupivacaine by 11%. Similar results are produced by animal studies done by Wang et al[6] and Harbhej Singh et al[7].

The highest sensory level achieved were T8 and T6 in Groups I and II respectively as also evidenced by Adkisson et al in their study[8]. However, there was no effect of Fentanyl on the onset of sensory anaesthesia. Also, there was no prolongation of motor blockade produced by the local anesthetic Bupivacaine 0.5% (Heavy), as previously reported by Hunt et al[9] for parturients undergoing Caesarean delivery.

Balzarena in his study found that the addition of 0.5 mic/kg and 0.75mic/kg if Fentanyl is given intrathecally, it increases the duration of postoperative analgesia in parturients following caesarean delivery (640+_140 min and 787+_ 161 min) respectively, however, this increased duration was associated with a decrease in the respiratory rate during the intraoperative period, and increased sedation and pruritis.[10]

Opioids and local anaesthetics exert their antinociceptive effect on the spinal cord by different mechanisms. The mu-agonist- Fentanyl exerts its action by opening the K+ Channel and reducing Calcium influx, resulting in inhibition of transmitter release. The mu- agonists also have a direct post-synaptic causing hyperpolarization and a reduction in neuronal activity[11].

Local anaesthetic Bupivacaine acts mainly by blockade of voltage-gated Sodium –ion channels in the axonal membrane. It may also inhibit the presynaptic transmission in addition to their effects on nerve conduction.

We had 3 patients (12%) belonging to Fentanyl group who experienced pruritis that corroborated with results of Hunt et al[9]. The pruritis may be due to the release of histamine. In this study the emetic episodes were lesser in the Fentanyl group than the control group commensurate with the observations of Dahlgren et al[12] and Manullang et al[13]. There was no significant difference in the number of patients experiencing episodes of bradycardia, respiratory depression, sedation or hypotension in our study.

The limitation of our study was the small sample size of the two groups because of which this cannot be extrapolated to a larger group.

Conclusion-

In conclusion, 25 microgram of Fentanyl added to 15 mg of 0.5% Injection Bupivacaine (heavy) intrathecally induced sensory subarachnoid block, increased duration of complete analgesia and the time for first requirement of rescue analgesic during the early postoperative period, with minimal side effects. This enabled early ambulation and physiotherapy in the early postoperative period. Our study demonstrates that intrathecal Fentanyl acts synergistically to potentiate the quality of subarachnoid block produced by hyperbaric Bupivacaine. However, further studies need to be done to corroborate our findings.

Table 1-Demographic Data-

Parameters	Group I (Control)	Group II (Study)
No. of patients	25	25
Age (yrs)	32.6+-8.67	31.84+-7.54
Weight (Kg)	60.84 +_5.79	62.16 +_5.98
Height (Cms)	161.84 +_6.83	162.72+_6.68
Sex (Male/Female)	13/12	12/13

Table 2- Characteristics of the sensory, motor block and analgesia-

Parameters	Group I (Control)	Group II (Study)
Highest Sensory Block level	T8 (T5-T8)	T6 (T5-T8)
Time taken to reach the highest sensory level (min)	8.08 +_1.87	7.84 +_1.62
Time for sensory regression to L1from highest sensory level (min)	191.12 +_14.28	211.24+_16.34 *
Onset of grade III motor block (min)	5.36 +_1.25	5.52 +_1.19
Duration of Motor Block	170.80 +_10.71	166.60 +_12.46
Duration of complete analgesia (min)	212.40 +_31.13	262.80+_46.86 *

* p- value <0.05- considered significant (unpaired t-test)

Table 3- Incidence of side-effects (intraoperative and early postoperative period)

Parameter	Group I(Control Group)	Group II (Study Group)
Hypotension (Fall of BP >30% from base level)	5 (20%)	7 (28%)
Bradycardia (HR <60/min)	4 (16%)	5 (20%)
Respiratory depression (Breaths <9/min)	0 (0%)	0 (0%)
Shivering	2 (8%)	0
Postoperative nausea and vomiting	5 (20%)	1(4%)
Pruritis	0 (0%)	3 (12%)

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