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Research Article

Randomized comparative study of Intrathecal Sufentanil and Fentanyl combined with Lignocaine for Caesarean Section

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Abstract

Aims and Objectives: To compare safety and efficacy of sufentanil and fentanyl in combination with lignocaine for caesarean section

Materials and Methods: A randomized comparative study was done on 50 parturient patients, divided into 2 group viz. Group I (12.5 mcg of fentanyl, 1.5 ml lignocaine 5% heavy 70mg) and Group II (5 mcg of sufentanil, 1.5 ml lignocaine 5% heavy 70mg) at Gandhi Medical College, Bhopal. Vital signs, sensory level, motor block and side effects were observed every 5 minute for first 30 minute and then every 15 minute till the completion of surgery.

Results: The duration of effective analgesia was significantly longer in Group II (268.4+26.384 min) compared to Group I (154.6+16.057 min) (p<0.05). Nausea and vomiting was observed in 4% patients in Group I whereas in Group II none of the patients showed nausea and vomiting. Pruritus was the significant side effect in Group II (48%) as compared to Group I (12%) (p<0.05).

Conclusion: Sufentanil provided significant longer duration of analgesia compared to fentanyl with better protection against nausea and vomiting.

Keywords: caesarean section, sufentanil, fentanyl, spinal anesthesia.

Introduction

Compared to epidural, spinal anesthesia has many advantages like simplicity of technique, rapid onset of action and quality in developing uniform sensory and motor blockade. The only disadvantage present is its short duration of action leading to short-lasting post-operative analgesia. ¹

To overcome this limitation of short duration of action and for improving quality of analgesia both intra-operatively and post-operatively, it is required to add intrathecal opiates along with bupivacaine. ¹

In 1979, opioid was first added to local anaesthetic for spinal anaesthesia with intrathecal morphine as a forerunner. Fentanyl is a lipophilic opioid, it has rapid onset of action following intrathecal administration while sufentanil is even more lipophilic compared to fentanyl. In many studies sufentanil alone has provided analgesia in the first stage of labour for between 1-3 hours.

Present study was undertaken with the idea of providing an effective intraoperative and early postoperative analgesia and to evaluate characteristics of subarachnoid block with lignocaine when fentanyl and sufentanil are used as adjuvant.

Materials and Methods

A randomized study was done on 50 healthy parturient (undergoing elective or emergency caesarean section) belonging to American Society of Anaesthesiologists grade I and II.

A written informed consent from all the patients and Ethical Committee approval was obtained before starting the study. All the patients were assessed before the surgery and judged for fitness. Patients with medical disorder, infection at the site of injection, coagulopathy and other bleeding diasthesis, severe hypovolemia, patients with foetal compromise, preeclampsia and eclampsia, respiratory diseases and any preexisting neurological deficit were excluded from the study. Patients were randomly divided into 2 groups, each having 25 patients' viz. Group I (12.5 mcg of fentanyl, 1.5 ml lignocaine 5% heavy 70mg) and Group II (5 mcg of sufentanil, 1.5 ml lignocaine 5% heavy 70mg).

All patients received 50 mg ranitidine and 4 mg ondensetron intravenously as premedication. Baseline measurement of blood pressure, pulse rate and arterial oxygen saturation was done. Subarachnoid block was given at L3-L4 interspinous space with 25 G spinal needle in the lateral decubitus position. After confirmation of free flow of cerebrospinal fluid, the drug was injected slowly intrathecally.

Patient in Group I received 1.5 ml lignocaine 5% heavy 70mg + Inj. fentanyl 0.25 ml (12.5 mcg) intrathecally and Group II received 1.5 ml lignocaine 5% heavy 70mg + Inj. sufentanil 0.1 ml (5 mcg) intrathecally.

The parturient was immediately turned supine after subarachnoid block and the uterus was displaced to the left using a wedge. All patients were given supplemental oxygen. The level of sensory blockade was assessed by pin prick method. The time for sensory blockade to attain the level was recorded.

Intraoperatively patients were monitored for pulse, blood pressure and respiratory rate and SpO2 every 5 minute for first 30 minute and then every 15 minute till the completion of surgery. Motor blockade was assessed by modified Bromage Scale.

Duration of motor and sensory blockade was observed postoperatively. The patients were monitored for 2hrs following procedure. They were questioned after 24 hrs about their views on the procedure and the satisfaction enquiry about the symptoms related to post dural puncture headache (PDPH).

All the data were analyzed using SPSS Version 20. Unpaired t-test and chi-square test were used as required. Data were expressed mean± SD; P < 0.05 was considered as significant.

Results

The mean age, weight, height and parity of the patients in both the groups were comparable (p>0.05) (table 1).

Table 1: Maternal Demographic Characteristics and parity

Characteristics	Group I	Group II	
Age (years)	23.46±2.13	22.02±4.54	
Weight (kg)	58.18± 12.23	59.60±9.03	
Height (cm)	152.48±13.41	154.24±11.2	
Primipara*	15 (60)	16 (64)	
Multipara*	10 (40)	9 (36)	

Data is expressed as mean±SD, *Data is expressed as no of patients (%), P>0.05 between both the groups, Group I; received 12.5 mcg of fentanyl, 1.5 ml lignocaine 5% heavy 70mg, Group II; received 5 mcg of sufentanil, 1.5 ml lignocaine 5% heavy 70mg

Table 2: Comparison of different parameters between groups

Parameters	Group I	Group II	P value
Time to T6 (min)	2.60±0.45	2.46±0.35	NS
Highest sensory level (Thoracic Dermatome)	5.72±0.45	5.60±0.50	NS
Time to regression to T12 dermatome (min)	67.81±15.59	68.21±11.29	NS
Duration of effective analgesia (min)	154.6±16.06	248.4±26.38	< 0.05
Onset of grade 0 motor block (min)	2.54±0.46	2.46±0.32	NS
Total duration of grade 0 motor block (min)	101.4±10.72	100.6±10.38	NS

Data is expressed as mean±SD, NS; not significant, F; fentanyl, S; sufentanil, Group I; received 12.5 mcg of fentanyl, 1.5 ml lignocaine 5% heavy 70mg, Group II; received 5 mcg of sufentanil, 1.5 ml lignocaine 5% heavy 70mg

In present study there was a fall in pulse rate after 10 minutes of spinal anesthesia in both Group I $(93.60\pm6.62 \text{ to } 82.93\pm4.73 \text{ per min})$ and Group II $(99.21\pm6.324 \text{ to } 82.82\pm3.055 \text{ per min})$ (p>0.05). Fall in blood pressure was noted after 10 minute's induction in Group I (118.4+7.461 to 115.2+5.830 mmHg) and Group II (116.81+6.377 to 112+6.782 mmHg) (p>0.05).

However the fall in pulse and blood pressure was not more than 20% from baseline and none of the patients required any treatment.

There was no significant difference in oxygen saturation at 120 min between both the groups and no patient required rescue analgesia (p>0.05).

Neonatal neurobehavioral assessment was done by Apgar score at 1 and 5 minutes after delivery. All neonates had Apgar score of 9/10 at 1 minute (p>0.05) and 10/10 at 5 minutes. None of the neonates had respiratory depression.

The patients were observed for intraoperative and postoperative complication. Three (12%) patients in Group I and 12 (48%) patients in Group II had pruritus which was the most common complication observed. Nausea or Vomiting was seen in 1 (4%) patients in Group I and none of the patients in Group II had Nausea or Vomiting. Shivering was observed in 2 (8%) patients in Group I and 1 (4%) patients in Group II. None of the parturient from either group had symptoms suggestive of respiratory depression, hypotension, bradycardia and post-dural-puncture headache (PDPH).

Discussion

Opioids along with local anesthetics improve the quality of intraoperative analgesia and also prolong the duration of post-operative analgesia. ³ Lipophilic opiates like fentanyl and sufentanil are better alternatives compared to morphine, because of their rapid uptake, fast onset and shorter duration of action. All these properties minimize the migration of the drug to the respiratory center thus avoiding delayed respiratory depression. ³ Sufentanil is pure agonists (an N-4 thienyl derivative of fentanyl). It is more lipids soluble, a better receptor ligand and is 7-10 times more potent analgesic than fentanyl. ³

In present study mean age, weight, height and parity was comparable (p>0.05).

In present study, the mean regression time to T12 sensory level was comparable in both the groups (p>0.05) which is in contrast with the study done by Dahlgrem and Meiningier et al which reported that mean regression time to T12 sensory level was significantly prolonged in fentanyl group compared to sufentanil group. ^{4,5}

The duration of effective analgesia was significantly longer in Group II compared to Group I (p<0.05). This prolonged duration of analgesia with sufentanil could be attributed to the known superiority of sufentanil over fentanyl in terms of potency. ⁶

The mean duration of grade 0 bromage scale was comparable in both the groups (p>0.05). Meiningies D et al has also reported that time from intrathecal injection to motor block bromage scale 1 was significantly shorter when fentanyl 5 μ g and sufentanil 2.5 μ g was added to mepivacaine. ⁵

Addition of opioid to intrathecal lignocaine prolongs duration of analgesia compared with either drug used alone.⁷ Evidence suggests that lignocaine increase the binding of morphine to opioids receptors, especially the highly dense kappa receptors, as the result of an associated conformational change in opioid receptors.⁷

A study done by Bangra J et al on synergistic effect of intrathecal fentanyl and lignocaine in caesarean section observed that onset of sensory blockade to T6 thoracic dermatome was faster with increasing doses of lignocaine alone or combination with fentanyl. In our study, the mean time of onset of sensory block at T6 is comparable in both the groups receving fentanyl (12.5 μ g) and sufentanil (5 μ g) (p>0.05). Although it was little faster in Group II but the difference was not statistically significant. This result is contrast with the studies done by Bogra et al which reported significantly shorter onset time of sensory block at T6 in group receiving sufentanil.

An initial fall in blood pressure was seen in our study patients of both the group, which may be attributed to the sympathetic blockade produced by local anesthetics.

Present study did not observe any significant change in the respiratory rate and oxygen saturation in both the groups. There was no evidence of respiratory depression as well.

Our observation correlates well with Dahlgren G, Braga A and Bogra J et al, these studies did not report any incidence of respiratory depression, bradycardia and hypotension, as the doses used by them were comparable with our study. ^{4, 8, 9}

Pruritus was the significant side effect in Group II (48%) as compared to Group I (12%). A study done by Ngiam S K observed that 35% of patients receiving sufentanil and 27.8% in fentanyl had pruritus. ¹⁰

However the other side effects like nausea, vomiting was less in Group II than Group I. Similar findings were observed in Dahlgren G et al which reported that incidence of nausea and vomiting was similar in patients receiving lignocaine, fentanyl and sufentanil. Braga AAD et al also observed that incidence of nausea was

lower in patients receiving sufentanil as compared to placebo. ⁹

In present study there was no statistically significant difference in the Apgar score of neonate between two groups. All newborn were healthy and cried immediately after birth. Similar results were observed by Ngian SKK and Brago AAD et al. ^{9, 10} The Apgar score at 1 and 5 minutes were satisfactory in both the group (p>0.05).

Conclusion

Intrathecal analgesia using sufentanil and fentanyl achieve high patient satisfaction and excellent sensory and motor blockage and improved intraoperative analgesia and prolonged the duration of effective analgesia without significant effect on neonate. Sufentanil provided significant longer duration of labour analgesia compared with fentanyl and intrathecal sufentanil provides better protection against nausea and vomiting as compared to fentanyl.

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