

TO STUDY THE EFFICACY (DIFFERENTIAL BLOCK) OF INTRA- THECAL FENTANYL IN PROLONGING THE POST -OPERATIVE ANALGESIA WHEN ADDED TO HYPERBARIC BUPIVACAINE IN CAESAREAN SECTION

Anaesthesiology

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ABSTRACT

BACKGROUND: Spinal anesthesia is commonly employed for caesarean delivery. However intra-thecl bupivacaine alone may be insufficient to provide complete analgesia despite the high sensory block. Patient had visceral pain even after intra-thecl administration of 15 mg of bupivacaine. Further more such large doses of intra-thecl bupivacaine were associated with severe hypotension and delayed recovery of motor block. Therefore smaller doses of bupivacaine supplemented by intra-thecl Opioids have been recommended for spinal anesthesia in parturients undergoing caesarean section delivery. Aim and objectives : To provide best intra-opertive and post-operative analgesia. To clinically evaluate the efficacy (differential block) and side effects of intra-thecl fentanyl in prolonging the post -operative analgesia when added to hyperbaric bupivacaine in caesarean section.

METHODS: After obtaining institutional ethical and scientific committee approval, we conducted the study in 60 patients, who were in ASA grade 1 and 2, aged between 19Y -55 Y posted for emergency and elective LSCS from August 2018 to August 2019. Who were divided into 2 groups I & II , and both the groups received spinal using 26 G spinal needle at the level of L3-L4. Following which both the groups were monitored for onset , duration and quality of neuraxial block in both the groups. In post operative period Severity of the pain was measured by visual analogue pain scale score (1-10).

RESULTS: 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.

CONCLUSION: Intrathecal fentanyl with Bupivacaine provide early onset, prolonged anesthesia and analgesia than Bupivacaine alone with acceptable side effects.

KEYWORDS

spinal anesthesia, Intra-thecl fentanyl, caesarean section.

INTRODUCTION

Spinal anesthesia is commonly employed for caesarean delivery. However intra-thecl bupivacaine alone may be insufficient to provide complete analgesia despite the high sensory block. Patient had visceral pain even after intra-thecl administration of 15 mg of bupivacaine.¹ Further more such large doses of intra-thecl bupivacaine were associated with severe hypotension and delayed recovery of motor block.² Therefore smaller doses of bupivacaine supplemented by intra-thecl Opioids have been recommended for spinal anesthesia in parturients undergoing caesarean section delivery.^{3,4,7.}

Intra-thecl opioids are synergistic with local anesthetics and intensify the sensory block without increasing sympathetic block. The combination makes it possible to achieve spinal anesthesia with otherwise inadequate doses of local anaesthetics.⁸

Fentanyl being a lipophilic opioid, has rapid onset of action following Intra-thecl administration, and improves the quality of intraoperative analgesia and also provide postoperative pain relief for longer duration. It does not tend to migrate to the fourth ventricle, even in high concentration to cause delayed respiratory depression.

This study was designed to evaluate the effects of intrathecally administered fentanyl (12.5µg) on the onset, duration of hyperbaric bupivacaine induced sensory and motor block, quality of intraoperative surgical anaesthesia and requirement of rescue analgesia during early postoperative period.

AIM: To provide painless intra-opertive and post-operative period and further early mobilization and discharge of patient.

OBJECTIVES

1) To clinically evaluate the efficacy (differential block) of intra-

thecl fentanyl in prolonging the post -operative analgesia when added to hyperbaric bupivacaine in caesarean section.

2) To evaluate the side effects caused by adding fentanyl to bupivacaine.

MATERIAL AND METHODS

This study had conducted on 60 patients posted for elective caesarean section at S. V R. R. G. G./G. M. H hospital, Tirupati during the period August 2018 to November 2019. All cases were underwent thorough clinical assessment preoperatively and relevant laboratory investigations.

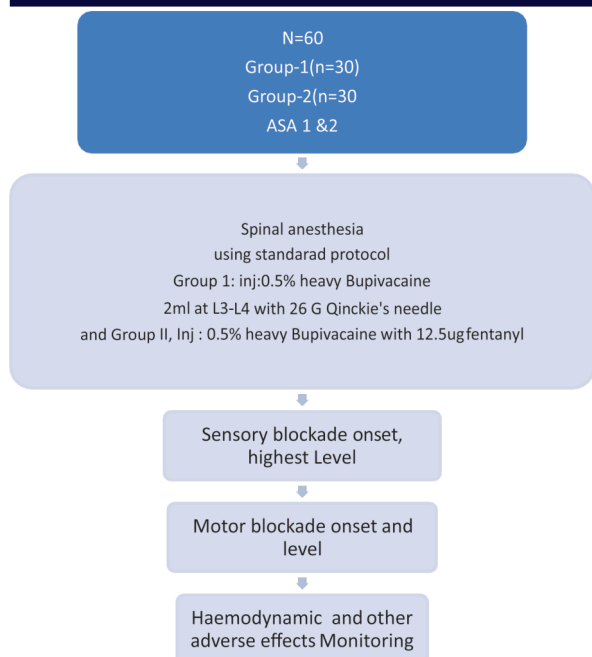
Inclusion criteria:

- Patients given Consent to participate in study.
- ASA grade I patients

Exclusion criteria:

- Patient refusal
- Bleeding disorder
- ASA 2 or more
- Patient with known hypersensitivity to bupivacaine or fentanyl
- Infection at the site of needle placement

The patient who is satisfy inclusion and exclusion criteria were randomly- allotted into two groups and pre anesthetic evaluation was done. In the operating room IV line secured and monitors attached. Base line vital parameters are noted. Patients are explained about the procedure. Pre loading was done with 15ml/kg Ringer's lactate solution. Left lateral position was given to the patient. Spinal anaesthesia was given at L3-L4 space with 26 gauge Quincke's needle under all aseptic precautions. The Spinal anaesthesia with: (GROUP I): 2 ml of 0.5% hyperbaric bupivacaine with 0.25 ml of saline , (GROUP II) : 2ml of 0.5% hyperbaric bupivacaine with 12.5µg of fentanyl. Patient are immediately placed in supine position and A wedge was placed under the right hip.



The patients were assessed for

1. Onset of analgesia- time taken to achieve analgesia at T10 dermatome assessed by pinprick method
2. Maximum level of analgesia- time taken from intrathecal injection to the highest level of sensory block assessed by pinprick method
3. Quality of motor blockade- assessed using Bromage scale
4. Duration of sensory blockade- time interval from highest sensory level achieved to complete recovery of sensory analgesia
5. Duration of motor blockade- time interval from the onset of motor blockade to complete recovery (Bromage 0)
6. Intraoperative period parameters- after the block patient was monitored for pulse rate and blood pressure every 2mins for first 10mins and every 15mins upto 1 hour and every 30mins thereafter till the sensory block regresses to L1 (2, 4, 6, 8, 10, 15, 30, 45, 60, 90, 120, 150, 180, 210, 240, 270)
7. Complications, all patients were observed for 24 hours and any side effects like nausea, vomiting, pruritus, respiratory depression or prolonged sedation were noted. Pain was evaluated using a standard 10 cm visual analog scale with 0 Corresponding to no pain and 10 to the worst pain possible.

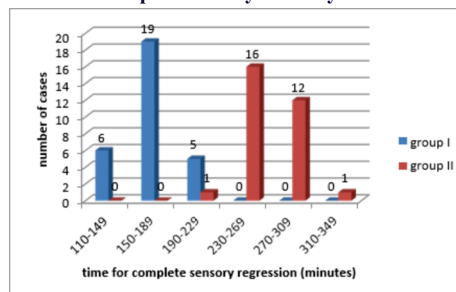
RESULTS:

The study population consists of 60 female patients posted for elective caesarian section delivery. They were divided into two groups of 30 each. Group I received 0.5% hyperbaric bupivacaine 10mg (2cc) + 0.25 ml of normal saline. Group II received 0.5% hyperbaric bupivacaine 10mg (2cc) + 12.5µg of fentanyl (0.25ml) intrathecally. The following observations were made during the course of the study

	Group I	Group II
mean age (years)	27.9 ± 3.28	28.03 ± 2.95
mean duration of surgery (mins)	60.83 ± 10.34	62.0 ± 9.61
mean time of onset of sensory analgesia at T10 (mins)	2.46 ± 0.79	1.9 ± 0.56
mean time for highest sensory level (mins)	4.96 ± 1.75	3.83 ± 1.41
mean time for two segmnt regression (mins)	88.5 ± 12.25	125 ± 19.73
mean time for sensory regression to L1 (mins)	154.33 ± 24.30	240.0 ± 20.844
mean time for complete sensory recovery (mins)	160.66 ± 23.18	263.33 ± 21.22
mean time of onset of grade III motor block (mins)	3.1 ± 1.09	2.26 ± 0.82
mean time of duration of grade III motor block (mins)	123.33 ± 19.88	171.3 ± 23.71
APGAR score	7,8,9,10	7,8,9,10

complications:		
hypotension (%)	33.33	46.67
nausea and vomiting (%)	10	6.67
shivering (%)	23.33	3.33
pruritus (%)	0	10
respiratory depression (%)	0	3.37

figure 1: Time for complete sensory recovery



In group I, onset of motor block was seen in 3-4 minutes in 16 patients (53.33%) and the mean time was 3.1 ± 1.09 minutes.

In group II, onset of motor block was seen in 1-2 minutes in 19 patients (63.33%) and the mean time was 2.26 ± 0.82 minutes, the mean time of onset of motor block in both the group is not statistically significant.

In group I, 13 patients (43.33%) had motor block in the range of 120-149 minutes and in group II, 15 patients (50%) in the range of 180-209 minutes. The difference was statistically significant ($p < 0.05$).

Figure 2 : Total duration of motor block

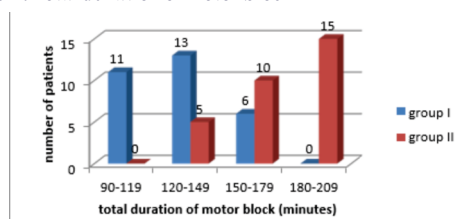
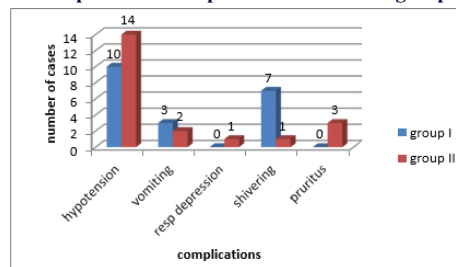


Figure 3 : Comparison of complications in both the groups



DISCUSSION

The most versatile and most commonly available anesthesia for lower half of the body is spinal anesthesia. The advantages of spinal anesthesia includes simplicity, easier to perform and has definitive end point. It is ideal in rapid onset and profound motor blockade (Hans Nolte et al., 1977). In addition, it may also help to prevent complications due to poly-pharmacy, nausea, vomiting, deep vein thrombosis associated with prolonged immobilization following general anesthesia.

Opioid added to local anesthetic for spinal anesthesia was first introduced into clinical practice in 1979 with intra-theal morphine as a forerunner. Neuraxial administration of opioids along with local anesthetics improves the quality of intraoperative analgesia and also provide postoperative pain relief for longer duration.^{6,9}

Administration of fentanyl intra-theally is an established method for Intra-operative anesthesia and to supplement postoperative analgesia (Mcqually HJ et al., 1989). The spread of fentanyl after administration into CSF include, movement from CSF into the opioid receptors or other non-specific binding sites in the spinal cord (Gourlay GK et al., 1989) and rostral migration via the CSF to supra-spinal sites. Because

of high affinity of fentanyl with non-specific binding sites on the lipid surface only a small proportion of administered dose migrate to the cervical region (Gourlay GK et al., 1989).

Fentanyl is more lipid soluble than morphine which is why it is readily eliminated from CSF making respiratory depression less likely. The advantage of using intra-theal fentanyl is due to its extremely rapid onset of action, getting desired level of analgesia and anesthesia with minimum doses of bupivacaine and fentanyl.

Results of this study showed that fentanyl 12.5 µg prolongs the duration of bupivacaine sensory blockade. This suggests a potential synergism between bupivacaine and fentanyl.

Hence when large doses of local anesthetics are used, the sensory and motor blocks develop rapidly as a result of large dose in relation to minimum concentration required to block the various nerve fibres. However this higher concentration is accompanied by side effects like bradycardia and hypotension. In this study we used 12.5 µg fentanyl with 10mg bupivacaine, is mid-range of doses quoted in literature,^{6,10} to study its effect on anesthesia quality, sensory block, motor block and duration of analgesia.

Sensory characteristics:

The duration of onset of sensory block, i.e. time taken from administration of the drug intra-theally to the loss of pinprick sensation at T10 dermatome level bilaterally.

In the present study most of the patients in Group I had onset of analgesia upto T10 in 2-3 minutes i.e. 50%. Rest 26.67% of the patients in Group I had onset in 3-4 minutes and 23.33% in 1-2 minutes. In Group II majority patients had onset of analgesia in 1-2 minutes i.e. 66.67%, rest 23.33% of the patients in 2-3 minutes and 10% in 3-4 minutes.

The mean time of onset of analgesia upto T10 in Group I is 2.46 ± 0.79 and in Group II is 1.9 ± 0.56 . The difference is statistically significant ($p < 0.05$). Addition of fentanyl to bupivacaine hastens the onset of Sensory blocked. B N Biswas et al. (2002) in their study used the same dosage of drugs and observed the similar results.

Catherine O' Hunt et al.⁶ (1989) studied the duration of analgesia for various Intra-theal fentanyl dosage with bupivacaine for patients undergoing caesarean delivery. In the present study, majority of the patients in both the groups achieved the highest sensory level of T4 and the range between (T3-T6) in both.

The time taken to achieve highest sensory level in Group I is 5-6 minutes whereas in Group II is 3-4 minutes. The mean time in Group I was 4.96 ± 1.75 minutes and in Group II was 3.83 ± 1.41 minutes ($p < 0.05$) which was statistically significant.

In the study by B N Biswas et al.¹¹ the highest sensory level (range) in Group A, i.e. (bupivacaine alone) was T7 (T6-T8) and in Group B, i.e. (Bupivacaine with fentanyl) was T5 (T4-T6). The mean time was taken to achieve this level in Group A is 8 ± 2.1 minutes and 7 ± 2.4 minutes in Group B.

According to Catherine O' Hunt et al.⁶ (1989) the onset time to T4 in Group O i.e. (bupivacaine alone) is 4.571 ± 2.76 minutes and in Group-F With fentanyl the mean time of onset was 4.222 ± 2.108 minutes.

The results of the present study concurs with the findings of the above authors. However, it was found that patients receiving a combination of fentanyl and bupivacaine had a statistically significant faster onset of action (Hunt et al., 1998).

Time for two segment regression, was 88.5 ± 12.25 minutes in Group I, and 125 ± 19.73 minutes in group II. The difference is statistically significant ($p < 0.05$). Time for two segment regression was prolonged with the addition of fentanyl to bupivacaine.

According to Harbhej Singh et al.¹² (1995) the time taken for two segment regression was prolonged in fentanyl with bupivacaine group. In Group I, i.e. bupivacaine alone time for two segment regression from the highest sensory level was 74 ± 18 minutes and in Group II, i.e. with fentanyl it was 93 ± 22 minutes, it was statistically significant. Our results concurs with findings of the above authors.

Similar results were noticed with Uma Srivastava et al.¹³ (2004) and Belzarena Sergio et al.¹ (1991) and Benhamou Dan et al.¹⁴ (1998) studies.

In the present study, the maximum time for complete sensory recovery in Group I was 210 minutes and the minimum time was 130 minutes and the mean time was 160.66 ± 23.18 minutes. In Group II the maximum time for complete sensory recovery was 300 minutes and minimum time was 220 minutes and the mean time was 263.33 ± 21.22 minutes. The difference between Group I and Group II was statistically significant ($p < 0.05$). The time for complete sensory recovery was prolonged in Group II when compared to Group I. According to B N Biswas et al.¹¹ (2002) in their studies the mean time taken for complete sensory recovery was 129 ± 9.5 minutes in bupivacaine alone group and 183 ± 9 minutes in the fentanyl with bupivacaine group which was statistically significant. Complete analgesia lasted longer in fentanyl group compared to bupivacaine alone group. Our results in the present study concurs with the study B N Biswas et al.¹¹ (2002). Similar results were also obtained with Belzarena et al.¹ (1991) and Harbhej Singh et al.¹² (1995).

Motor blockade characteristics

In the present study by adding 12.5 µg of fentanyl to 10mg (2cc) of Bupivacaine the time of onset of grade III motor block was not statistically significant ($p > 0.05$) in the both groups. The mean time of onset of grade III motor block in Group I was 3.1 ± 0.88 minutes and in Group II it was 2.26 ± 0.82 minutes. The addition of fentanyl to bupivacaine did not affect the onset of motor block. Similar results were noticed in the studies conducted by the authors B N Biswas et al.¹¹ (2002), Harbhej Singh et al.¹² (1995) and Catherine O'Hunt¹⁵ (1989).

In the present study, the mean time for complete motor recovery was 123.33 ± 19.88 minutes in Group I, and 171.3 ± 23.71 minutes in Group II. B N Biswas et al.¹¹ (2002) Observed complete motor recovery of 125 ± 6.7 minutes in Group I, and 127 ± 7.1 minutes in fentanyl with bupivacaine group. Similar results were noticed with Harbhej Singh et al.¹² (1995) study i.e. 151 ± 46 minutes in Group I and 169 ± 37 minutes in Group II, but results of above studies were statistically not significant. The results of our study were more or less similar to above studies.

Complications

Hypotension is considered as fall in systolic blood pressure of more than 30% of the baseline systolic pressure or systolic pressure < 90 mmHg. Hypotension was observed in 33.33% of the patients in Group I and 46.67% of the patients in Group II and these patients were treated with 6 mg of injection mephentermine IV and rapid infusion of IV fluids. The mean values of pulse rate changes per minute recorded in Group I and Group II were almost similar.

Similar results were obtained in the studies done by B N Biswas et al. (2002), Group I, i.e. bupivacaine alone was 20% of the patients and it was 30% in Group II, i.e. fentanyl 12.5 µg. Whereas bradycardia seen in 15% patients and 20% respectively. And the similar results were also noticed in Harbhej Singh et al. (1995).

In the present study hypotension was seen in 33.33% of patients in Group I and 46.67% in Group II. All patients responded to rapid infusion of intravenous fluid and 6 mg incremental dosage of injection mephenteramine injection IV.

Nausea vomiting was seen 10% in Group I and 6.67% in Group II patients and was treated with inj Ondansetron 4 mg IV.

Shivering was observed in 23.33% of the patients in Group I and 6.6% in Group II, which was statistically significant in Group I ($p < 0.05$). These patients were treated with oxygenation with face mask.

Pruritus was observed in 10% of patients in Group II and not observed in any patients in Group I. However it was well tolerated and did not require any treatment. Sahar M Siddik Sajjid et al.¹⁶ (2002) also observed pruritus in 26% of patients in Intra-theal fentanyl group and 8% in IV fentanyl group. Buvaendran Asokumar et al.¹⁷ (1998) in their study noticed pruritus in 95% of patients in fentanyl (25 µg) alone group and 36.4% of patients in fentanyl with bupivacaine group. Our results are concurs with the results of Sahara M Siddik Sayyid et al.¹⁶ (2002) study and Catherine O'Hunt et al.⁶ (1989).

In the present study we noticed respiratory depression in 1 patient in Group II postoperatively. No incidence of respiratory depression was noticed in the studies conducted by B N Biswas et al.¹¹ (2002), Catherine O'Hunt et al.⁶ (1989) and Herbej Singh et al.¹² (1995). Belzarena et al. (1992) however noticed a significant low respiratory rate in the initial 40 minutes when dose of fentanyl was more than 0.5 µgm kg⁻¹. But there was no respiratory depression. None of the patients in this study experienced any neurological complication during postoperative follow-up.

In the present study follow-up to 24 hours postoperatively did not reveal symptoms suggestive of post dural puncture headache or radicular irritation. None of the patients required supplementation with general anaesthesia in our present study.

There were no differences in neonatal APGAR scores among the groups, which were similar with observations of B N Biswas et al.¹¹ (2002), Catherine O'Hunt et al.⁶ (1989) and Shende et al. (1998) study.

CONCLUSION

1. Onset of sensory analgesia was achieved in 2-3 min in majority of patients in Group I and 1-2 min in majority of patients in Group II.
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. The addition of fentanyl 12.5 µg to bupivacaine 2 ml (10 mg) was not associated with any significant hemodynamic changes.
4. Hypotension, nausea-vomiting, shivering, pruritus were the only few side effects observed and treated accordingly.

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