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Original Research Article

Comparative Study of Intrathecal Fentanyl Versus Intravenous Fentanyl For Supplementation of Subarachnoid Block During Caesarean Section

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ABSTRACT

Background: Pain during cesarean section is a common phenomenon which results release of stress hormone during surgery. In contrast, effective analgesia may permit improved mother-child bonding, early ambulation, discharge, greater patient satisfaction and early breastfeeding. Now a days the use of intrathecalfentanyl as multimodal analgesia became a popular technique for cesarean section, because of synergistic effect with local anaesthetic and intensify sensory block without increasing sympathetic block.

Aims: To evaluate the efficacy and compare intrathecal fentanyl and intravenous fentanyl for supplementation of subarachnoid block with intrathecal bupivacaine during caesarean section and to evaluate any adverse maternal or neonatal outcome.

Methods: This study was carried out on 60 patients posted for elective LSCS. Patients were randomly allocated into two groups compromising of 30 patients each. Intrathecal fentanyl group patients received bupivacaine 10mg (2ml) and fentanyl 12.5microgram (0.25ml) intrathecally and 0.25ml normal saline intravenously. Intravenous fentanyl group patients received bupivacaine 10mg bupivacaine (2ml) and 0.25ml of normal saline intrathecally and 0.25ml fentanyl (12.5microgram) intravenously. All patients were preloaded with 500ml ringer lactate solution. Lumber puncture was performed in the sitting position by midline approach at L2-3 or L3-4 intervertebral space with 25 gauge spinal needle. Immediately after intrathecal administration of local anaesthetic 12.5microgm (0.25ml) fentanyl was administered intravenously in intravenous fentanyl group whereas 0.25 ml normal saline was injected in the intrathecal fentanyl group patients.

Results: There are no significant differences between the intrathecal fentanyl group and intravenous fentanyl group with respect to age, height, weight, gestational age and parity. Intrathecal injection to delivery time and duration of surgery didn't differ between the two groups. There was a significant difference in time required for T6 sensory block , duration of sensory block and time of first rescue post-op analgesia with intrathecal fentanyl group giving better results. The incidence of severe hypotension defined as BP<90mmHg and mephentermine requirement was more frequent in the intravenous fentanyl group as compard with the intrathecal group. There was no significant statistical difference in incidence of adverse effects such as nausea, vomiting, pruritis. Respiratory depression was absent in all patients and neonates of both the groups. The apgar scores of all neonates in both groups were ≥8 at 1 min and ≥9 at 2 min.

Conclusion: Addition of intrathecalfentanyl as an adjuvant to bupivacaine for emergency cesarean section increased duration of analgesia, reduced postoperative analgesia consumption and request time without any maternal and fetal effect. We recommend the use of intrathecal fentanyl for emergency caesarean section in our set up.

Keywords: Spinal Anaesthesia; Caesarean Delivery; Intrathecal Fentanyl; Postoperative Analgesia.

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INTRODUCTION

Caesarean delivery (CD) can be the best way to ensure the safety of the mother and the baby especially, if the baby is in distress in the later stage of pregnancy. The choice of anaesthesia for caesarean section depends on the reason for the operation, degree of urgency, the desires of the patient and the judgment of anesthesiologist.[1] General anaesthesia for the CD is associated with relatively greater maternal risk than regional anaesthesia. Spinal Anaesthesia (SA) has therefore become more widely

practiced anaesthetic technique in CD. It is simple to institute, rapid in its effect and produces excellent operating conditions. It also avoids fetal as well as maternal risks of GA, requires minimum postoperative anaesthesia care and provides adequate postoperative analgesia.[2]

Bupivacaine is the most commonly used drug worldwide for spinal anaesthesia in CD. Its effect lasts longer than other local anaesthetists with minimal side effects and it is also affordable. Spinal anaesthesia with local anaesthetic agents, especially bupivacaine, has side effects such as hypotension, respiratory depression, vomiting and shivering in a dose dependent fashion.[3] Hypotension is one of the commonest side effects and can affect both the mother and the fetus or the neonate. Its side effects are dose dependent, therefore different approaches have been attempted in order to avoid spinal-induced complication including the use of small dose of bupivacaine or by lowering the dose of local anaesthetic and mixing it with additives like neuraxialopioids.[4]

With isobaric bupivacaine the sensory blockade reaching may be insufficient and additional intraoperative analgesia is required.[5] Higher doses of bupivacaine, increasing the level of blockade are likely to enhance hypotension and induce breathing difficulties but reducing the dose of bupivacainedoes not prevent hypotension.[6] So co-administration of small doses of intrathecal or intravenous opioids with bupivacaine for spinal anaesthesia is advisable and advantageous in order to decrease the intensity as well as severity of spinal complications associated with spinal anaesthesia.[7]

Caesarean delivery requires traction of peritoneum and handling of intraperitoneal organs, resulting in intraoperative visceral pain which is a poorly localized type of pain from deep structures in the body. With higher doses of hyperbaric bupivacaine the incidence of intraoperative visceral pain is reduced, but increasing the dose of bupivacaine increases the risk of high block. Postoperative pain after CD is an unpleasant outcome for women and may result in delayed ambulation, prolonged time for discharge from hospital, poor bonding with the newborn, low satisfaction scores and delay breastfeeding. In addition to this inadequate analgesia leads to elevated plasma catecholamine concentrations, resulting in adverse effect on all organ systems.[8] In contrast, effective analgesia may permit improved mother - child bonding, early ambulation and discharge, greater patient satisfaction and early breastfeeding. Neuraxial administration of opioids along with local anesthetics improves the quality of intraoperative analgesia and provides postoperative pain relief for a longer duration than local anaesthetics alone.[9] Fentanyl is a synthetic lipophilicopioid with a rapid onset of action and, unlike morphine, has fewer tendencies to migrate rostrally to the fourth ventricle in sufficient concentration to cause delayed respiratory depression. Intrathecal fentanyl has faster onset of action, it improves quality of intraoperative analgesia, reduces intrathecal doses of local anaesthetic drugs and is associated with less side effects and good postoperative analgesia.[10] Many studies have been performed to compare quality of anaesthesia and postoperative analgesic effect of intrathecal fentanyl and bupivacaine in elective cesarean section. Most of these studies have been conducted in the developed world and in western populations. The presence of racial, cultural, genetic and socio demographic difference in the perception of pain has been well documented,[11] meanwhile intraoperative & early postoperative pain is a major problem which needs an immediate and sustainable solution. Mothers who undergo elective cesarean section are more stable in terms of intraoperative complications, general morbidity and mortality than those who undergo emergency cesarean section, so knowing the effectiveness of intrathecal fentanyl with spinal anesthesia in terms of intraoperative anaesthesia quality and postoperative analgesia helps for better outcomes of the fetus and maternal satisfaction. This research can also help as a back ground for future research on related topic. This study aimed to assess postoperative analgesic effect of intrathecal fentanyl as an adjuvant to spinal anaesthesia in comparison with intravenous fentanyl spinal supplementation with bupivacaine among laboring mothers who undergone emergency cesarean delivery at our hospital .

AIMS AND OBJECTIVES

1) To compare the efficacy of intrathecal fentanyl versus intravenous fentanyl for analgesic supplementation of subarachnoid block with intrathecal bupivacaine during caesarean section

2) To evaluate any adverse maternal or neonatal outcome peroperatively and postoperatively.

MATERIALS AND METHODS

After obtaining the approval from hospital academic and ethics committee and written informed consent from patients and their relations, a randomized, double-blinded, prospective study was performed in 60 patients (n=60) scheduled for lower segment caesarean section. They were divided into two groups of 30 each. The study design was randomised, double blinded.

Preanaesthetic Evaluation

A detailed preanaesthetic check-up (PAC) which consisted of detailed history and physical examination including height, weight, routine laboratory investigations, gestational age and parity was undertaken in all patients.

Patient Selection Criteria

1. ASA grade I or II.
2. No contraindication to spinal anaesthesia.

Exclusion Criteria

1. Complicated pregnancies such as multipara.
2. Pregnancy-induced hypertension (PIH).
3. Morbidly obese patients.
4. Any contraindication to spinal anaesthesia e.g. spine deformity, local infection at the site of block, neurological disorder, haemodynamic instability, coagulopathy, patient refusal.
5. Allergic history to study drug.

The patients were allocated into 2 groups of 30 patients each.

IT Fentanyl group (BF group): In this group patients received 10 mg of hyperbaric bupivacaine 0.5% and 12.5 µg (0.25ml) of fentanyl intrathecally and 0.25 ml normal saline IV.

IV Fentanyl group (BN group): In this group patients received 10 mg of hyperbaric bupivacaine 0.5% and 0.25 ml of normal saline intrathecally and IV fentanyl 12.5µg (0.25ml).

After wheeling in the patient on operating table, all patients were preloaded with a rapid IV infusion of 500 mL of ringer lactate solution. Electrocardiogram, pulse oximetry, and noninvasive blood pressure were monitored. Patients were positioned in sitting

postion and after all aseptic precautions of painting and drapping Lumbar spinal subarachnoid puncture was performed at the L2-3 or L3-4 intervertebral space using 25 gauge spinal needle. In the IT Fentanyl group, IT bupivacaine and fentanyl were used, whereas in the IV Fentanyl group, bupivacaine was mixed with normal saline to achieve the same final volume as in the IT bupivacaine-fentanyl group.

Immediately after IT administration of the local anesthetic mixture, 12.5 µg of fentanyl (0.25 mL) was administered IV in the IV Fentanyl group, whereas 0.25 mL of IV normal saline was injected in the IT Fentanyl group. Immediately after the block, each parturient was placed supine with 15° to 20°left sided for left uterine displacement by tilting the operating table to left to avoid aortocaval compression. Oxygen @ 4-6L/min was given via a face mask during the surgery.

Sensory block level was measured by pinprick technique at the midclavicular line every minute until the block reaches T6 dermatome. Thereafter, the level was checked every 2 min until the maximum sensory block level was confirmed. The degree of motor block was assessed with the Bromage scale (BS).

Pain was evaluated with verbal rating scale (VRS). The use of the VRS was explained to each patient before surgery. Each time VRS exceeded (3), 25-µg incremental dose of fentanyl IV was administered every 5 min until the VRS became < (3).

The level of maternal sedation was noted by using a graded score. After delivery of baby, the Apgar scores were assessed at 1 and 2min. Time to first rescue postoperative analgesia required by the patient was recorded. Side effects (if any) observed.

Stastistical analysis with comparison of continuous variables between the groups was performed using Student's t test. Nominal categorical data between the groups were compared using Chi-squared test or Fisher's exact test as appropriate. For all statistical tests, a p value less than 0.05 was taken to indicate a significant difference.

Table 1: Demographic and anaesthetic base line characteristics

Group	BF (n=30)	BS (n=30)	P value
Age in years (Mean ± SD)	28.20 ± 2.65	28.10 ± 2.45	0.880
Weight in kilogram	56.27 ± 3.70	55.37 ± 4.56	0.405
Height in meter	1.56 ± 8.01	1.56± 7.82	0.764
Gestational age in week	37.57 ± 0.89	37.70 ± 0.75	0.535
ASA status :- ASA 1	82%	74%	0.334
ASA2	18%	26%	
Parity:- Para 1	53.3%	46.7%	
Para 2	43.3%	50%	0.871
Para 3	3.3%	3.3%	
Duration of surgery in minute	89 ±7.12	86 ± 7.7	0.123
Time from intrathecal injection to delivery of child	12.50 ± 2.08	13.07 ± 2.06	0.294

Table 2: Characteristic of spinal anaesthesia and duration of analgesia

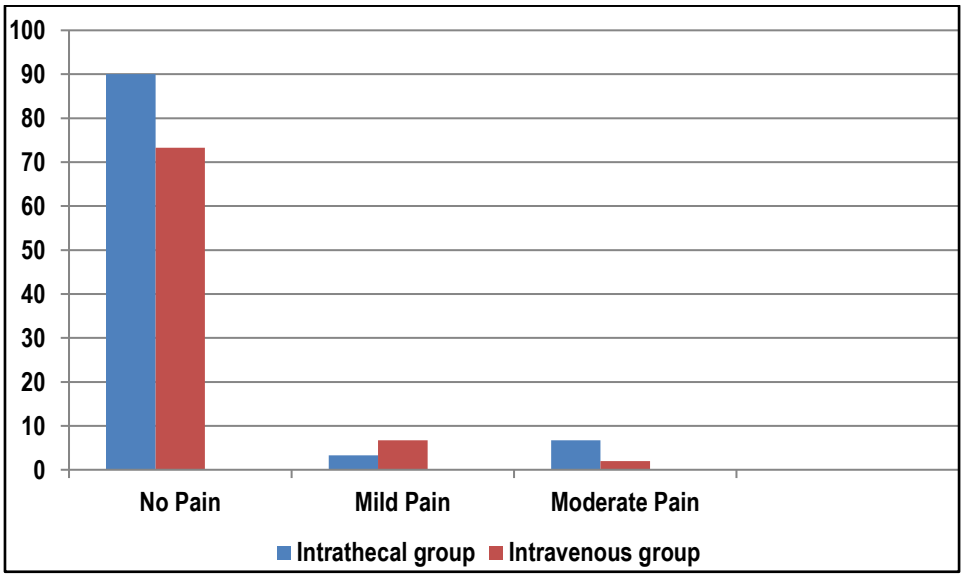
Group	BF (n=30)	BS (n=30)	P value
Highest sensory level(dermatome)	T6	T6	-
Onset of sensory block (minute)	2.53± 0.17	3.22± 1.14	0.006
Grade of onset of motor block(minute)	5.68 ± 0.89	5.65 ±0.82	0.861
Duration of grade 0 motor block	157.5 (59)*	272.5 (81)*	0.001
Duration of analgesia(minute)	275.10± 42.43	156.10 ± 34.45	0.001

Table 3: Haemodynamic parameters

	INTRATHECAL FENTANYL		INTRAVENOUS FENTANYL		P value
	Mean ± SD	Min - Max	Mean ± SD	Min - Max	
PreOP HR	97.83 ± 12.44	74 125	94.67 ± 11.36	80 - 120	0.308
PreOP SBP	124.73 ± 7.65	110 - 140	122.60 ± 10.34	100 - 140	0.368
PreOP DBP	78.73 ± 5.23	70 - 90	80.20 ± 5.73	70 – 90	0.305
PreOP SPO_2	98.30 ± 0.75	97 - 99	98.43 ± 0.67	97 – 99	0.473

Table 4: VRS Pain analysis

Pain	INTRATHECAL FENTANYL		INTRAVENOUS FENTANYL		P value
	Frequency	%	Frequency	%	
No	27	90%	22	73.3%	0.241
Mild	1	3.3%	2	6.7%	
Moderate	2	6.7%	6	20%	
Total	30	100%	30	100%	



RESULTS

A total of 60 patients were given spinal anaesthesia. All 60 laboring mothers who underwent caesarean delivery under spinal anaesthesia during the study period were included with a response rate of 99%. Of these patients, 30 mothers were given intrathecal fentanyl (12.5mcg) with (10mg) 0.5% bupivacaine (BF) and 30 patients with 10mg (0.5%) bupivacaine with intravenous fentanyl (12.5mcg) (BS group).

The demographic characteristics (age, height, weight, gestational age, duration of surgery) were comparable between the groups as shown in Table 1. Regarding with ASA physical status, 82 % of BF group and 74 % of SB group were ASA I while 18 % of BF group and 26% of SB group were ASA II.

There was no difference in highest sensory level, onset of sensory block and onset of motor block. But there was a prolonged motor block in BS group than BF group 272.5 (81) vs.157.5 (59) in minutes. The duration of analgesia (time from subarachnoid injection to first report of pain) was reduced in BF group (275.10 ± 42.43 minutes) vs. (156.10 ± 34.45 minutes) in BS group (Table 2). There was no statistical significant difference in haemodyanmic parameters at various time intervals in both groups as shown in Table 3.

Although statistically insignificant the number of patients who had VRS of moderate pain is more in intravenous fentanyl group. Two patients had VRS of moderate pain in intrathecal group while as six patients had VRS of moderate pain in intravenous group.

Although insignificant but intravenous fentanyl top ups were required more in intravenous group than in intrathecal group.

P value for time required for SMAX is statistically insignificant but P value for time of first rescue post-op analgesia is statistically significant implying that analgesia provided by intrathecal fentanyl group lasted longer compared to intravenous fentanyl group.

Table 5: Fentanyl Topup

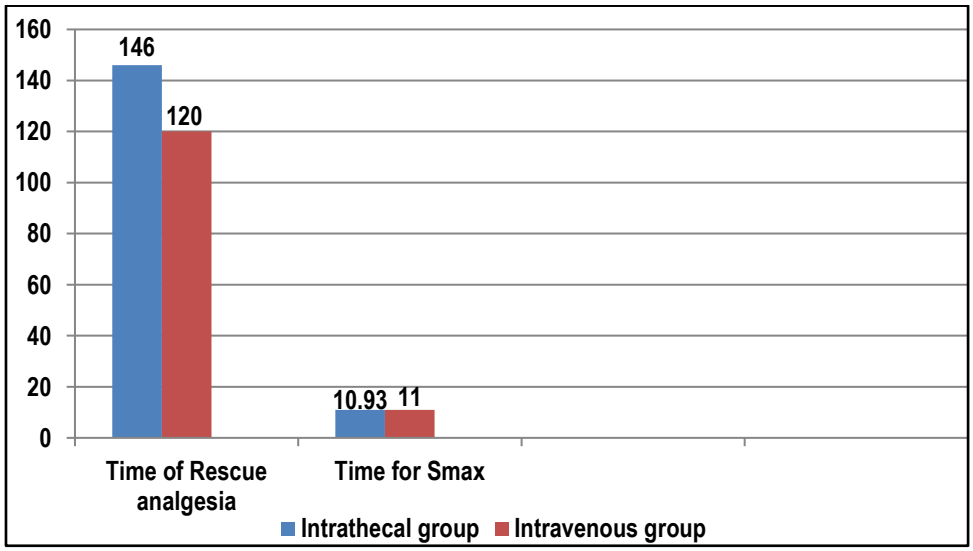
TIME REQ. FOR IV FENTANYL TOPUPS	INTRATHECAL FENTANYL			INTRAVENOUS FENTANYL			P value
	N	Mean ± SD	Min - Max	N	Mean ± SD	Min - Max	
Once	2	14 ± 1.41	13-15	6	24.67 ± 12.16	12 - 40	0.085
Twice	0	-		3	56.67 ± 5.77	50 - 60	

Table 6: Rescue Analgesia and SMax

	INTRATHECAL FENTANYL		INTRAVENOUS FENTANYL		P value
	Mean ± SD	Min - Max	Mean ± SD	Min - Max	
Time Of First Rescue Postop. Analgesia	146 ± 9.32	130 - 170	120 ± 6.94	110 - 130	<0.001*
Time Required For SMax	10.93 ± 0.64	10-12	11 ± 0.64	10-12	0.689

Table 7: Incidence of perioperative complications

Complications	BF (n=30)	BS (n=30)	P value
Hypotension	8(25%)	11(36,6%)	0.198
Nausea	2(6.6%)	11(37%)	0.001
Vomiting	1 (3.33%)	7(23%)	0.002
Shivering	9(30%)	17(57%)	0.005
Pruritis	4(13%)	0(0)	0.006
Respiratory depression (SPO_2 < 90% or RR < 9bpm)	0%	0%	
Fetal bradycardia (HR < 120 bpm)	0%	0%	
Total iv fluid given intraop (lts)	2.00± 1.00*	2.00± 0.665*	0.414
APGAR score At 1 minutes	7 – 9	7 – 10	0.748
At 2 minutes	7 - 10	7 – 10	0.939



DISCUSSION

Spinal anaesthesia is often used for elective caesarian section, however, intrathecal bupivacaine alone may not be sufficient alone to provide complete analgesia, for which larger doses of bupivacaine need to be given. Such large doses of intrathecal bupivacaine are associated with severe hypotension and delayed recovery of motor blockade. Therefore, smaller doses of bupivacaine supplemented by intrathecal opioids have been recommended for spinal anaesthesia in patients undergoing caesarian section. A significant amount of an intrathecally administered lipophilicopioid, such as fentanyl, is lost by diffusion into the epidural space and subsequently into the plasma, suggesting that intrathecally administered fentanyl may induce analgesia by a systemic rather than by a spinal action. It will produce at best the same effects as the same dose injected intravenously. We conducted this study, which compared the effect of intrathecal fentanyl versus the same dose of intravenous fentanyl on the amount of intraoperative analgesic supplementation in women undergoing elective caesarian section.

In our study 30 patients received 10mg of hyperbaric bupivacaine plus 12.5µg of fentanyl intrathecally and 30 patients received only bupivacaine intrathecally plus same dose fentanyl intravenously.

There were no significant differences between the intrathecal group and intravenous fentanyl group with respect to age, height, parity or gestational age in both studies.

Intrathecal injection to delivery time and duration of surgery did not differ between the two groups. Also level of analgesia to pin prick, the onset of sensory block were similar in both groups.

The degree of motor block in all patients reached a bromage scale of 3 in both the studies. There was significant difference in need for supplementation with intravenous fentanyl, no patient in intrathecal fentanyl group needed intraoperative analgesic supplementation as compared with 8 patients in the intravenous fentanyl group in the said study. In our study two patients in intrathecal group and six patients in intravenous group needed analgesic supplementation. Our results were similar to results deduced by Siddick-Sayyid et al[12] in their study.

In our study there were no statistical significant in mean heart rate and mean arterial blood pressure at various time intervals in both groups, which was similar finding with Dhumal PR, et al. and Shashikala TK et al.[13] However, a study in Nepal showed that the incidence of bradycardia was 5.7% in control Group and 2.8% in Group BF with no significant variation in the group. A similar study in Texas showed that bradycardia occurred 3 patients in treatment group and 4 patients in control group which was not significant.[14] In comparison to the above two studies there were no cases of bradycardia in our patients. This might be due to case selection difference (our cases were emergency cesarean section compared to the above studies which were elective cases), so that there was a continuous labour pain which may have caused sympathetic nervous system stimulation in our case.

In the said study conducted by Siddick-Sayyid et al VAS (visual analogue scale) was used to assess pain, in our study VRS (verbal rating scale) was used. In the said study no patient in the intrathecal fentanyl group had VAS >3 whereas six patients in the intravenous fentanyl group had VAS>3. In our study 2 patients had VRS of moderate pain in intrathecal fentanyl group whereas in intravenous fentanyl group two patients had VRS of mild pain and 6 patients had VRS of moderate pain. In terms of intra-operative hypotension, our study showed that 8 (25%) patients in BF group & 11 (36%) in BS group developed hypotension which was treated with IV fluid. None of them needed vaso-active drugs. Our finding was similar to that of Olanrewaju NA, et al.[15] In his study eight of the patients in his control group BS (26.67%) group vs. six patients (20%) in FB group had hypotension that required rapid infusion of crystalloid. Even if our study is not statistically significant it is clinically important in our setup since we do not have vaso-active drugs like ephedrine and phenylephrine to treat hypotension. Intrathecal fentanyl could be the only option to prevent hypotension.[15] The effect of intrathecal fentanyl on shivering is because it is highly ionized, lipophilic µ- receptor agonist and unionized component is rapidly transferred into the spinal cord to act the thermo-regulator and affect spinal afferent thermal inputs at the spinal cord. In our study, shivering occurred in 9 (30%) patients in BF vs. 17 (57%) in BS group with *P*-value of 0.005. A study by Ali Sadegh et al showed 22 patients (55%) in Group BS had shivering during recovery and no patient in Group BF had shivering.[16] In our study, more patients in BF group developed shivering compared to study by Ali. This might be due to different factor like environmental factor and set up of the operation room.

Pruritus induced by intrathecal fentanyl is not due to histamine release but is likely due to the cephalic migration of the opioid in CSF and its subsequent interaction with opioid receptors in the

trigeminal nucleus. In our study, none of group BS patients developed pruritus but 4 (13%) in group BF developed mild pruritus, which did not need treatment. A similar study showed thatmild itching was observed in 2 (5%) patients receiving intrathecalfentanyl without any rash and it subsided without any treatment.[17] Our study showed more pruritis compared to the above studies. This might be due to an increased dose of fentanyl, 25mcg compared to the dose of 12.5mcg.

APGAR scores were similar between two groups in our study at 1minute which was 7 – 9 in BF group vs. 7- 10 in BS group and at 2 minutes 7 – 10 in both groups respectively. Even though APGAR scores is not a highly sensitive means of neonatal assessment. Umbilical cord blood gas analysis and neonatal neuro-behavioral scores may have revealed more subtle effects . A study in India using small dose of (12.5mcg) fentanyl compared to our study (25mcg) showed that, there were no significant APGAR score difference at 1 and 5 minutes which was, 8 -9 ,9-10 in control group and 7- 9, 9-10 in BF group respectively.[18] A similar study by Gajanan et al.[17] using 25mg intrathecal fentanyl in elective cesarean section also showed no APGAR score differences . Even if our cases were emergency cesarean section compared to the above two studies, our study did not show significant Apgar scores between the groups. Also there was no neonatal bradycardia or respiratory depression noticed in our study. These showed that use of 25 mcg intrathecal fentanyl seems safe in emergency cesarean section. In our study, none of the patients developed respiratory depression (SPO_2 90%) which was supported by many studies.[10,13] This might be due to high affinity of fentanyl with nonspecific binding sites on the lipid surface only a small proportion of the administered dose migrates to the cervical region.

CONCLUSION

In the present study entitled “Comparative study of intrathecal versus intravenous fentanyl for supplementation of subarachnoid block during caesarian section” carried out at ShantiMukand Hospital New Delhi between August 2009 and February 2012 following conclusions were made:

1. Intraoperative supplementation of bupivacaine spinal anaesthesia with intrathecal fentanyl results in a better quality of spinal anaesthesia.
2. Intrathecal fentanyl supplementation of spinal anaesthesia is better than supplementation with the same dose of intravenous fentanyl.
3. Time to first post-op rescue analgesia is longer with intrathecal fentanyl in bupivacaine spinal anaesthesia.
4. Spinal administration of fentanyl is associated with a decreased incidence of side effects such as severe hypotension, nausea, vomiting and respiratory depression.
5. Spinal administration of fentanyl is associated with longer duration of sensory block compared with intravenous fentanyl.

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