*Original Research Article*

Indian Journal of Anesthesia and Analgesia
2019; 6(4) (Part - I): 1197-1201
DOI: http://dx.doi.org/10.21088/ijaa.2349.8471.6419.21

# Efficacy of Intrathecal Fentanyl with 0.5% Hyperbaric Bupivacaine in Intraoperative and Post Operative Analgesia in Cesarean Section: A Randomized Controlled Trial

**Reji S Varghese[1], Archana Amol Gautam[2]**

[1]Assistant Professor, Department of Anesthesia, Pushpagiri Medical College & Hospital, Thiruvalla, Kerala 689101, India. [2]Assistant Professor, Department of Anesthesia, Krishna Institute of Medical Sciences, Satara, Maharashtra 415539, India.

**Abstract**

*Background:* Caesarean delivery requires significant traction of peritoneum and intra-abdominal organs. Intra operative visceral pain is sometimes a problem during spinal anaesthesia. Increasing the dose of local anaesthestic is associated with less intra operative visceral pain. *Objective:* To evaluate the quality of intra operative analgesia and post-operative analgesia when fentanyl is added to intrathecal bupivacaine for caesarean section. *Methods:* Double blind, randomized controlled trial was conducted among 80 patients aged between 18-35 years from February 2007 to January 2008. 80 patients of the age group 18-35 years undergoing cesarean section, belonging to ASA Grade 1 were considered for this study. The patients were randomly divided into two groups of 40 patients each. Epi info 7 was used for analysis. *Results:* age and anthropometric characters (height and weight) were calculated in terms of mean and Standard deviation. As seen no significant difference was seen either in age, height or weight ($p>0.05$). For Mean BP at the time of arrival and during positioning for intrathecal injection: $p > 0.05$- not significant. After intrathecal injection: $p < 0.01$- highly significant. 1 min, 2 min, 3 min, 4 min, 5 min, 6 min, 7 min after intrathecal injection: $p > 0.05$ – not significant. *Conclusion:* Addition of fentanyl (12.5 µg) to 0.5% hyperbaric Bupivacaine (10 mg) provides early onset of sensory blockade, improvement in intraoperative analgesia and significant increase in the duration of postoperative analgesia.

**Keywords:** Analgesia; Fentanyl; Bupivacaine; Cesarean Section.

**How to cite this article:**

Reji S Varghese, Archana Amol Gautam. Efficacy of Intrathecal Fentanyl with 0.5% Hyperbaric Bupivacaine in Intraoperative and Post Operative Analgesia in Cesarean Section: A Randomized Controlled Trial . Indian J Anesth Analg. 2019;6(4):1197-1201.

## Introduction

Caesarean delivery requires significant traction of peritoneum and intra-abdominal organs. Intra operative visceral pain is sometimes a problem during spinal anaesthesia. Increasing the dose of local anaesthestic is associated with less intra operative visceral pain, but higher sympathetic blockade. Neuraxial administration of opioids in conjunction with local anaesthetic improves the quality of intraoperative analgesia and prolongs the duration of post-operative analgesia [1]. The advantages of post-operative analgesia are better

**Corresponding Author: Archana Amol Gautam**, Assistant Professor, Department of Anesthesia, Krishna Institute of Medical Sciences, Satara, Maharashtra 415539, India.

**E-mail:** drarchanaranjalkar@gmail.com

**Received on** 27.03.2019, **Accepted on** 04.05.2019

pulmonary function, early ambulation and low risk for deep vein thrombosis [2]. Fentanyl is a synthetic & lipophilic opioid it has rapid onset of action following intrathecal administration and it does not tend to migrate higher up to cause delayed respiration. Being a lipophilic opioid, it has rapid onset of action following intrathecal administration and it does not tend to migrate higher up to cause delayed respiratory depression. So, the rationale behind the study was to evaluate the effects of intrathecally administered Fentanyl (12.5 µg) on the onset and duration of sensory blockade of 0.5% hyperbaric bupivacaine (10 mg), quality of intra operative analgesia and post-operative analgesia.

## Materials & Methods

*Study Area*- Tertiary care teaching– Major operation theatre, Department of Anaesthesiology, Pushpagiri Institute of Medical Sciences, Thiruvalla, Kerala.

*Study type*- Double blind, randomized control study.

*Study population*- 80 patients of the age group between 18 and 35 years who presented for cesarean section.

*Study duration*- February 2007 to January 2008.

Sampling technique- Purposive Sampling Technique.

*Inclusion criteria*- Patients admitted for cesarean section of age group between 18 and 35 years of ASA Grade I.

*Exclusion criteria*-

1. Age less than 18 years and more than 40 years.
2. Body weight more than 70 kg.
3. Co-existing system illness like hypertension, diabetes mellitus, bronchial asthma, cardiovascular disease.
4. Patients with fetal distress, fetal anomalies.
5. Patients with known drug allergies.

*Methodology*- 80 patients of the age group 18-35 years undergoing cesarean section, belonging to ASA Grade 1 were considered for this study. The patients were randomly divided into two groups of 40 patients each.

*Group A*- 40 patients of this group received 2 ml of 0.5% injection hyperbaric bupivacaine (10 mg) with 0.25 ml of normal saline.

*Group B*- 40 patients of this group received 2 ml of 0.5% injection hyperbaric bupivacaine (10 mg) with 0.25 ml (12.5 µg) fentanyl. All study agents are introduced intrathecally and total volume of agents administered were 2.25 ml. All patients were kept fasting for 8 hrs prior to surgery. They were premedicated with Tab Ranitidine 150 mg and Metoclopramide 10 mg in elective cases and injection Ranitidine 50 mg and injection Metoclopramide 10 mg respectively in emergency cases. In the operating room, all patients were preloaded with 15 ml/Kg Ringer lactate. Baseline heart rate, blood pressure, rate of respiration, fetal heart rate were recorded before spinal anesthesia.

*Study tool*- In order to compare the data and to draw conclusions; the mean and standard deviation of heart rate, BP, Respiratory rate, Mcgill Pain Score, Bromage scale and duration of analgesia were calculated.

*Consent Type*- Written Informed consent

*Ethical Considerations*- The study was approved by ethics committee of the medical faculty, Pushpagiri Institute of Medical Sciences, Thiruvalla.

*Statistical Analysis*- Data will be consolidated and entered a Microsoft Excel spreadsheet and then transferred to Epi info version (7.1.3.0. centre for disease control and prevention, Atlanta, Georgia, USA, 2013) software for analysis. student t- test was used.

## Results

**Table 1:** Mean body characteristics in Group A and Group B

| Parameters | Group | Mean | + SD | t value | p value |
|---|---|---|---|---|---|
| Age (years) | Group A | 26.55 | 2.44 | 0.741 | > 0.05 |
| | Group B | 26.15 | 2.39 | | |
| Height (cm) | Group A | 157.83 | 3.74 | -1.534 | > 0.05 |
| | Group B | 161.85 | 16.17 | | |
| Weight (kg) | Group A | 64.23 | 3.04 | 0.767 | > 0.05 |
| | Group B | 62.88 | 10.66 | | |

As per table 1 age and anthropometric characters (height and weight) were calculated in terms of mean and Standard deviation. As seen no significant difference was seen either in age, height or weight ($p>0.05$).

**Table 2:** Mean systolic BP in Group A and Group B

| SBP | Group | Mean | + SD | t value | p value |
|---|---|---|---|---|---|
| At the Time of Arrival | Group A | 118.60 | 9.98 | -1.757 | > 0.05 |
| | Group B | 122.63 | 10.50 | | |
| Positioning | Group A | 118.03 | 10.25 | -1.666 | > 0.05 |
| | Group B | 121.93 | 10.69 | | |
| After Intrathecal Injection | Group A | 111.08 | 9.11 | -3.092 | < 0.01 |
| | Group B | 117.73 | 10.10 | | |
| After Injection – 1 minute | Group A | 107.48 | 14.67 | -0.400 | > 0.05 |
| | Group B | 108.68 | 12.04 | | |
| After Injection – 2 minute | Group A | 101.93 | 10.95 | -0.767 | > 0.05 |
| | Group B | 104.13 | 14.45 | | |
| After Injection – 3 minute | Group A | 100.80 | 12.30 | -0.902 | > 0.05 |
| | Group B | 103.18 | 11.22 | | |
| After Injection – 4 minute | Group A | 104.03 | 11.79 | 0.394 | > 0.05 |
| | Group B | 102.98 | 12.06 | | |
| After Injection – 5 minute | Group A | 106.60 | 11.44 | 0.987 | > 0.05 |
| | Group B | 104.33 | 9.03 | | |
| After Injection – 6 minute | Group A | 108.23 | 8.54 | 1.575 | > 0.05 |
| | Group B | 105.08 | 9.33 | | |
| After Injection – 7 minute | Group A | 111.25 | 9.32 | 1.846 | > 0.05 |
| | Group B | 107.68 | 7.94 | | |
| After Injection – 8 minute | Group A | 113.05 | 7.17 | 2.127 | < 0.05 |
| | Group B | 109.63 | 7.23 | | |
| After Injection – 9 minute | Group A | 114.05 | 5.52 | 1.603 | > 0.05 |
| | Group B | 111.55 | 8.17 | | |
| After Injection – 10 minute | Group A | 115.90 | 8.85 | 5.875 | < 0.001 |
| | Group B | 111.98 | 8.52 | | |
| After Injection – 20 minute | Group A | 114.45 | 6.68 | 0.973 | > 0.05 |
| | Group B | 112.93 | 7.32 | | |
| After Injection – 30 minute | Group A | 115.93 | 6.01 | 0.662 | > 0.05 |
| | Group B | 114.90 | 7.72 | | |

In table 2 At the time of arrival and during positioning for intrathecal injection: $p > 0.05$- not significant. After intrathecal injection: $p < 0.01$- highly significant. 1 min, 2 min, 3 min, 4 min, 5 min, 6 min, 7 min after intrathecal injection: $p > 0.05$ – not significant. After 8 minutes of intrathecal injection: $p < 0.05$ – significant. After 9 minutes of intrathecal injection: $p > 0.05$ – not significant. After 10 minutes of intrathecal injection: $p < 0.001$- highly significant. After 20 and 30minutes of intrathecal injection: $p > 0.05$- significant.

As per Figure 1- at the arrival, positioning, and after intrathecal injection the mean diastolic BP was higher in group B and after that it was higher in group A which was found to be highly significant ($p<0.05$).

As per Figure 2 the mean values of heart rate was higher in group B patients and was significant except in time interval of 8 min, 9 min and 10 min were group A has higher mean heart rate then group B which was also significant. ($p<0.05$).

In Figure 3 mean respiratory values was calculated after injection which shows the rates in group A was not crossed rates of group B patient and they were found to be highly significant ($p<0.05$).

## Discussion

The addition of opioid to local anaesthetics has become a well-accepted practice in the

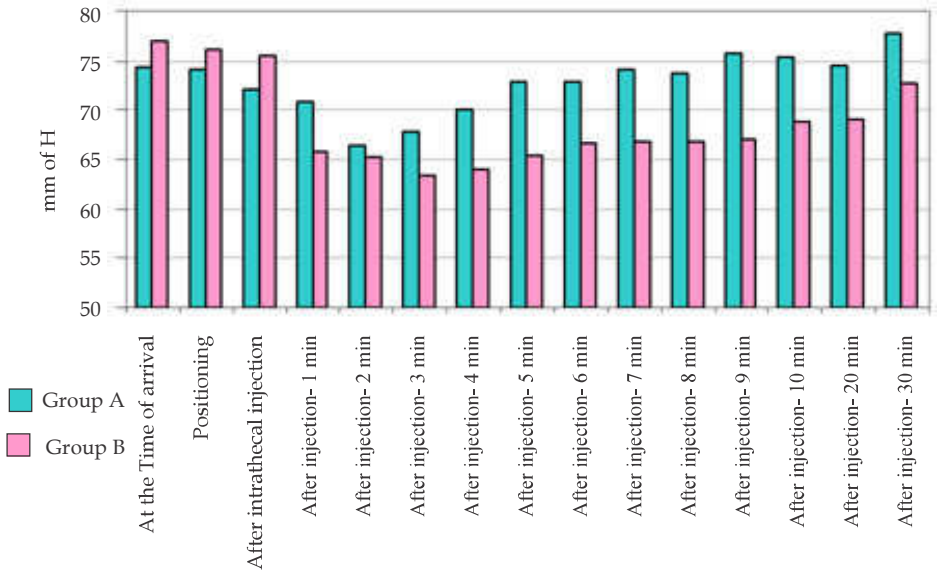


**Fig. 1:** Mean Values of Diastolic BP in both the groups

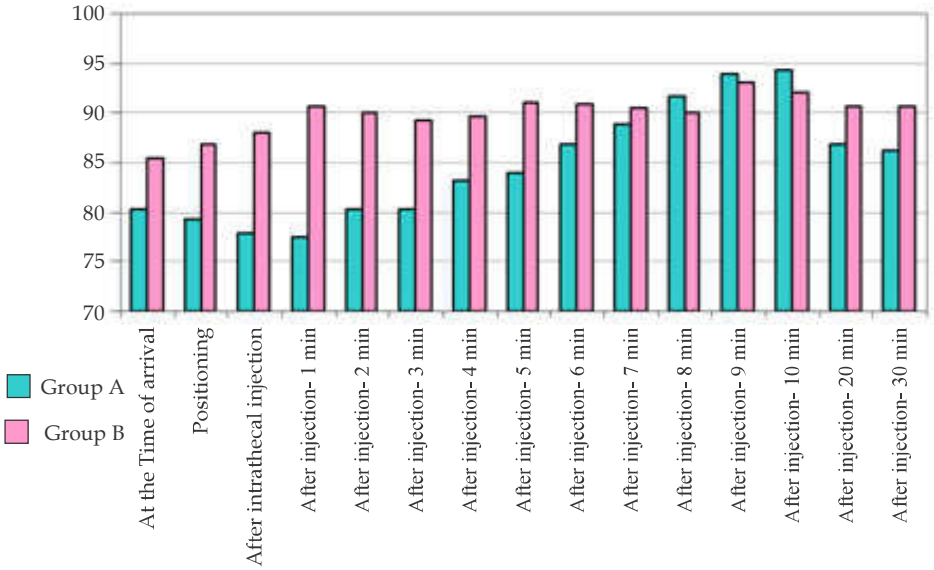


**Fig. 2:** Mean Values of Heart Rate in both groups

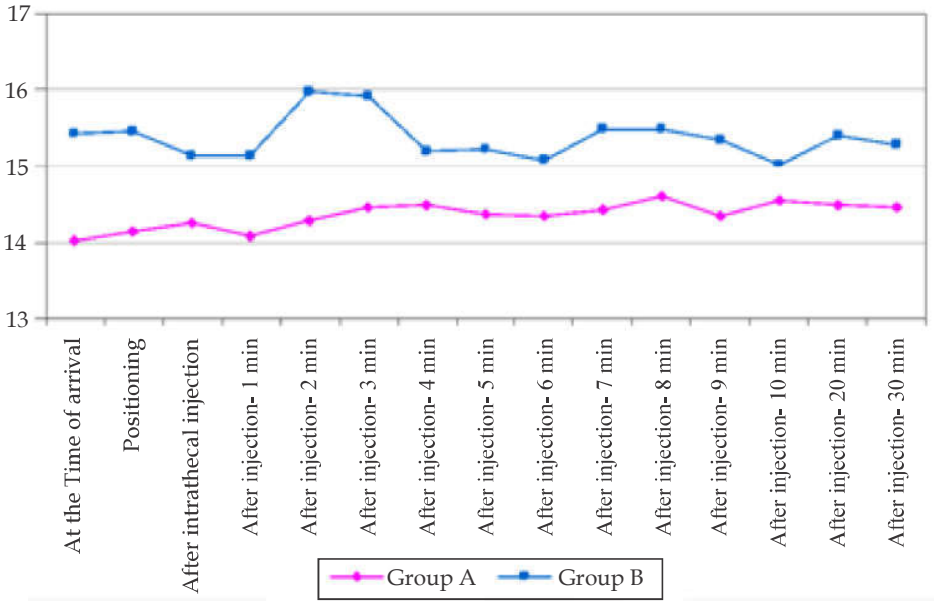


**Fig. 3:** Mean values of Respiratory Rate in both the groups

management of spinal anaesthesia for cesarean section. Use of morphine via subarachnoid route has limited use due to respiratory depression in the routine postoperative pain management. Fentanyl which is more lipid soluble than morphine has a rapid onset of action and it does not migrate higher up to cervical region. The evidence of side effects particularly respiratory depression is limited. Advantage of using intrathecal Fentanyl is its extremely rapid onset of action. Analgesia has been reported to occur within five to ten minutes. The present study was undertaken to evaluate the effects of intrathecally administered fentanyl (12.5 µg) on the onset and duration of sensory blockade of hyperbaric Bupivacaine, quality of intra operative analgesia, duration of post-operative analgesia and incidence of side effects. This dose of fentanyl was chosen because of studies by Ferrante *et al.* [5] showed that this was the optimal dose of intrathecal fentanyl with maximum clinical effect. This was a prospective randomized study conducted on two groups of 40 patients each.

Systolic blood pressure was recorded and fall in systolic blood pressure from baseline value was

recorded. Fall in blood pressure more than or equal to 30% from baseline was taken as hypotension. This study showed that Group B patients had incidence of fall in systolic blood pressure more than Group A. This study is consistent with the study by Cousins *et al.* [2] where it was found that there was no incidence of fall in heart rate in either groups. This is supported by the study by Ferrante *et al.* [5] where it was found that incidence of intraoperative hypotension is more with injection Bupivacaine - Fentanyl group [Bupivacaine 10 mg injection + Fentanyl 12.5 µg] than with injection Bupivacaine (10 mg). Similarly, there was no significant difference in number of patients experiencing fall in heart rate in both Group A and Group. 4 With respect to respiratory rate, no incidence of fall in rate of respiration in both Group A and Group B. The difference is found to be statistically not significant ($p > 0.05$) at all intervals of time. This study is consistent with studies by Cousins *et al.* [2] where it was found that there was no incidence of fall in rate of respiration in either groups.

The duration of effective analgesia was assessed using McGill scoring system. The duration of effective analgesia was taken as the interval between administration of spinal drug and time at which the patient complained of discomfort due to pain (McGill pain score). At that time rescue analgesic was given. The mean time for effective analgesia (minutes) in Group. A was 153.23 minutes. The mean time for effective analgesia (minutes) in Group B was 226.18 minutes.The difference in mean time for complete analgesia was found to be statistically significant ($p <0.001$). This study is consistent with studies with Cousins [2], Rexed *et al.* [3] and Melzack *et al.* [6] In studies by Cousins *et al.* [2] and Kelly *et al.* [8], Christopher *et al.* [9], Carles *et al.* [10] it was found that the mean time for effective analgesia (minutes) in injection Bupivacaine group was 150 ± 10.48 minutes and the mean time for effective analgesia (minutes) in injection Bupivacaine-Fentanyl group was 248 ± 11.76 minutes.

## Conclusion

Addition of fentanyl (12.5 µg) to 0.5% hyperbaric Bupivacaine (10 mg) provides early onset of sensory blockade, improvement in intraoperative analgesia and significant increase in the duration of postoperative analgesia. Further studies with larger sample size is advised to determine the desired results.

*Source of Funding*- None

*Conflict of Interest*- None declared

## References

1. IASP Sub-committee on Taxonomy. Pain Terms: A list with definition and notes on usage pain. 1979; 6:249.
2. Cousins MJ, Bridenbaugh PO. Neural Blockade in Clinical Anaesthesia and Management of Pain 3rd edn. Philadelphia: Lippincott –Raven. 1998.pp.472–5.
3. Rexed B. The Cyto Architectonic organization of the spinal cord in the cat. J Comp Neurolo. 1952;96:415.
4. Ready LB, Miller RD. Acute perioperative pain**.** 5th edn. Churchill Livingstone Inc. 2000.pp.23–25.
5. Ferrante FM. Acute postoperative pain management. In: Longnecker DE, Tinker DH and Morgan GE (ed.) Principles and Practice of Anaesthesiology. Mosby Year Book Inc. 1998;2331–45.
6. Melzack R. The Mc Gill Pain Questionnaire. Major properties and scoring methods. Pain. 1975;1: 277–99.
7. Hammer M. Control of Post operative pain nausea and vomiting. In: Morgan GE and Hall GM (ed.) Short Practice of Anaesthesia. Chapman and Morgan. 1998.pp.853–58.
8. Kelly DJ, Ahmmad M, Brull SJ. Pre emptive analgesia. Recent advances and current trends. Can J Anaesthesia. 2001;48:1091–01.
9. Christopher L Wu. Acute Postoperative Pain In: Ronald D Miller (ed.). Anaesthesia. Churchill Livingstone Inc. 2005;2732–44.
10. Carles RB, Gary RS. Local Anaesthetics In: Ronald D Miller (ed.) Anaesthesia. Churchill Livingstone Inc. 1994.pp.297–10.