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Research Paper

Effect of Addition of Intrathecal Fentanyl to 0.5% Bupivacaine Heavy in Lower Segment Caesarean Section done under Subarachnoid Block - A Randomised Controlled Trial

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Abstract

Objective: *After the discovery of opioid receptors in the spinal cord and direct opioid action at this level, possibility of synergism between opioids and local anaesthetics co-administered intrathecally has been explored in obstetric population undergoing LSCS. The synergistic action of local anaesthetic with opioid is of great benefit in achieving adequate anaesthesia with lesser dose of local anaesthetics thereby reducing the chances and severity of hypotension and to provide postoperative analgesia for longer duration.*

Design: *The study was conducted in 90 parturients divided in two groups of 45 each scheduled to undergo elective Lower Segment Caesarian Section under spinal anaesthesia. After securing iv line, Group I patients received 0.5% (H) hyperbaric bupivacaine 10mg and Group II received 0.5%(H) Bupivacaine and 12.5mcg fentanyl intrathecally in L3-L4 space in left lateral position. After spinal, patients were made supine with wedge kept under right hip. All patients were assessed for time of onset of sensory analgesia ,maximum level of sensory blockade achieved, degree of motor blockade(Modified Bromage score),Duration of effective analgesia, any possible side effects*

Results: *The time of onset of analgesia was shortened in Group II. In both groups mean height of analgesia was T4.The mean time to achieve highest sensory level was 3.96±1.65 min in Group II as compared to 5.29±1.93 min in Group I. Mean time for complete sensory recovery was 277.2±33.33 min in Group II as compared to 185±29.8 min in Group I which was significant. Total duration of analgesia was prolonged in Group II, there were no significant side effects.*

Conclusions: *From this study, we conclude that addition of 12.5 mcg of fentanyl decreases the time of onset of sensory analgesia, improves the quality of intraoperative anaesthesia, prolongs the duration of sensory analgesia without having significant effect on characteristics of motor blockade. It does not cause any significant haemodynamic changes and side effects in mother as well as neonate. It also reduced the demand for postoperative analgesia*

Keywords: *Bupivacaine, Fentanyl, Lower segment caesarean section, Subarachnoid block.*

Background

Caesarean section is one of the most common surgeries done in our country and subarachnoid block is the technique of choice for this procedure. Intrathecal bupivacaine is the most preferred drug for caesarean section with high potency and long duration of action. However higher doses of bupivacaine (12-15 mg) are required to get adequate level of anaesthesia and to alterate intraoperative visceral pain resulting in severe hypotension. After the discovery of opioid receptors in the spinal cord and direct opioid action at this level, possibility of synergism between opioids and local anaesthetics co-administered intrathecally has been explored in obstetric population undergoing LSCS. The synergistic action of local anaesthetic with opioid is of great benefit in achieving adequate anaesthesia with lesser dose of local anaesthetics thereby reducing the chances and severity of hypotension and to provide postoperative analgesia for longer duration. The present study was therefore undertaken using low dose bupivacaine (10 mg) with low dose fentanyl (12.5 mcg) in patients undergoing elective lower caesarean section to assess the hemodynamic stability, perioperative surgical anaesthesia and to evaluate any maternal and neonatal side effects .

Methods

Study Design

The study was done from a period of October 2019 – October 2020 in 90 patients of ASA physical status I and II coming for elective caesarian section. After getting informed consent, patients were allotted into 2 groups of 45 each using computerized randomised sampling. Patients in control group (Group I) received 0.5% hyperbaric bupivacaine 10 mg (2cc)+0.25 ml of normal saline (total volume of 2.25 ml) intrathecally. Patients in study group (Group II) received 0.5% hyperbaric bupivacaine 10 mg(2cc)+0.25 ml i.e. 12.5 mcg of fentanyl (total volume 2.25 ml) intrathecally. After detailed preanaesthetic check up and investigations, patients were kept NPO for 6 hrs . On the day of surgery, after shifting to OT, an iv line was secured with 18 G cannula and baseline readings of pulse rate, blood pressure, oxygen saturation, respiratory rate and foetal heart rate were recorded. In left lateral position, under aseptic precautions subarachnoid block was performed in the L3-L4 interspinous space. Patients were positioned in supine position and a wedge of 10 cm height. Level of sensory blockade was tested by pinprick every 20 sec. Observations like patient's blood pressure, pulse rate, oxygen saturation, ECG and respiratory rate were monitored continuously

All patients were assessed for:

Time of onset of sensory analgesia at T10 segment

- Maximum level of sensory blockade achieved.
- The time taken to achieve the maximum level of analgesia.
- Degree of motor blockade(Modified Bromage score)
- Duration of effective analgesia
- Duration when patient demand for rescue analgesia
- Cardiovascular status
- Any complications or side effects like nausea, vomiting, shivering, pruritus[52], respiratory depression if any

After the block patient was monitored for pulse rate and blood pressure every 2min for 10 min, then every 15 min up to 1 hr and then every 30 min till the sensory block regresses to L1. Postoperatively, patients were monitored in post anaesthesia care unit for 24 hr sand Time taken for recovery of sensory level and adverse side effects were noted.

Statistical Analyses

The data was analysed using SPSS (Statistical Package for Social Science) Version 16.01. The data collected was scored and analyzed, Continues variables were presented as means with Standard deviation (sd) and categorical variables were presented as frequency and percentages. Student t-

test was used for testing the significance of all the variables (Mean & Sd) in both the group. Chi-square test was used to compare proportions. All the Statistical results were considered significant at P value < 0.05.

Results

Both the groups were homogenous in both age and weight characteristics and in mean duration of surgery.

Table-1: Mean Time of onset of Sensory Analgesia (Mins)

Group	Mean	Standard Deviation
Group-I	2.23	0.62
Group-II	1.67	0.53
t-value	4.52	
p-value	0.000 (p < 0.05)	
Significant	**Significant**	

Figure 1: Time of onset of sensory analgesia

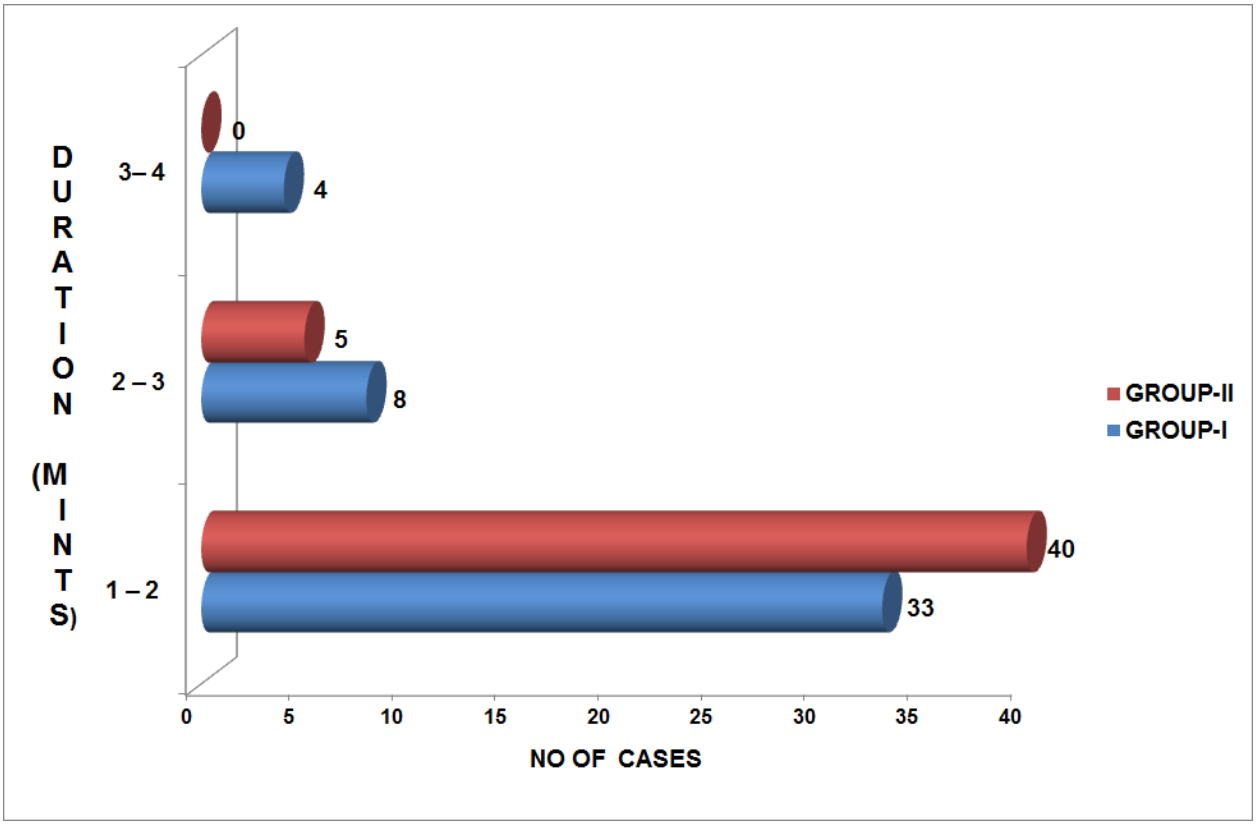


Table-2: Highest Level of Sensory Anaesthesia

Height of analgesia (Highest Level of Analgesia)	GROUP-I		GROUP-II	
	No of Patients (N)	Percentage (%)	No of Patients (N)	Percentage (%)
T3	5	11.10	11	24.40
T4	25	55.60	29	64.50
T5	0	0	3	6.70
T6	15	33.30	2	4.40
TOTAL	45	100	45	100

Figure 2: Highest level of sensory anaesthesia

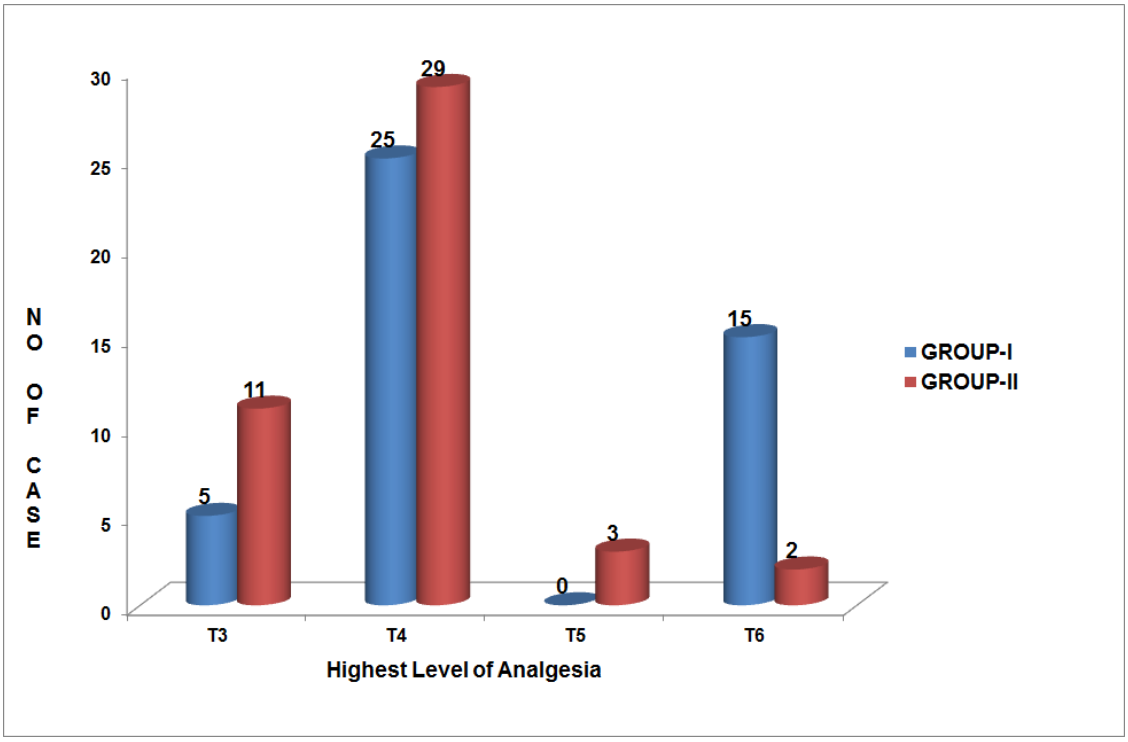


Table-3: Mean Time taken to achieve highest level of sensory analgesia (Mints)

Group	Mean	Standard Deviation
Group-I	5.29	1.93
Group-II	3.96	1.65
t-value	3.53	
p-value	0.001 (p < 0.05)	
Significant	**Significant**	

Figure-3: Time to achieve highest level of sensory analgesia (minutes)

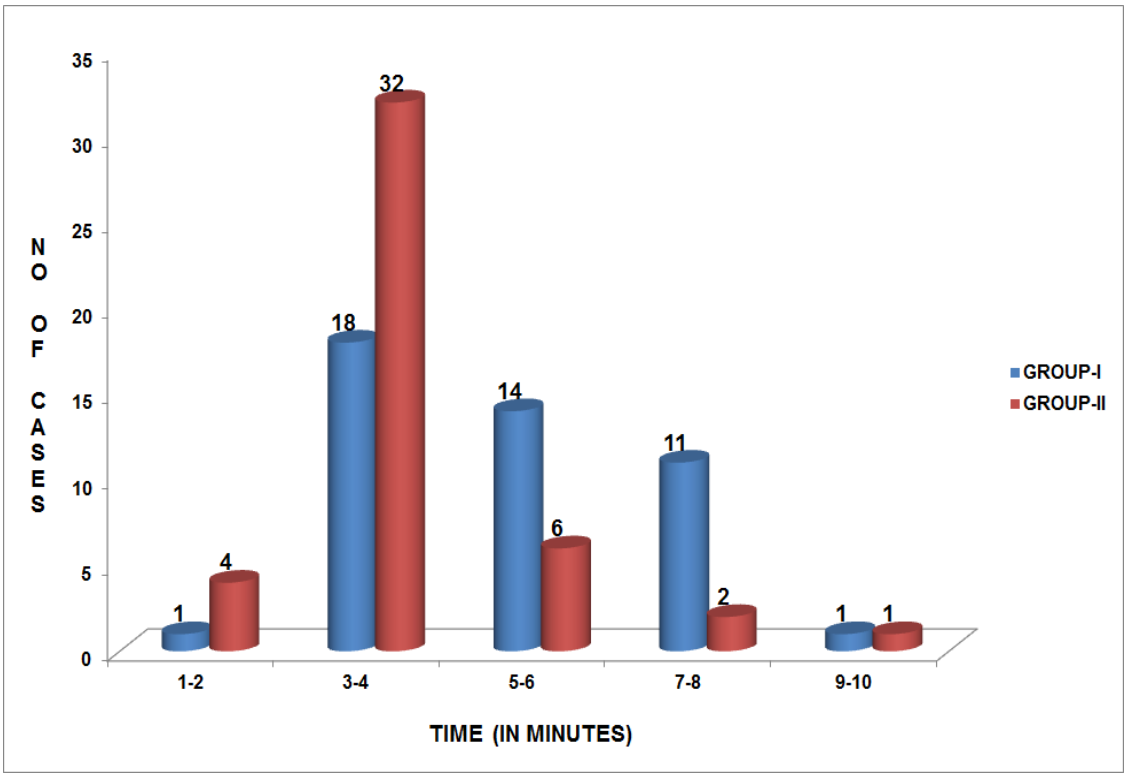


Table 4: Time for two segment sensory Regression (minutes)

Group	Mean	Standard Deviation
Group-I	96.11	16.65
Group-II	123.44	31.17
T value	5.19	
p-value	0.000 (P< 0.05)	
Significant	**Significant**	

Figure-4: Time for two segment sensory regression (minutes)

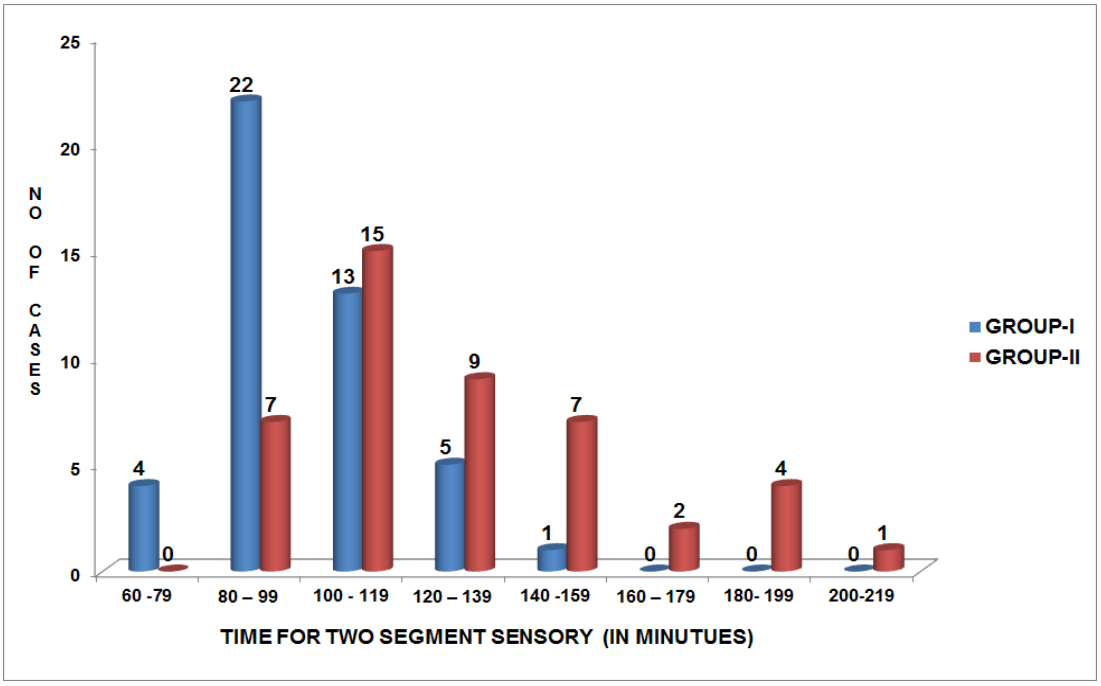


Table 5: Time for complete sensory recovery (minutes)

Group	Mean(min)	Standard Deviation
Group-I	185.0	29.8
Group-II	277.2	33.3
p-value	0.01 (P < 0.05)	
Significant	**Significant**	

Figure 5: Time for complete sensory recovery (min)

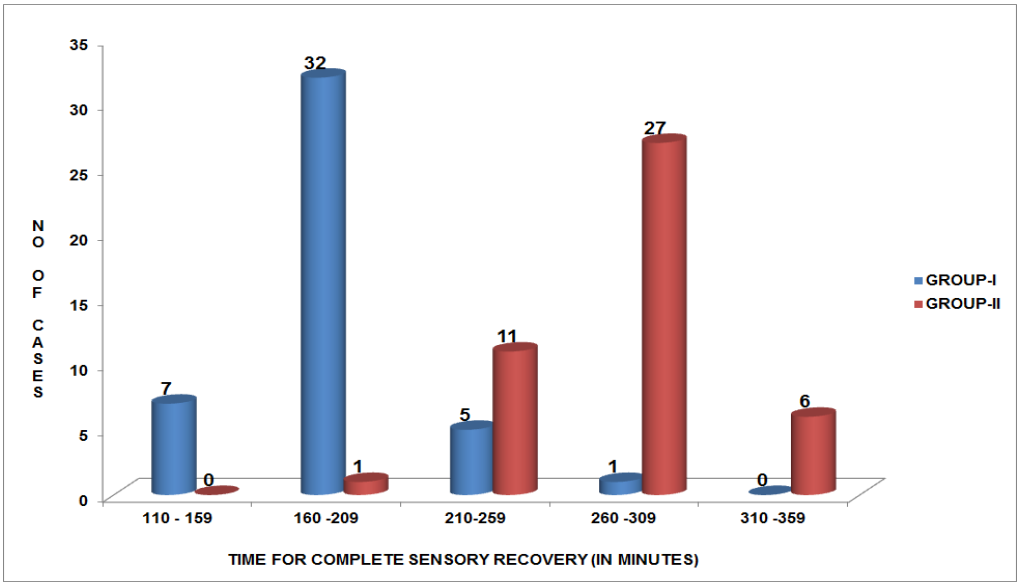


Table 6: Time of onset of motor Block (min)

Group	Mean	Standard Deviation
Group-I	2.73	0.84
Group-II	2.60	0.78
t-value	0.78	
p-value	0.44	
Significant	**Not Significant**	

Table-7: Total Duration of Motor block (minutes)

Group	Mean	Standard Deviation
Group-I	110.78	19.39
Group-II	118.31	29.27
t-value	1.44	
p-value	0.15	
Significant	**Not Significant**	

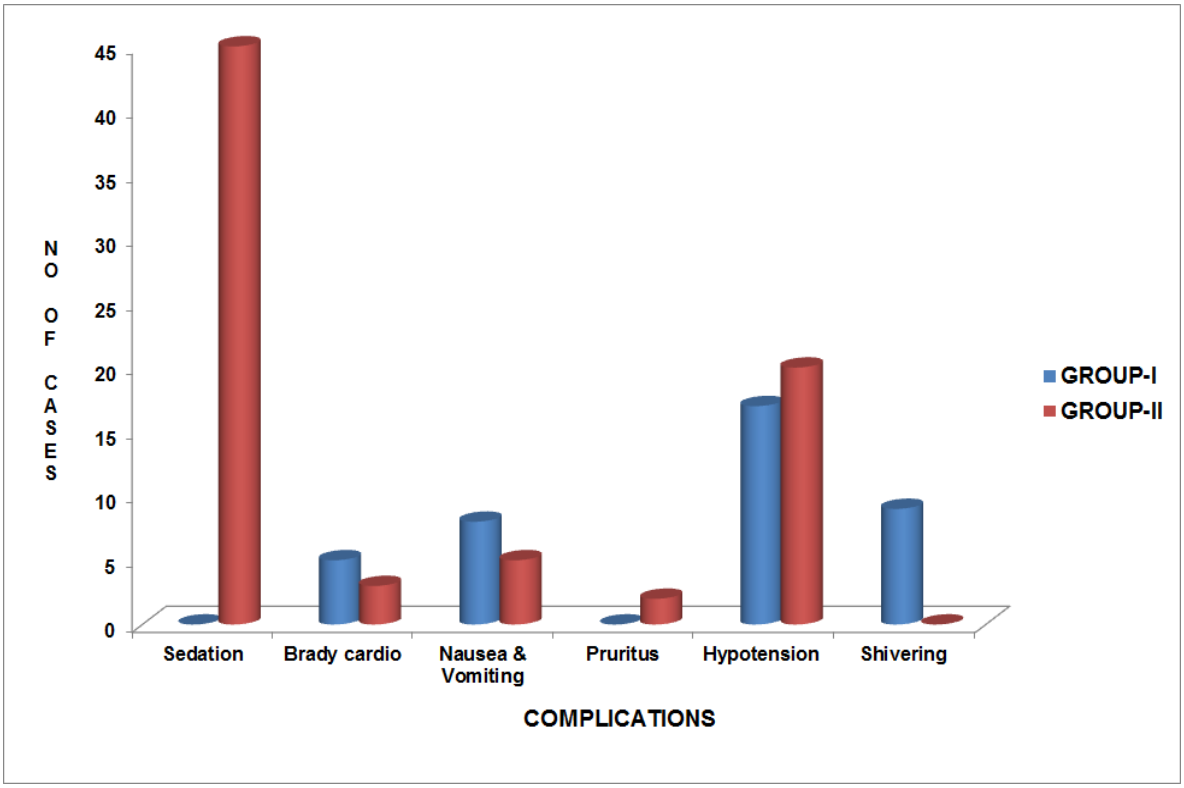
Table-8: Total duration of analgesia (mins)

Group	Mean	Standard Deviation
Group-I	176.44	30.20
Group-II	271.44	35.11
t-value	13.76	
p-value	0.0001 (P < 0.05)	
Significant	**Significant**	

Cardiovascular Parameters

There were no significant hemodynamic alterations in cardiovascular parameters. The mean value of pulse rate changes per minute and arterial pressure changes in mm Hg recorded in Group I and Group II were almost similar and not statistically significant

Figure-6: Complications during anaesthesia



Discussion

Spinal anaesthesia is often used for both elective and emergency caesarean section**. Alahuhta et al** showed that pain during surgery was recorded in nearly half of patients undergoing caesarean section with epidural or spinal anaesthesia. Small dose of opioids has been added along with the local anaesthetic solution for improving the intraoperative analgesia during regional anaesthesia. In our study we used 12.5mcg fentanyl to 10mg (2cc) bupivacaine to study its effect on anaesthesia quality, sensory block, motor block and duration of analgesia.

Sensory Characteristics

The time of onset of Sensory Block

The mean time of onset of analgesia at T10 in Group I was 2.23± 0.62 min and in Group II was 1.67 ±0.53 min which was statistically significant ($p < 0.05$). This showed addition of fentanyl to bupivacaine hastened the onset of sensory block.

In the present study, majority of the patients in both the groups **achieved the highest sensory level of T4.**

The time taken to achieve highest sensory level in Group I was 5.29± 1.93minutes and in Group II was 3.96± 1.65minutes ($p < 0.05$) which was statistically significant.

Time for two segment regression In Group I mean time was 96.11± 16.65 minutes. In Group II, i.e. with fentanyl, it was 123.44± 31.17 minutes which was statistically significant ($p < 0.05$). This showed that time for two segment regression was prolonged with the addition of fentanyl to bupivacaine.

In the present study**, the time for complete sensory recovery** in Group I, i.e. bupivacaine alone was 185.0 ±29.8 minutes and In Group II the time was 277.2 ± 33.3 minutes which was statistically significant ($p< 0.05$).

The effect of fentanyl on sensory characteristics can be explained by potential synergism between fentanyl and bupivacaine . The μ agonist fentanyl exerts its action by opening K^+ channel and decreasing calcium influx resulting in less transmitter release. μ agonist have direct post synaptic effect causing hyperpolarization and reduction in neuronal activity. Local anaesthetic acts by blockade of voltage gated sodium channel in axonal membrane and inhibiting presynaptic calcium channels and hence inhibiting nerve conduction. Hence when both drugs used together will have enhanced anti-nociceptive effect.

Motor Blockade Characteristics

The mean **time of onset of grade III motor block** in Group I was 2.73 ± 0.84 minutes and in Group II,was 2.6± 0.78 minute which was not statistically significant. **The mean time for complete motor recovery** was 110.78 ±19.39 minutes in Group I and 118.31± 29.27 minutes in Group II which was not statistically significant (p>.This showed **that addition of fentanyl had no effect on motor recovery**.

Total Duration of Analgesia

In the present study mean time of total duration of analgesia was 176.44 ±30.2 minutes in Group I and 271.44± 35.11 minutes in Group II .which was statistically significant ($p <0.05$). This improved analgesic duration can be explained by synergistic inhibitory action of these two agents on Aδ and C fibres.

Cardiovascular Changes

Hypotension was observed in 37.8% of the patients in Group I and 44.44% of the patients in Group II and these patients were treated with 6 mg of injection ephedrine IV and rapid infusion of IV fluids.

The mean values of pulse rate changes per minute and mean arterial pressure changes recorded in Group I and Group II were almost similar and statistically not significant.

Complications:

Nausea and vomiting was seen in 17.8% in Group I, i.e. bupivacaine alone and 11.1% in Group II patients, i.e. bupivacaine with fentanyl which was statistically significant ($p < 0.05$). and was treated by inj Ondonsetrone 4 mg IV.

Shivering was observed in 20% of the patients in Group I i.e. bupivacaine alone and 0% in Group II, i.e. bupivacaine with fentanyl group which concluded that combination of a low dose fentanyl

to Bupivacaine reduced the incidence of intraoperative and postoperative shivering.

Pruritus was observed in 4.4% of patients in Group II and not observed in any patients in Group I. It was well tolerated and did not require any treatment. .

In the present study we did not notice any incidence of **respiratory depression** upto 24 hours postoperative

There were no difference in APGAR score in both groups.

Conclusion

From this study, we conclude that addition of 12.5 mcg of fentanyl decreases the time of onset of sensory analgesia, improves the quality of intraoperative anaesthesia, prolongs the duration of sensory analgesia without having significant effect on characteristics of motor blockade. It does not cause any significant haemodynamic changes and side effects in mother as well as neonate. It also reduced the demand for postoperative analgesia

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