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A COMPARATIVE STUDY OF NALBUPHINE AND FENTANYL AS AN INTRATHECAL ADJUVANT TO 0.5% HYPERBARIC BUPIVACAINE

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ABSTRACT

The combination of intrathecal opioids and local anaesthetics provide better analgesia than administration of individual drugs alone because these two drugs act at different sites. The present clinical study aims to compare the clinical efficiency of nalbuphine and fentanyl as an intrathecal adjuvant to 0.5% hyperbaric bupivacaine. The primary objectives included assessment of sensory and motor blockade characteristics and duration of postoperative analgesia. The secondary objectives were intraoperative hemodynamic changes, and incidence of side effects, if any (e.g. nausea, vomiting, hypotension and pruritis). This prospective, randomized, double-blind, interventional study was approved by the Institutional Ethical Committee and written informed consent was obtained from all subjects. 100 patients of age between 18 to 65 years of age, scheduled for lower abdominal and lower limb surgery were randomly allocated into 2 groups: **Group A (n=50)** – Bupivacaine (0.5%) 2.5ml with fentanyl 0.5ml (25mcg) and **Group B (n=50)** – Bupivacaine (0.5%) 2.5ml with nalbuphine 0.8mg. The results show that addition of nalbuphine 0.8 mg to hyperbaric bupivacaine 0.5% (12.5mg) provides efficient and prolonged postoperative analgesia with minimum or no side effects (pruritus, nausea, vomiting, bradycardia, respiratory depression) than addition of fentanyl 25 mcg to same baricity and dose of bupivacaine.

INTRODUCTION

Spinal anaesthesia, the most common regional anaesthesia for lower abdomen and lower limb surgeries, is beneficial due to rapid onset and reliability. It additionally avoids the risk of airway complications and hemodynamic changes associated with laryngoscopy and intubation.

Post-operative pain after lower abdomen and lower limb orthopaedic surgery is reported to be moderate to severe and is associated with neuroendocrine responses and catecholamine release. Since spinal anaesthesia offers postoperative analgesia only for a limited period and surgical response peaks during postoperative period. Numerous intrathecal adjuvants are being used with local anaesthetics for prolongation of duration and quality of block. A pain-free and stress-free postoperative period helps in early recovery and rehabilitation, thus reducing morbidity and mortality.

The combination of intrathecal opioids and local anaesthetics provide better analgesia than administration of individual drugs alone because these two drugs act at different sites. The local anaesthetics produce its effects by acting at nerve axon and opioids via their receptors in the spinal cord.[1] This combination provides lesser side effects and better hemodynamic profile than individual agent.

Intrathecal opioids such as fentanyl and morphine (pure mu agonists) are the most common neuraxial adjuvants used. Nalbuphine (a derivative of 14-Hydroxymorphine) is a synthetic opioid with mixed kappa agonist and mu antagonist properties,[2] when added as adjuvant to intrathecal bupivacaine, it acts principally on kappa receptors in the dorsal horn of spinal cord producing analgesia. Its action on kappa receptors attributes good sedative properties, whereas, partial agonism at the mu receptor induce a ceiling effect on respiratory depression. It does not cause addiction because of its mu antagonist effects. It also produces lesser adverse effects like pruritus, nausea and vomiting due to antagonism at the mu receptor.[3] Fentanyl is a lipophilic opioid with a rapid onset following intrathecal injection. It does not migrate to the 4th ventricle in sufficient concentration to cause respiratory depression. It improves the quality of anaesthesia without producing significant side effects and improves postoperative analgesia and hemodynamic stability.

The study aims to compare the postoperative analgesic effect of intrathecal nalbuphine and intrathecal fentanyl as an adjuvant to 0.5% bupivacaine during lower abdomen and lower limb orthopaedic surgical procedures.

AIMS AND OBJECTIVES

The present clinical study aims to compare the clinical efficiency of nalbuphine and fentanyl as an intrathecal adjuvant to 0.5% hyperbaric bupivacaine. The primary objectives included assessment of sensory and motor blockade characteristics and duration of postoperative analgesia. The secondary objectives were intraoperative hemodynamic changes, and incidence of side effects, if any (e.g. nausea, vomiting, hypotension and pruritis).

MATERIAL AND METHODS

This prospective, randomized, double-blind, interventional study was approved by the Institutional Ethical Committee and written informed consent was obtained from all subjects. 100 patients of age between 18 to 65 years of age, scheduled for lower abdominal and lower limb surgery were randomly allocated into 2 groups:

1. **Group A (n=50)** – Bupivacaine (0.5%) 2.5ml with fentanyl 0.5ml (25mcg).
2. **Group B (n=50)** – Bupivacaine (0.5%) 2.5ml with Nalbuphine 0.8mg.

Inclusion criteria

- All the patients who are posted for lower abdominal and lower limb surgery.
- Age group- 18- 65 years,
- ASA 1 and 2.
- Weight 50-70 kg.
- Height 160+-10 cm.

Exclusion criteria

- Patients refusal.
- Allergy to local anesthetics and opioids.
- Local site infection.
- Raised intracranial tension.
- Progressive neurodegenerative disorder.
- CNS infections.
- Spine deformities.
- Hypovolemic shock.

- Bleeding diathesis and coagulopathy.

Patients who met the inclusion criteria were randomly allocated to one of the two equal (n=50) groups. Randomization was performed by computer generated random numbers method by an anaesthesiologists involved in studied drug. Further procedure and monitoring were performed by another investigator unaware of group allocation. Patients were also blinded to the drug regimen utilized for spinal anaesthesia. All patients were examined in the evening before surgery to confirm preanaesthetic findings and informed consent was taken. Fasting status for solid and clear liquid was explained, premedication with oral tablet metoclopramide10 mg, and tab ranitidine150 mg night before and on the morning of surgery with sips of water were advised.

An intravenous line was secured using 18G cannula and the patients were preloaded with approximately 10-15 ml/kg lactated Ringer's Solution. Baseline blood pressure, heart rate and respiratory rate were noted. All patients were made aware of their pain measurement by VAS (Visual Analogue Scale) score.

All the patients were monitored for cardiorespiratory problems, side-effects if any, and were given supplemental oxygen. General anaesthesia was planned in case of failed or inadequate block. Fluid management was done according to requirements including the fluid deficit, maintenance, blood loss etc. Postoperatively vital signs were recorded every initially every 5 minutes up to 15 minutes, then after every 15 minutes. Degree of pain and severity was assessed using the Visual analogue scale (VAS) every 30 min during the 1st hour and hourly thereafter.

Monitoring

Monitoring was done with multipara monitor and included Lead II Electrocardiography, Non-invasive blood pressure (NIBP), heart rate, respiratory rate and oxygen saturation by pulse-oximetry. On arrival to the operating room, standard monitors were placed and baseline parameters were recorded. All patients were preloaded with lactated ringer solution (15mg/kg) via the peripheral 18 gauge intravenous catheter. Before the commencement of spinal anaesthesia, patients were explained about the procedure and methodology of monitoring methods. In the lateral decubitus position under standard aseptic precautions, using a midline approach, a lumbar puncture was performed at L3-L4 or L4-L5 intervertebral space by 25 gauge Quincke spinal needle. After confirming the free flow of cerebrospinal

fluid through the spinal needle, the study drugs were injected intrathecally over a period of 10-15 seconds and patients were turned to the supine position.

The primary outcome is the comparison of block characteristics and duration of postoperative analgesia. The secondary outcome is the comparison of hemodynamic parameters and adverse events.

The onset of sensory block was tested by pin-prick method using a blunt 27-gauge hypodermic needle. The time of onset was taken from Zero -time to loss of bilateral pinprick sensation. The level of sensory blockade was assessed bilaterally (by pinprick method) in the mid-clavicular line in an ascending fashion from T10 dermatome and T10 was taken as onset time. The time interval between Zero-time to the patient's inability to lift the straight extended leg (Modified Bromage scale 1) was recorded as onset time.

Motor blocked was assessed according to the Modified Bromage score where
0: Patient able to move hip, knee, ankle,
1: Unable to move hip, able to move knee and ankle,
2: Unable to move hip and knee, able to move ankle,
3: Unable to move hip, knee and ankle.

The highest level of sensory blockade was assessed by pinprick method using a blunt hypodermic needle. The highest dermatomal level blocked was decided by waiting for 5 minutes at the given level, if the block doesn't ascend upwards to next level, above mentioned level was selected as the highest level of sensory blockade. All patients, in whom the desired level of anaesthesia was not achieved within 20 min, were considered as block failures and managed by performing general anaesthesia. These cases were excluded from the study.

Duration of sensory analgesia was noted and recorded from the time when the spinal drug was given to postoperative follow up until the patient first complained of pain. Patients were asked to point out the intensity of their pain on the visual analogue scale. Time at which patients complained of pain more than 3 cm on the Visual analogue scale was noted. That point was taken as the end of fair analgesia.

The nature of the procedure was explained and the patients were taught to assess the intensity of pain using the visual analogue scale (VAS). In the visual analogue scale, the patients were shown a scale of 10 cm length. Zero end of the scale was taken as "No Pain" and 10 cm marked as "Maximum Pain". The intensity of pain increases gradually from "0" to "10". Patients were instructed to point the intensity of pain on the scale.

Patients were monitored for heart rate, blood pressure and respiratory rate at 0, 5, 15, 30, 60, 120, 300, 1440 minutes after administration of spinal anaesthesia. Such as Nausea, Vomiting, Hypotension, Bradycardia, Sedation, Shivering and Respiratory depression were observed for, recorded and treated accordingly. Duration of complete analgesia will be assessed from the time of onset of analgesia until the appearance of pain for the first time (first rescue analgesia). Rescue analgesia is provided with injection Diclofenac 1.5mg/kg slow IV.

Any episode of hypotension (systolic blood pressure <90 mmHg or >25% below baseline) was managed by Ephedrine (5 mg) and an additional fluid bolus of ringer lactate solution. Bradycardia (<50 beats/min) was managed by injection Atropine 0.6mg IV bolus.

Postoperatively, pain score (VAS) was assessed 1 h for the first 4 h and at 12 and 24 h. The duration of effective analgesia (time from the intrathecal injection to the first rescue analgesic requirement (i.e. VAS score >3) was noted. Intravenous diclofenac (75 mg) was administered as rescue analgesia, and the total number of rescue analgesics required postoperatively in 24 h period was recorded. Patients were also assessed for side effects such as nausea, vomiting, hypotension, pruritus, and bradycardia.

OBSERVATIONS AND STATISTICAL ANALYSIS

Summary statistics and frequency tables were used to summarize baseline patient's characteristics. Descriptive statistics such as mean, standard deviations were calculated for the study outcomes. Statistical comparison was made by comparison between groups by applying two-sample t-test by SPSS software.

(A) Demographic Profile and Duration of surgery

Table 1: Age, Weight, Height and Duration of surgery.

	Group A		Group B		P- value
	Mean	SD	Mean	SD	
Age (years)	35.3	11.98	40.16	11.82	0.718
Weight (kg)	63.43	5.34	62.63	6.21	0.529

Height (cm)	156.9	5.41	157.43	5.22	0.475
Surgery duration (minutes)	66.26	29.14	55.41	9.99	0.08

Above table shows that all the demographic variables like age, weight, height and duration of surgery were comparable in both groups (Table 1)

(B) Characteristics of spinal anaesthesia

Table 2: Sensory onset upto T10 level.

	Group A		Group B		P- value
	Mean	SD	Mean	SD	
Sensory onset (seconds)	97.71	8.84	98.67	10.81	0.75

Table 2 shows that there were no difference in the onset of sensory level in both groups.

Table 3: Motor onset.

	Group A		Group B		P - value
	Mean	SD	Mean	SD	
Motor onset (seconds)	395	27.23	390	26.45	0.39

The onset of motor blockage were comparable in both groups. (Table 3)

Table 4: Peak sensory.

	Group A		Group B		P – value
	Mean	SD	Mean	SD	
Peak sensory (seconds)	271.8	17.99	270.6	11.66	0.87

The time to attain peak sensory level were comparable in both groups. (Table 4)

Table 5: VAS score.

	Group A		Group B		P - value
	Mean	SD	Mean	SD	
VAS 1 hour	0	0	0	0	
VAS 2 hour	0	0	0	0	
VAS 5 hour	1.79	0.55	0.25	0.42	< 0.005
VAS 12hour	0.87	0.79	0.83	0.71	0.86
VAS 24 hour	1.05	0.82	0.88	0.74	0.42

There were no pain in both groups at 1st and 2nd hours. At 5th hours after surgery VAS score was significant as p- value <0.05 but at 12 hours and 24 hours, it was statistically non-significant as p- value > 0.05. (Table 5)

Table 6: Time of first rescue analgesia.

	Group A		Group B		P – value
	Mean	SD	Mean	SD	
Rescue analgesia (minutes)	191.63	8.72	217.94	6.15	< 0.001

The time to first analgesic requirement was significantly prolonged in Group B as compared to Group A ($p < 0.001$). (Table 6)

Table 7: Number of rescue analgesia in 24 hours.

	Group A		Group B		P – value
	Mean	SD	Mean	SD	
Number of rescue analgesia	2.09	0.67	1.45	0.45	0.0001

The requirement of rescue analgesia was more in group A compared to group B in first 24 hours. (Table 7)

Hemodynamics changes

Table 8: Heart rate.

	Group A		Group B		P- value
Heart rate (bpm)	Mean	SD	Mean	SD	
Pre op	84.67	5.89	80.91	5.38	0.06
At 5 min	79.73	5.04	73.9	4.96	< 0.05
At 10 min	79.61	4.73	74.06	4.38	< 0.05
At 15 min	80.23	5.24	74.46	4.05	< 0.05
At 30 min	78.53	5.04	74.46	3.36	0.0005
At 45 min	78.93	4.85	75.13	4.05	0.001
Post op	78.73	5.89	75.3	4.21	0.003

There were significant reductions in heart rate in group B. (Table 8) However, the decrease in heart rate was not to such extent to require any intervention

Table 9: Systolic blood pressure.

SBP(mmHg)	Group A		Group B		P-value
Interval (min)	Mean	SD	Mean	SD	
0	122.77	8.21	124.5	4.12	0.3
5	114.23	8.10	113.36	4.71	0.22
10	112.71	9.20	113.77	4.63	0.26
15	112.67	7.05	112.17	4.34	0.72
30	111.47	7.59	114.23	3.85	0.87
45	116.73	7.30	116.3	4.46	0.71
Post op	118.83	7.21	118.5	4.50	0.82

There was no significant reduction in systolic blood pressure in both the groups. (Table 9)

Table 10: Diastolic blood pressure variation.

DBP(mmHg)	Group A		GroupB		P-value
Interval(min)	Mean	SD	Mean	SD	
0	85.34	5.40	83.20	4.22	0.01
5	76.43	6.56	76.30	4.21	0.35
10	72.33	6.19	70.81	4.66	0.14
15	71.20	3.81	69.32	4.94	0.12
30	72.70	4.4	72.15	4.25	0.13
45	76.70	4.70	76.40	3.09	0.12
Postop	78.10	4.66	77.10	3.29	0.07

There was no significant reduction in diastolic blood pressure in both the groups. (Table 3)

Table 11: Mean arterial pressure.

MAP (mmHg)	Group A		Group B		P-value
Interval (min)	Mean	SD	Mean	SD	
0	99.27	5.62	97.66	3.50	0.192
5	90.30	6.54	91.2	3.72	0.94
10	85.66	6.56	83.6	3.65	0.46
15	84.65	3.92	82.1	4.22	0.16
30	88.10	4.64	83.71	3.36	0.22
45	90.40	4.52	92.42	3.16	0.66
Postop	91.5	4.70	91.05	3.25	0.18

There was no significant reduction in mean arterial pressure in both the groups. (Table 11)

Side effects

Table 12: Side-effects in the groups A and B.

Side effects	Group A	Group B
Hypotension	4	3
Bradycardia	0	0
Respiratory depression	0	0
Nausea and vomiting	0	0
Pruritus	0	0

Hypotension occurred in both the groups but not in significant manner. (Table 12) There was no case of bradycardia, respiratory depression, nausea and vomiting and pruritus in any of the groups.

DISCUSSION

In our present clinical study, we have compared the clinical efficiency of fentanyl and nalbuphine as an intrathecal adjuvant to 0.5% hyperbaric bupivacaine by assessing the sensory and motor blockade characteristics and duration of postoperative analgesia as the primary endpoints and intraoperative hemodynamic changes, nausea and vomiting, sedation, pruritus, and respiratory depression as the secondary endpoints.

Local anaesthetics work by inhibiting voltage-gated sodium channels in the spinal cord by interfering with afferent and efferent sensory and motor impulses while intrathecal opioids activate opioid receptors in the dorsal gray matter of the spinal cord (substantia gelatinosa) to modulate the function of afferent pain fibers. The combination of adjuvants to local anaesthetic is synergetic for producing the analgesia of prolonged duration without measurably increasing sympathetic or motor blockade, thus allows early ambulation of patients and reduction in dosages of local anesthetics, hence the decline of their systemic side effects.

The presence of intrinsic opioid apparatus in the CNS has popularized their use both intrathecal and in epidural space. Intrathecal opioids do not produce analgesia solely by acting on spinal cord receptors, a phenomenon described as spinal selectivity of an opioid. Some of the intrathecal opioids absorb back in the bloodstream and produces analgesia by stimulating opioid receptors at the brain level. Degree of this absorption is mainly determined by lipophilicity of the drug. Highly lipid-soluble opioids like fentanyl or sufentanil diffuse into the bloodstream quickly compared to less lipophilic morphine, therefore, producing a short duration of analgesia. The analgesic property of the intrathecal opioids is attributed to spinal selectivity. The lipophilic ones due to their good vascular uptake and redistribution rapidly reach a higher concentration in the brain as well.[4] It allows early ambulation of patients because of their sympathetic and motor nerve-sparing activities with disadvantages of respiratory depression and sedation, nausea and vomiting, pruritus and urinary retention.[5,6,7]

Nalbuphine is a very useful adjunct to intrathecal local anesthetics because of the good duration of analgesia, anti-pruritic, anti-shivering properties, lesser respiratory depression, nausea and vomiting.[8]

Chu et al. found that all patients receiving 12.5 and 15 μg of intrathecal fentanyl with 0.5% hyperbaric bupivacaine experienced excellent intraoperative and postoperative analgesia contrary to patients receiving 7.5 mcg of fentanyl.[9]

Goel et al. found that the patients receiving 7.5mcg of fentanyl in combination with low-dose bupivacaine 5mg had a significantly higher number of failed blocks (almost 27%) than those receiving 10 or 12.5mcg of fentanyl.[10]

Culebras et al. are the first study used intrathecal nalbuphine for cesarean section patients. In this study, they compared morphine 0.2 mg added to hyperbaric bupivacaine with different dose of intrathecal nalbuphine 0.2, 0.8, and 1.6 mg added to hyperbaric bupivacaine and concluded that nalbuphine 0.8 mg have significantly prolonged duration with minimal side effects, but nalbuphine 1.6 mg did not increase efficacy but increased incidence of adverse effects.[11]

Khandelwal et al. evaluated the potentiating effect of intrathecal nalbuphine with bupivacaine for postoperative analgesia in three different doses (0.8, 1.6, and 2.4 mg) in a randomized control study. They concluded that the combination of intrathecal bupivacaine with nalbuphine significantly prolonged postoperative analgesia as compared to the control group and a 1.6 mg dose showed the best results.[12] Pal et al. had compared 100 patients undergoing orthopedic lower limb surgeries under spinal anesthesia. They used different doses of nalbuphine 0.2, 0.4, and 0.8 mg added to 0.5% bupivacaine and they concluded that 0.4 and 0.8 mg have significantly prolonged the duration of analgesia but adverse effect higher with 0.8 mg dose.[13]

Tiwari et al. had compared intrathecal nalbuphine 0.2 and 0.4 mg added to hyperbaric bupivacaine with bupivacaine alone. They concluded that prolonged duration of analgesia was seen in nalbuphine 0.4 mg without adverse effects.[14]

Yoon et al. studied 60 obstetric patients scheduled for caesarean section under SAB to receive morphine 0.1 mg or nalbuphine 1 mg or morphine 0.1 mg with nalbuphine 1 mg in addition to 0.5% bupivacaine 10 mg and concluded that effective analgesia was prolonged in the morphine group and morphine with nalbuphine group, but the incidence of pruritus was significantly lower in the nalbuphine group, while the incidence of nausea and vomiting did not differ in the different groups.[15]

Fournier et al. studied the analgesic effects of intrathecal morphine 160 mcg and nalbuphine 400 mcg in geriatric patients scheduled for elective total hip replacement under continuous spinal anesthesia, given in the postoperative period, in the recovery room, and concluded that administration of intrathecal nalbuphine resulted in a significantly faster onset of pain relief and a shorter duration of analgesia than intrathecal morphine.[16]

As for dose concern, nalbuphine had been used in various doses from 0.2mg, 0.3mg, 0.4mg, 0.6mg, 0.8mg, 1.6mg, 1mg and even 2 mg doses in which dose above 0.8mg shows no significant changes in postoperative analgesia due to a ceiling effect. Increase in dose increase the risk of side effects. We choose minimum dose as 0.25mg as per negligible side effects for use in pregnant patients.

Gupta et al. studied intrathecal nalbuphine versus intrathecal fentanyl as an additive with bupivacaine for orthopedic surgery of lower limbs in 2016. They concluded that duration of rescue analgesia was prolonged by 39.9 ± 7.75 min when 2 mg of nalbuphine +17.5 mg of hyperbaric bupivacaine was given intrathecally as compared to 25 mcg of fentanyl +17.5 mg of hyperbaric bupivacaine intrathecally. This prolonged duration of rescue analgesia was statistically significant.[17]

Gomaa et al. compared two groups, one group received intrathecal nalbuphine 0.8 mg with bupivacaine and the other group received 25 µg of fentanyl with bupivacaine intrathecally in cesarean section, and they studied postoperative analgesic efficacy and concluded that intrathecal nalbuphine 0.8 mg and intrathecal fentanyl 25 µg combined with 10 mg bupivacaine both result in good intraoperative and early postoperative analgesia in cesarean section.[18] Compared to our study, a lesser dose of nalbuphine was used with good postoperative analgesia with reduced side effects.

Singh et al. did a comparative study and concluded that the addition of nalbuphine to intrathecal bupivacaine has prolonged the duration of sensory block and postoperative analgesia and requirement of analgesics in the postoperative period is also decreased without increasing the side effects or complications. Addition of fentanyl has the same effect but lesser than nalbuphine.[19]

Bisht and Rashmi have done a comparison of intrathecal fentanyl and nalbuphine: a prospective randomized controlled study in patients undergoing total abdominal

hysterectomy – Group FB: 15 mg of 0.5% bupivacaine (3 ml) plus 25 mcg of fentanyl and Group NB: 15 mg of 0.5% bupivacaine (3 ml) plus 1 mg nalbuphine (0.5 ml). Onset of sensory blockade in Group NB was 4.20 ± 0.52 and in Group FB it was 3.09 ± 0.47. The onset of sensory block was faster in Group FB than in Group NB, which was statistically significant.[20] But our study didn't get any difference in sensory and motor onset in both groups.

Mostafa et al. compared the analgesic efficacy and duration of analgesia with side effects of intrathecal tramadol 50 mg with nalbuphine 2 mg for postoperative analgesia after transurethral resection of the bladder tumor. They found no clinically significant difference for intensity and duration of motor block and sensory analgesia. The incidence of hypotension, bradycardia, itching, respiratory depression, nausea, and other side effects was minimal and was well tolerated by the patients. The number of rescue analgesia was less in the nalbuphine group.[21] They found a statistically significant difference in the duration of motor and sensory block in the their study between fentanyl and nalbuphine groups. All patients were calm and comfortable during surgery, and no drug-related side effects occurred.

There is limited data on comparison of spinal effects of nalbuphine and fentanyl; the latter being more lipid-soluble has a rapid tissue uptake compared to nalbuphine.

The present study showed no statistically significant difference in the onset and cephalic extension of the sensory blockade of hyperbaric bupivacaine when intrathecal fentanyl or nalbuphine was used as an adjuvant. The duration of sensory block was significantly enhanced by the addition of intrathecal nalbuphine as compared to intrathecal fentanyl in the present study. The results of the present study correlate well with other studies where it was observed that the addition of nalbuphine allowed a significant reduction in pain score.[22,23]

In our study, a significant difference was observed in HR between the two groups at 5, 10, and 15 min. Lower HR was observed in the nalbuphine group than the fentanyl group during the above-said durations. There was no bradycardia in Group BN as well as Group BF. In our study, there was hypotension in both groups which was statistically nonsignificant (p-value >0.05).

Respiratory depression is a deleterious side effect of intrathecal opioids, which may have serious consequences such as respiratory arrest and even death. The risk factors for the

development of 'respiratory depression' include increasing age, the concomitant use of long-acting sedatives, and co-existing respiratory disease. Belzarena et al. reported a decrease in the respiratory rate in patients receiving 0.5 and 0.75 μg/kg of intrathecal fentanyl, as early as 4 min after the drug administration, but the respiratory rate did not fall below 10 breaths/min.[24] Most authors used doses below 25 μg in later studies and did not find respiratory depression in any patient.[25,26] The study findings are consistent with the previous studies as none of the patients were reported to have respiratory depression. In our study, we used a low dose of fentanyl i.e. 25 mcg, and also didn't get respiratory depression as reported by previous studies.

Hunt et al. observed a significant increase in the overall incidence of itching in patients who received 25 and 50mcg of intrathecal fentanyl.[27] Similarly, Belzarena et al. also found that the group of patients who received 20 μg of intrathecal fentanyl showed a significantly higher incidence of pruritus.[24]

Seewal et al. found a high incidence of pruritus with increasing the dose of fentanyl above 10 μg in lower abdominal surgery.[28] On the contrary, some studies have shown non-significant pruritus in patients receiving 25 μg and less of intrathecal fentanyl.[29,30,31,32] In our study, we didn't get pruritus, nausea and vomiting as well as sedation in both groups.

SUMMARY AND CONCLUSION

On the basis of present clinical study, we come on the conclusion that when hyperbaric bupivacaine 0.5% (12.5 mg) used along with opioid adjuvants for spinal anaesthesia for lower abdominal and lower limbs surgery it provides adequate anaesthesia with sound intraoperative conditions with desired postoperative analgesia with stable hemodynamics. When comparing between fentanyl and nalbuphine, addition of Nalbuphine 0.8 mg to hyperbaric Bupivacaine 0.5% (12.5mg) provide efficient and prolonged postoperative analgesia with minimum or no side effects (pruritus, nausea, vomiting, bradycardia, respiratory depression) than addition of fentanyl 25 mcg to same baricity and dose of bupivacaine.

Unlike other narcotics, nalbuphine is not included under the narcotic act, so easily available on prescription and can be used to the centres where fentanyl is not easily available and cost-effective also.

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