16

COMPARISON OF INTRATHECAL BUPIVACAINE WITH NALBUPHINE AND BUPIVACAINE WITH FENTANYL IN INGUINAL HERNIA SURGERY

-Dr. Sushmita K Shah (Assistant Professor),

Dr. Drashti A Vavadia (3rd year resident) ,

-Dr. Vidhi A Gajjar(Assistant Professor),

-Dr. Pinal Bhikadiya (2nd year resident) ,

-Dr. Aishwarya Raj(1st year resident),

-Dr. Vibhuti Shah (Professor and HOD).

Name: Dr. Sushmita K Shah, Anaesthesia Department, AMC MET MEDICAL COLLEGE, LG HOSPITAL, Maninagar, Ahmedabad. sushmiasmi@gmail.com

Correspondence Address: Dr. Drashti A Vavadia, Anaesthesia Department, AMC MET MEDICAL COLLEGE, LG HOSPITAL, Maninagar, Ahmedabad. Email address-Drashtivavadia27@gmail.com

ABSTRACT

CONTEXT-

Opioids as an adjuvant to hyperbaric Bupivacaine improves perioperative analgesia with minimal side effects.

AIM-

The aim of the study is to compare the effect of intrathecal Nalbuphine and Fentanyl as adjuvants to hyperbaric Bupivacaine on onset and duration of sensory blockade, onset and duration of motor blockade, two segment sensory regression time, duration of effective postoperative analgesia and incidence of side effects.

STUDY DESIGN-

Prospective observational study

ETHICAL ASPECT AND METHODS-

After all ethical committee clearance and written informed consent, 60 patients of ASA grade I and II undergoing inguinal hernia surgery will be randomly divided into two groups: Group I – 0.5 % Bupivacaine(heavy) 3 ml + Nalbuphine 0.1 ml (1 mg) and Group II – 0.5% **Bupivacaine(heavy) 3 ml + Fentanyl 0.5 ml (25 μg).**

RESULT-

There was no significant difference in onset of sensory and motor blockade. Duration of sensory blockade was significantly prolonged (111.42 ± 9.21 min) in Group I than in Group II (102.32 ± 6.45 min) and duration of motor block was significantly extended in patients of Group I(144.65± 15.12 min) than Group II (130.42 ±11.12 min). The duration of effective analgesia was significantly more in group I than group II, with no significant side effects.

CONCLUSION-

1 mg Nalbuphine in 3 ml 0.5% hyperbaric Bupivacaine in patients increases the duration of sensory and motor block as compared to Fentanyl as well as provides effective analgesia time more than Fentanyl in patients scheduled for inguinal hernia surgery under subarachnoid block.

KEYWORDS- Bupivacaine, Fentanyl, Nalbuphine, Spinal Anaesthesia, Inguinal Hernia Surgery.

INTRODUCTION

Pain is one of the primary concerns for patients after surgery. It causes distress, hampers well-being, and prolongs their hospital stay. There are myriad choices of pharmacological agents and techniques to select for postoperative pain management. The use of opioid as adjuvants in regional analgesia techniques has been one of the cornerstones in postoperative pain management in recent decades.[1]

Subarachnoid blockade is a commonly used technique for lower abdominal and lower limb surgeries. It is safe and reliable with rapid onset of anesthesia, providing adequate intra- and post-operative analgesia.[2]

The chemical name of Bupivacaine is l-*n*-butyl- DL-piperidine-2-carboxylic acid-2,6 dimethylanilide hydrochloride. Bupivacaine hydrochloride is an amide type of local

anesthetic drug, which was synthesized by Ekenstam in 1957 and used clinically in 1963. Bupivacaine acts mainly by blockade of voltage-gated Na^+ channels in the axonal membrane and possibly has a further effect on presynaptic inhibition of calcium channels.[3,4]

Opioid analgesics activate opioid receptors located on the primary afferent neurons, resulting in the activation of pain modulating systems. Their activation may either directly decrease neurotransmission or inhibit the release of excitatory neurotransmitters. Opioid receptors are classified as mu, delta, and kappa receptors. Opioid agonist acts on mu receptors and are principally responsible for supraspinal and spinal analgesia along with sedation, nausea, vomiting, pruritus, and respiratory depression. Opioid, an agonist–antagonist, act principally on kappa receptors. Site of action in the spinal cord is substantia gelatinosa. Analgesia with neuraxial opioids is dose- related and specific for visceral rather than somatic pain.[5]

Both fentanyl and nalbuphine are opioid analgesics. Fentanyl is an opioid agonist and acts on μ- opioid receptors.[6] Nalbuphine is a synthetic opioid analgesic with agonist–antagonist activity and acts as antagonist at μ- receptors and agonist at κ- receptors to provide reasonably potent analgesia. Nalbuphine, when used as adjuvant to hyperbaric bupivacaine, has improved the quality of
perioperative analgesia with fewer side effects.[7]

AIM OF STUDY

To compare efficacy of Fentanyl versus Nalbuphine in subarachnoid block with Bupivacaine.

OBJECTIVES

- To compare onset and duration of sensory blockade in subarachnoid block
- To compare onset and duration of motor blockade
- To compare side effects

MATERIAL AND METHODS

STUDY DESIGN-

Prospective observational study

INCLUSION CRITERIA-

- Age- 20 - 60 years
- ASA Grade- I and II
- Patients undergoing elective inguinal hernia surgery.

EXCLUSION CRITERIA-

- Patients refusal
- Allergic to study drug
- Emergency surgeries
- Gross spinal abnormality
- Localized skin sepsis
- Hemorrhagic diathesis

METHODOLOGY-

After institutional ethical committee clearance and written informed consent, 60 patients of ASA grade I and II undergoing inguinal hernia surgery were randomly divided into two groups- Group I and Group II.

All patients had undergone thorough preoperative checkup and all routine and specific investigations, as required, were done.

All patients had undergone overnight fasting. No premedication was given.

After shifting the patient to OT, all routine monitor were applied including pulse oxymetry, ECG, NIBP and base line vitals were recorded. 18 G i.v. line was secured and patients were preloaded with 10 ml/kg of RL solution.

Spinal anaesthesia was given in sitting position in L_3-L_4 subarachnoid space with 25 G spinal needle after free flow of CSF with:-

Group I – 0.5 % Bupivacaine(hyperbaric) 3 ml + Nalbuphine 0.1 ml (1 mg)

Group II – 0.5% Bupivacaine(hyperbaric) 3 ml + Fentanyl 0.5 ml (25 µg)

Following observations were done-

1. Onset of sensory block – evaluated by pinprick method at every 1 minute interval. Sensory block was defined adequate when level reaches T_6. Postoperatively 2 segment regression time was noted to assess recovery of block. Duration of effective analgesia was till administration of first rescue analgesia. VAS ≥3 was considered as study end point.
2. Onset of motor block – assessed by modified Bromage scale

   Grade 0- No block- full knee and ankle flexion

   Grade 1- Partial block- just able to flex knee, full flexion of ankle

   Grade 2- Almost complete block- unable to flex knee, full flexion of ankle

   Grade 3- Complete block – unable to flex knee and ankle

   Duration of motor blockade was considered, when modified Bromage scale returns to zero.

3. Complications-

Hypotension- mean BP falls > 30% of baseline value.

Treatment- Fluids and Inj. Mephentermine

6 mg iv stat.

Bradycardia- HR < 60/min,

HR <50/min in patients on ß-blockers

Treatment- Inj. Atropine 0.6 mg iv.

STATISTICAL ANALYSIS-

Comparison between 2 groups was done using unpaired t-test and difference was considered significant if p value ≤0.05 and highly significant if p value ≤0.01. Statistical analysis was performed with SPSS computed programme.

ETHICAL ASPECT-

All the study drugs are US FDA approved and are not known to cause any major side effects on intrathecal injection and well informed written consent was taken.

OBSERVATION AND RESULTS

Our study compared the clinical efficacy of Nalbuphine (1 mg) with Fentanyl (25 µG) as intrathecal adjuvants to 0.5% hyperbaric Bupivacaine in 60 adult patients scheduled for elective inguinal hernia surgery under subarachnoid block. Outcomes were measured in terms of sensory and motor blockade characteristics, duration of analgesia, intra-operative hemodynamic changes and adverse effects like hypotension and bradycardia. There were no surgical or anaesthetic complications.

Demographic variables of all patients were depicted in Table I. There was no significant

difference between study groups regarding mean age, weight, height, gender and duration of surgery. **(Table I)**

TABLE I. Demographic Variables

PARAMETERS	**Group I**	**Group II**	**p-Value**
Age (Years)	42.45 ± 10.35	42.92 ± 12.11	0.8722 NS
Weight (Kgs)	63.24 ± 7.12	62.12 ± 6.42	0.5248 NS
Height (cms)	155.68 ± 6.31	158.24± 5.63	0.1027 NS
Sex (M:F)	24:6	25:5	0.88 NS

Duration of Surgery (Mins)	104.24 ± 15.72	101.34 ± 17.12	0.4971 NS

The time to reach T10 sensory level, that is the onset of sensory blockade was 3.14 ± 0.58 min in patients of Group I and 3.35 ± 0.32 min in patients of Group II with no statistical significance (P = 0.08). Time for two segment sensory regression was significantly prolonged in patients of Group I (111.42 ± 9.21 min) as compared to patients of Group II (102.32 ± 6.45 min) with P < 0.0001.

(Table II)

The mean time required for the onset of motor block to Bromage grade 3 was 7.57 ± 2.51 min in patients of Group I and 8.23 ± 3.25 min in patients of Group II, but there was no significant difference (P = 0.38). The mean duration of motor block was significantly extended Group I (144.65± 15.12 min) as compared to group II (130.42 ±11.12 min) with p value as 0.0001.

The mean duration of effective analgesia was 290.42 ± 22.64 min in Group I patients which was significantly prolonged as compare to patients of Group II (248.14 ± 20.12min) with P < 0.0001. **(Table II)**

Table II. Characteristic of sensory and motor blockade and Duration of Analgesia

Characteristics	Group I	Group II	p-Value
Time to reach T10 Sensory Block Level	3.14 ± 0.58	3.35 ± 0.32	0.0878 (>0.05)
Time for 2 Segment Sensory Regression	111.42 ± 9.21	102.32 ± 6.45	<0.0001 (<0.05)
Time Taken to Achieve Complete Motor Block	7.57 ± 2.51	8.23 ± 3.25	0.3823 (>0.05)
Duration of motor blockade	144.65± 15.12	130.42 ±11.12	0.0001 (<0.05)
Duration of Effective Analgesia	290.42 ± 22.64	248.14 ± 20.12	<0.0001 HS

FIGURE I. HEART RATE

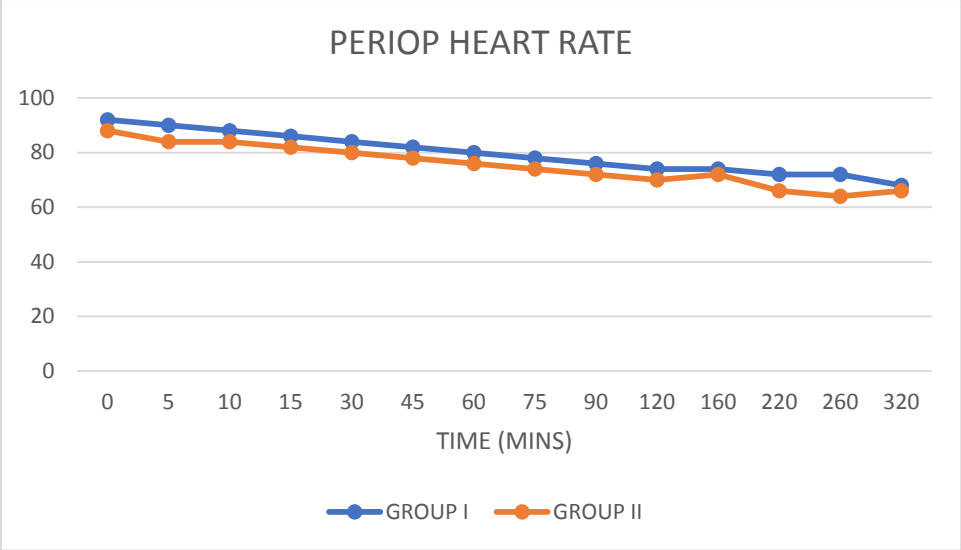

FIGURE II. MEAN ARTERIAL PRESSURE

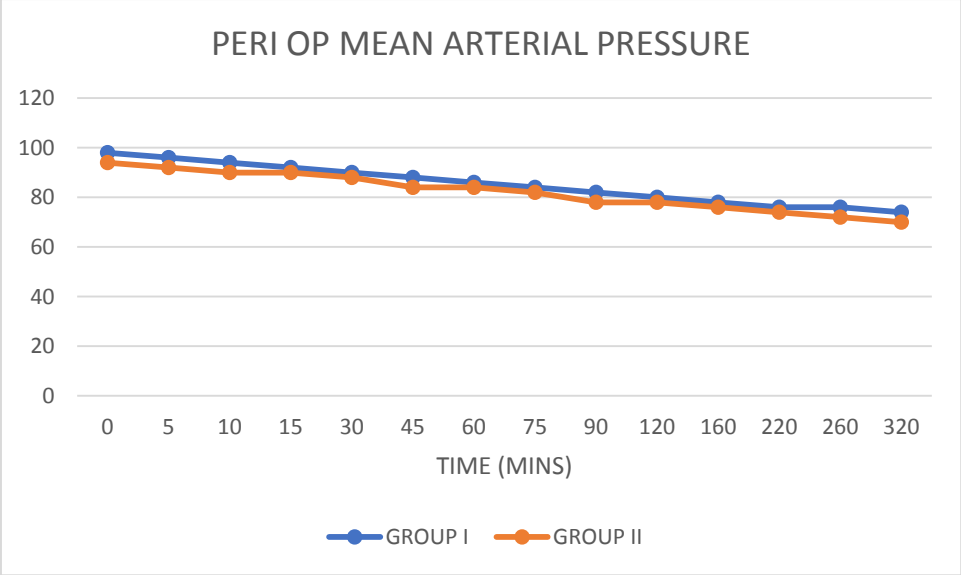

Figure I and II showed the heart rate (HR) and mean arterial pressure (MAP) in two groups perioperatively. There was decrease in heart rate and MAP but was not clinically and

statistically significant. Incidence of hypotension and bradycardia during intraoperative period was minimal and did not require any medical intervention. The SpO2 was well maintained above 98% on air in all patients intraoperatively as well as postoperatively. There was no occurrence of intraoperative nausea, vomiting, respiratory depression, shivering, hypotension and bradycardia among all groups. None of the patient needed supplemented analgesia during surgery.

DISCUSSION

Spinal anesthesia is the preferred technique for the lower abdominal surgeries. Opioids as adjuvants to local anesthetics provide better perioperative sensory and motor blockade with prolongation of postoperative analgesia. By reducing the local anesthetic dosage, they decrease their toxicity and the side effects associated with higher level of blockade. Use of

opioid adjuvants such as morphine, fentanyl, and nalbuphine along with bupivacaine has been very well established.[5,8,9]

Jyothi B et al observed that increasing Nalbuphine dose from 0.8 to 1.6 mg and 2.4 mg did not increase analgesic efficacy.[10]

Culebras et al compared intrathecal Nalbuphine with intrathecal Morphine with different doses of 0.2 mg, 0.8 mg and 1.6 mg Nalbuphine and concluded that intrathecal Nalbuphine 0.8 mg provides efficient intraoperative and postoperative analgesia, without side effects. They found that intrathecal Nalbuphine 1.6 mg did not increase the analgesic efficacy but increased the adverse effects.[11] It implies that by increasing the dose of Nalbuphine, analgesic efficacy increases only up to a certain point beyond which there is no further increase with the dose increment i.e. Nalbuphine exhibits a ceiling effect to analgesia.

So, in our study the dose of Nalbuphine was taken as 1 mg to compare its efficacy with Fentanyl.

Gomaa et al. compared intrathecal nalbuphine 0.8 mg and fentanyl 25 µg and found that there was no statistically significant difference in onset of sensory block between fentanyl and nalbuphine group.[12]Similarly Naaz et al[13], Gupta et al [14], and Ahmed et al [15], also found no significant difference in two groups. However, Venkata et al[16] found significantly faster onset of sensory block with fentanyl as adjuvant.

In our study, it was found that onset of sensory block was comparable in the two groups and there was no significant difference between mean time to achieve T10 sensory level block in two groups (P=0.08).

Gupta et al[14]and Gurunath et al [2] also observed that duration for two segment sensory

regression in Nalbuphine group was significantly prolonged as compared to Fentanyl group. But Bindra et al[17] outlined that time of two-segment sensory regression was less in patients with Nalbuphine as compared to Fentanyl but it was not statistically significant. In our study, the mean duration of sensory block was longer (111.42 ± 9.21 min) in patients with Nalbuphine than patients with Fentanyl (102.32 ± 6.45 min) and this difference was statistically significant (P <0.0001).

Gupta et al [14] and Bindra et al[17] noticed no significant difference between time to achieve complete motor block in two groups. In our study, it was observed that the difference in the time to achieve complete motor block was 7.57 ± 2.51 mins in group I and 8.23 ± 3.25 mins in group II, which was not significant in two groups (P= 0.38).

Patients with Nalbuphine had prolonged duration of motor block (144.65± 15.12 mins) than in patients with Fentanyl (130.42 ±11.12 mins) and this was significant (P=0.0001). Gupta et al[14] also found similar results in their study.

Mostafa et al[18] and Tiwari et al[19] concluded that Nalbuphine had prolonged duration of analgesia than Fentanyl. Gomaa et al[12] compared postoperative analgesia between 25 µg of intrathecal Fentanyl with 0.8 mg of Nalbuphine and did not find any significant difference in the duration of analgesia between the two groups.

In our study, VAS ≥3 was considered as study end point. We found that patients with Nalbuphine as an adjuvant had a significantly longer duration of effective postoperative analgesia than in patients with Fentanyl. The mean duration of postoperative analgesia in patients with Nalbuphine was 290.42 ± 22.64 mins and in patients with Fentanyl was 248.14 ± 20.12 mins.

Gurunath et al[2] compared intrathecal nalbuphine with fentanyl as spinal adjuvant and observed delay in onset of sensory blockade, prolonged sensory block and more duration of analgesia with minimal side effect in patients with nalbuphine as adjuvant than in patients with fentanyl. Singh et al [20] in his study concluded that addition of nalbuphine to intrathecal bupivacaine had prolonged the duration of sensory block and post-operative analgesia without increasing side effects or complications.

In our study, side effects like minimal hypotension and decreased heart rate following administration of spinal anaesthesia was noted in both the groups, but it was not statisfically significant.

CONCLUSION

Inj.Nalbuphine (1mg) as intrathecal adjuvant to 0.5% hyperbaric Bupivacaine increases the duration of sensory block, motor block and the effective analgesia time more efficiently than Inj. Fentanyl in patients scheduled for elective inguinal hernia surgery under subarachnoid block. So, intrathecal Nalbuphine can be used as an alternative to intrathecal Fentanyl in inguinal hernia surgeries providing better postoperative analgesia with no significant complications.

REFERENCES

1. Buvanendran A, Kroin JS. Useful adjuvants for postoperative pain management. Best Pract Res Clin Anaesthesiol 2007;21:31-49.
2. Gurunath BB, Madhusudhana R. Postoperative analgesic efficacy of intrathecal fentanyl compared to nalbuphine with bupivacaine in spinal anesthesia for lower abdominal surgeries. Anesthesia, essays and researches. 2018 Apr;12(2):535.
3. Colin VJ. Principles of Anesthesiology. 3rd ed. Philadelphia: Lea and Febiger; 1993. Spinal anesthesia-principles; pp. 1445–97.
4. Stoelting RK, Hillier SC. Local anaesthetics. In: Flood P, Rathmell JP, Shafer S, editors. Pharmacology and Physiology in Anesthetic Practice. 4th ed. Ch. 7. Philadelphia: Lippincott Williams & Wilkins; 2006. pp. 179–99.
5. Hindle A. Intrathecal opioids in the management of acute postoperative pain. Continuing education in anaesthesia, critical care and pain. Br J Anaesth 2008;8:81- 5.
6. Tejwani GA, Rattan AK, McDonald JS. Role of spinal opioid receptor in the antinociceptive interaction between intrathecal morphine and bupivacaine. Anesth Analg 1992;74:726- 34.
7. Gunion MW, Marchionne AM, Anderson TM. Use of the mixed agonist- antagonist nalbuphine in opioid based analgesia. Acute Pain 2004;6:29- 39.
8. Singh H, Yang J, Thornton K, GieseckeAH. Intrathecal fentanyl prolongs sensory bupivacaine spinal block. Can J Anaesth 1995;42:987-91.
9. Ben-David B, Solomon E, Levin H, Admoni H, Goldik Z. Intrathecal fentanyl with small-dose dilute bupivacaine: Better anesthesia without prolonging recovery. Anesth Analg 1997;85:560-5.

10. Jyothi B, Gowa S, Shaikh SI. A comparison of analgesic effect of different doses of intrathecal nalbuphine hydrochloride with bupivacaine and bupivacaine alone for lower abdominal and orthopedic surgeries. Indian J Pain 2014;28(1):18-23.
11. Culebras X, Gaggero G, Zatloukal J, et al. Advantages of intrathecal nalbuphine, compared with intrathecal morphine, after cesarean delivery: an evaluation of postoperative analgesia and adverse effects. Anesth Analg 2000;91(3):601-5.
12. Gomaa HM, Mohamed NN, Zoheir HA, et al. A comparison between post-operative analgesia after intrathecal nalbuphine with bupivacaine and intrathecal fentanyl with bupivacaine after caesarean section. Egypt J Anaesth 2014;30(4):405-10.
13. Naaz S, Shukla U, Srivastava S, Ozair E, Asghar A. A comparative study of analgesic effect of intrathecal nalbuphine and fentanyl as adjuvant in lower limb orthopaedic surgery. J Clin Diagn Res 2017;11:UC25- 8.
14. Gupta K, Rastogi B, Gupta PK, et al. Intrathecal nalbuphine versus intrathecal fentanyl as adjuvant to 0.5% hyperbaric bupivacaine for orthopedic surgery of lower limbs under subarachnoid block: a comparative evaluation. Indian J Pain 2016;30(2):90- 5.
15. Ahmed F, Narula H, Khandelwal M, et al. A comparative study of three different doses of nalbuphine as an adjuvant to intrathecal bupivacaine for postoperative analgesia in abdominal hysterectomy. Indian J Pain 2016;30(1):23-8.
16. Venkata HG, Pasupuleti S, Pabba UG, et al. A randomized controlled prospective study comparing a low dose bupivacaine and fentanyl mixture to a conventional dose of hyperbaric bupivacaine for cesarean section. Saudi J Anaesth 2015;9(2):122-7.
17. Bindra TK, Kumar P, Jindal G. Postoperative analgesia with intrathecal nalbuphine versus intrathecal Fentanyl in cesarean section:a double-blind randomized comparative study. Anesth Essays Res 2018;12(2):561-5.

18. Mostafa MG, Mohamad MF, Farrag WS. Which has greater analgesic effect: intrathecal nalbuphine or intrathecal tramadol? J Am Sci 2011;7:480-4.
19. Tiwari AK, Tomar GS, Agrawal J. Intrathecal bupivacaine in comparison with a combination of nalbuphine and bupivacaine for subarachnoid block: a randomized prospective double-blind clinical study. Am J Ther 2013;20(6):592-5.
20. Singh N, Kumar S, Tyagi RK. A clinical comparative study of intrathecal nalbuphine versus intrathecal fentanyl added to 0.5% hyperbaric bupivacaine for perioperative anaesthesia and analgesia in lower abdominal surgeries. IOSR J Dent Med Sci 2017;16(3):33-40.