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A comparative clinical study of intrathecal nalbuphine versus intrathecal fentanyl as an adjuvant to 0.5% hyperbaric bupivacaine for lowerlimb orthopedic surgery under subarachanoid block

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Abstract

Introduction: Spinal anaesthesia is the technique of choice for, lower limb surgeries. Various adjuvants are used intrathecally with local anaesthetics to improve the duration of action and analgesic effect. Among various adjuvants, intrathecal opioids has provide an effective prolongation of postoperative analgesia after orthopedic surgical procedure.[1]

Fentanyl and nalbuphine are opioid analgesics. Fentanyl is a opioid agonist and acts on µ opioid receptor.[2] Nalbuphine is a synthetic opioid analgesic with agonist-antagonist activity and acts as antagonist at µ receptor and agonist at k receptor. Nalbuphine, when used as adjuvant to hyperbaric bupivacaine has improved the quality of perioperative analgesia with fewer side effects.[3]

The availability of fentanyl and other µ opioids is difficult compared to nalbuphine which is easily available and has lesser side effects. Therefore a prospective controlled comparative clinical study of intrathecal nalbuphine 0.4mg versus intrathecal is being taken up.

Fentanyl l 25µg with 12.5mg of 0.5% bupivacaine in patients undergoing lowerlimb orthopedic surgeries

Aim: To compare the onset and duration of sensory and motor block as well as postoperative analgesia provided by intrathecal 0.4mg nalbuphine and intrathecal 25µg fentanyl when used as adjuvants to 2.5ml of 0.5% bupivacaine.

Methodology: 50 patients of [American Society of Anesthesiologists (ASA) physical status I and II], aged 18 to 60 years, posted for lower limb orthopedic surgeries under spinal anaesthesia will be included in the study after obtaining ethical committee clearance and written informed consent from the patients. Group BF will receive 2.5ml bupivacaine 0.5% and fentanyl 25 µg (0.5ml) and Group BN receives 2.5ml of bupivacaine 0.5% and nalbuphine 0.4mg (made in to 0.5ml with normal saline)

The total amount of the intrathecal mixture was constant (3ml) in both the groups

Intra and post operatively patients were assessed for hemodynamic parameters, sensory and motor blocked, analgesia, sedation and side effects.

Results: The demographic data (age, weight, sex, and ASA grading) were comparable and statistically non-significant. Mann Whitney U test is used for statistical analysis. The mean time for 2 segment regression of sensory blockade was more in Group BN (112.52 ± 6.15minutes) whereas it was 99.68 ± 5.66minutes in Group BF. Statistically highly significant and The p value was<0.0001*

The duration of motor block was highest for group BN with 153.12 minutes, Where as group BF had shorter duration at 137.04 minutes. The p value <0.0001 (statistically highly significant)

The mean time of resue analgesia was 211.92 ± 6.73 min in group BN and 178.68 ± 2.65 min in grop BF. The p value is < 0.0001 which is highly significant. Hence the patients in group BN needed analgesia after much longer duration compared to group BF

Conclusion: Intrathecal nalbuphine is better compared to intrathecal fentanyl when used as adjuvant to 0.5% hyperbaric bupivacaine for lower limb orthopedic surgery under subarachanoid block.

Keywords: bupivacaine, fentanyl nalbhuphine, adjuvants, neuraxial block

Introduction

Spinal anaesthesia is the technique of choice for, lower limb surgeries. Various adjuvants are used intrathecally with local anaesthetics to improve the duration of action and analgesic effect. Among various adjuvants, intrathecal opioids has provide an effective prolongation of postoperative analgesia after orthopedic surgical procedure [1]. Fentanyl and nalbuphine are opioid analgesics. Fentanyl is a opioid agonist and acts on µ opioid receptor [2] Nalbuphine is a synthetic opioid analgesic with agonist-antagonist activity and acts as antagonist at µ receptor and agonist at k receptor. Nalbuphine, when used as adjuvant to hyperbaric bupivacaine has improved the quality of perioperative analgesia with fewer side effects [3].

The availability of fentanyl and other µ opioids is difficult compared to nalbuphine which is easily available and has lesser side effects. Therefore a prospective controlled comparative clinical study of intrathecal nalbuphine 0.4mg

versus intrathecal is being taken up.
Fentanyl 25µg with 12.5mg of 0.5% bupivacaine in patients undergoing lower limb orthopedic surgeries

Materials and Methods

Source of Data: 50 Patients posted for lower limb orthopedic surgeries at KVG Medical College Hospital from January 2019 to June 2020 will be assessed for the inclusion and exclusion criteria and will be included in the study after obtaining written informed consent.

Sampling method: Random sampling

Study design: Prospective controlled comparative clinical study

Inclusion criteria

1. Patients aged between 18 to 60 years of either sex.
2. Elective surgeries of lower limb regions lasting not longer than 3 hours
3. American Society of Anesthesiologists physical status I and II

Exclusion Criteria

Patients belonging to the following classes:

- Patients having any absolute contraindications for spinal anesthesia like raised intracranial pressure, severe hypovolemia, injection site infection.
- Patients with spinal deformities.
- Refusal by the patient.
- History of allergy to any of the drugs used in the study..
- Patients shorter than 150 cm, morbid obesity.
- Patients with history of bleeding disorders or abnormal coagulation profile.
- Patients with neuro-muscular disorders.
- Patients sensory or motor deficit in the limb before surgery
- Patients with cognitive impairment or psychiatric diseases.
- Pregnant patient

Sample size: 25 patients in each group (group BN and group BF.

Statistical analysis: The data was entered in Microsoft Office Excel 2007 and SPSS version 21 was used for analysis. Results obtained are expressed in the form of frequencies, percentages, mean and standard deviation. Mann Whitney U test is used to find the difference between the two groups.

Methodology

After obtaining approval from the institutional ethics committee and obtaining written informed consent,the study will be conducted on 50 pts (25 in each group) belonging to ASA 1 and ASA II, aged 18 to 60 yrs posted for lower limb orthopedic surgeriesPre anaesthetic evaluation was carried out as necessary.
Written informed consent was obtained after the study procedure was explained.
Operating room preparation was checked, all patients were connected to multipara meter monitors and subarachnoid block was achieved using the appropriate study drug accourding the group assigned. Onset time of sensory and motor block, total duration of sensory and motor block, time taken to 2 dermatome regression of sensory analgesia, time to rescue analgesic, haemo dynamic parameters were recorded. Post-Operative pain was assessed using VAS score
Patients will be followed up for 24 hours in post-operative ward or in recovery room. Duration of analgesia is defined as the time taken from the completion of the injection of the study drug till the post-operative VAS score ≥4 and treated with intravenous infusion of Paracetamol 1.5mg/kg. Time to Rescue dose of Paracetomal will be recorded. If satisfactory pain relief is not be achieved or the patient has contraindication for Paracetamol, Inj Tramadol 75mg IV will be given

Results

The demographic data (age, weight, sex, and ASA grading) were comparable and statistically non-significant. Mann Whitney U test is used for statistical analysis.
The mean time for 2 segment regression of sensory blockade was more in Group BN (112.52 ± 6.15minutes) whereas it was 99.68 ± 5.66minutes in Group BF. Statistically highly significant and the p value was<0.0001*
The duration of motor block was highest for group BN with 153.12 minutes, where as group BF had shorter duration at 137.04 minutes.
The p value <0.0001 (statistically highly significant) The mean time of resue analgesia was 211.92 ± 6.73 min in group BN and 178.68 ± 2.65 min in grop BF. The p value is < 0.0001 which is highly significant. Hence the patients in group BN needed analgesia after much longer duration compared to group BF From above findings it is evident that Nalbuphine as intrathecal adjuvant to 0.5% hyperbaric bupivacaine clinically more efficient than fentanyl for extending the duration of sensory motor block and postoperative analgesia

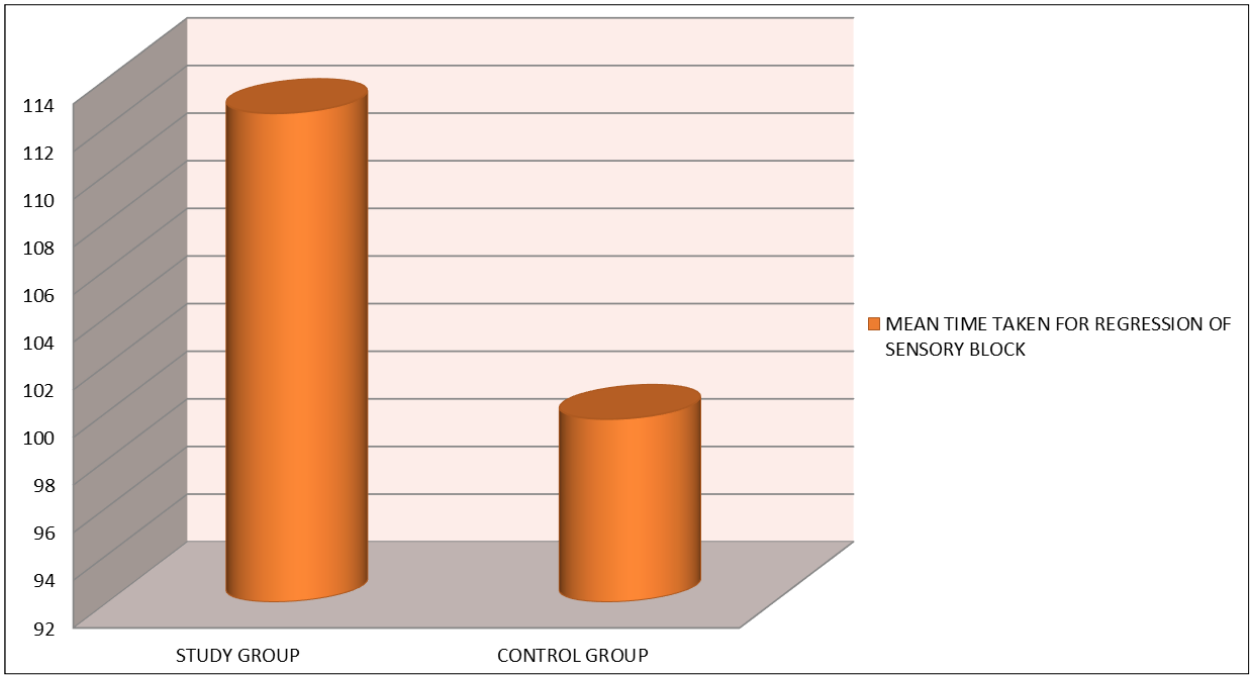

Fig 1: Mean Time Taken For Regression of Sensory Block in Both the Groups

The mean time for 2 segment regression of sensory blockade was more in Group BN (112.52 ± 6.15minutes) whereas it was 99.68 ± 5.66minutes in Group BF. Statistically highly significant and the p value was<0.0001*

Table 1: Duration of Motor Block in Minutes

Duration of Motor Block		N	Mean	Std. Deviation	Minimum	Maximum	U VALUE	P VALUE
Motor Block	Group BN (Study Group)	25	153.12	5.35	140	162	8.5	<0.0001*
	Group BF (control Group)	25	137.04	4.56	130	147		
	Total	50	145.08	9.49	130	162		

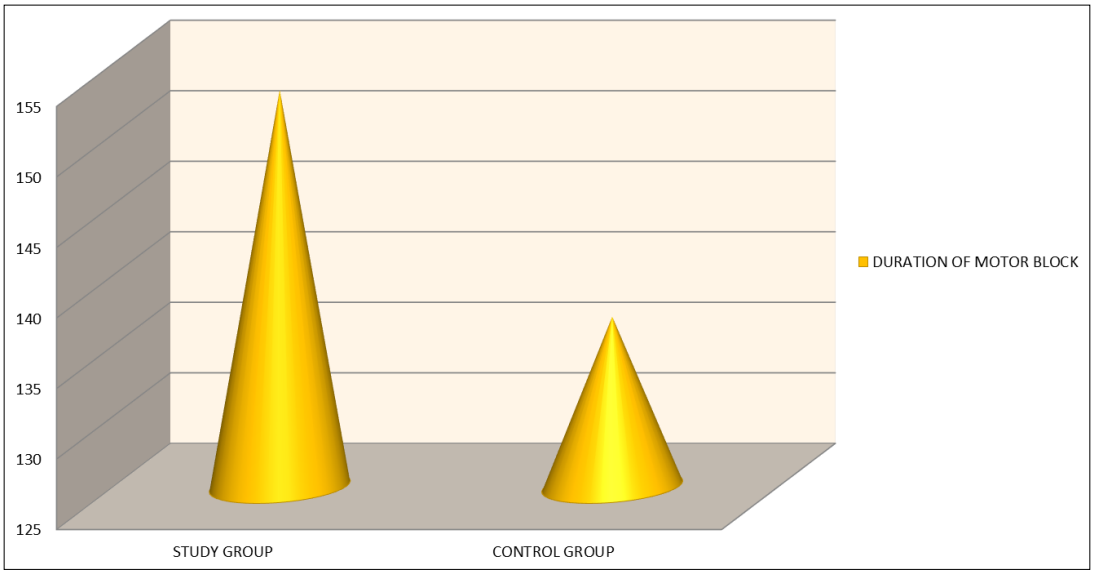

Fig 2: Duration of Motor Block in Both the Groups

The mean time for 2 segment regression of sensory blockade was more in Group BN (112.52 ± 6.15minutes) whereas it was 99.68 ± 5.66minutes in Group BF. Statistically highly significant and the p value was<0.0001*

Table 2: Timing to Rescue Analgesia

Difference In Vas Between The Two Groups		N	Mean	Std. Deviation	Minimum	Maximum	U VALUE	P VALUE
VAS	Group bn (study group)	25	211.92	6.73	200	225	0	<0.0001*
	Group bf (control group)	25	178.68	2.65	175	184		
	Total	50	193.5	17.53	175	225		

The mean time of resue analgesia was 211.92 ± 6.73 min in group BN and 178.68 ± 2.65 min in grop BF. The p value is < 0.0001 which is highly significant. Hence the patients in group BN needed analgesia after much longer duration compared to group BF

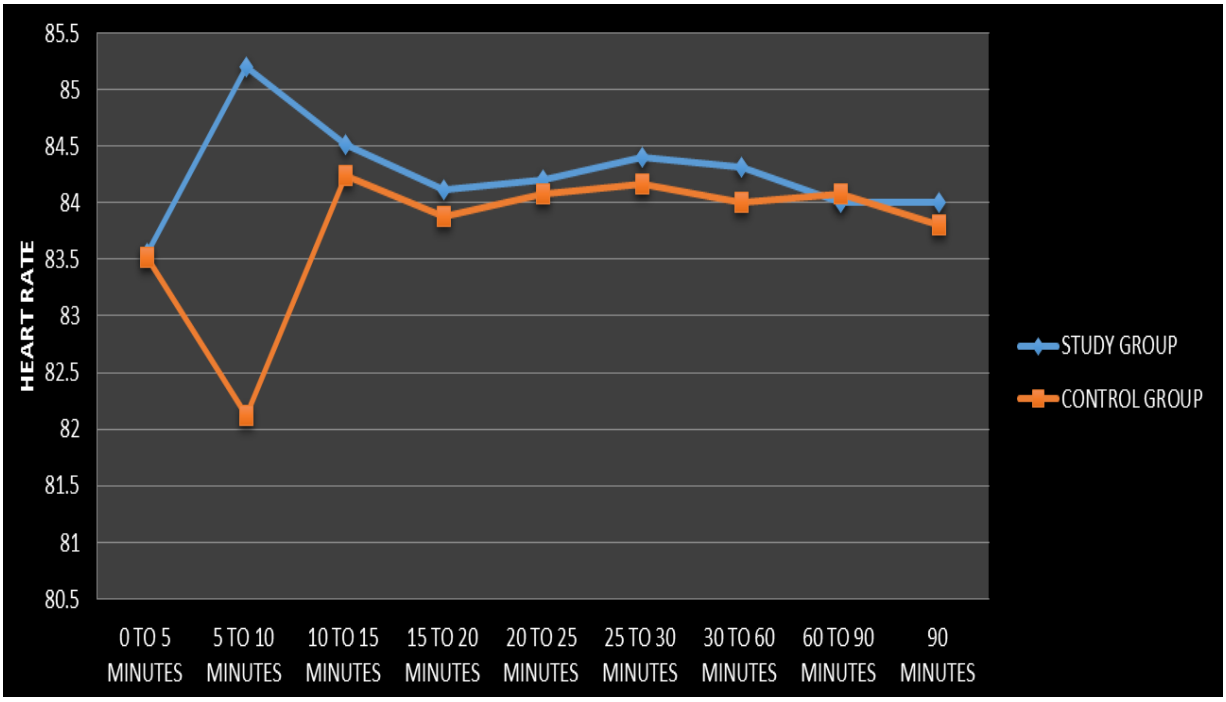

Fig 3: Heart Rate at Different Time Intervals In Both The Groups

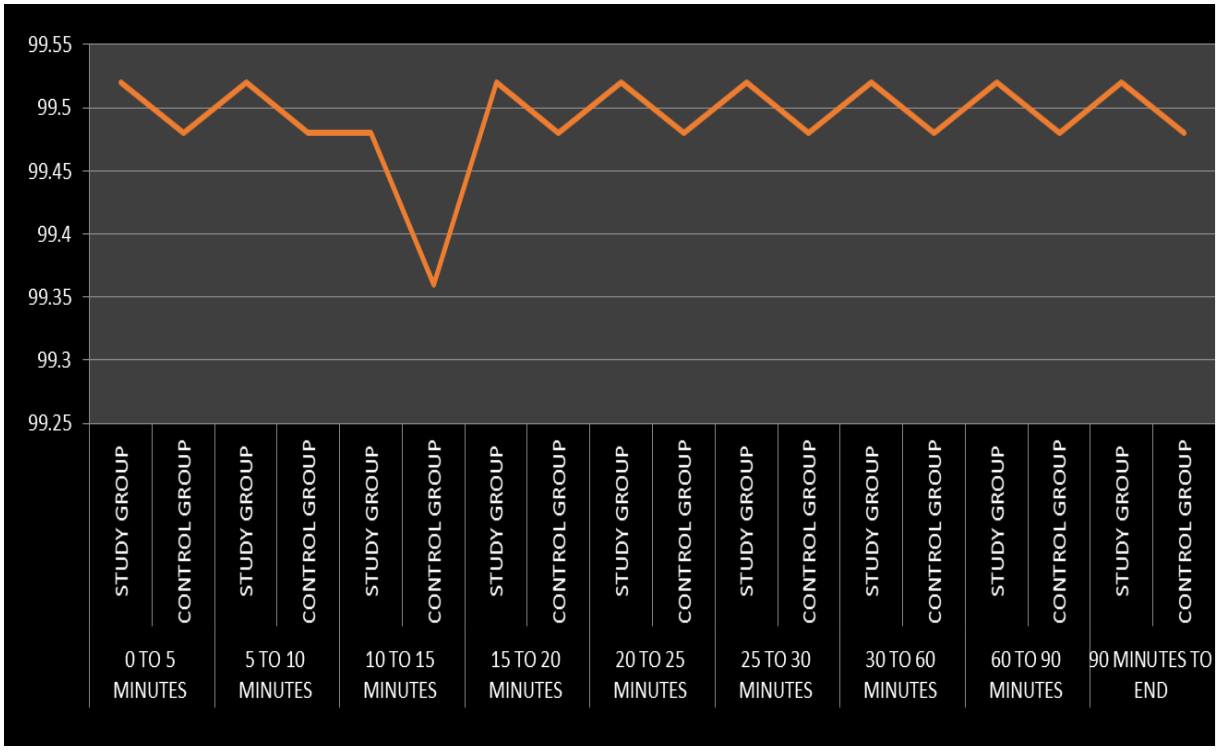

Fig 4: Mean Oxygen Saturation at Different Time Intervals

Discussion

Nalbuphine, when used as adjuvant to hyperbaric bupivacaine has improved the quality of perioperative analgesia with fewer side effects. [3] Fentanyl and nalbuphine are opioid analgesics. Fentanyl is A opioid agonist and acts on μ opioid receptor [2]. Nalbuphine is a synthetic opioid analgesic with agonist-antagonist activity and acts as antagonist at μ receptor and agonist at k receptor,

In our study we chose to add 0.4mg nalbuphine and based on study conducted by Mukerjee *et al* concluded that adittion of nalbuphine to bupicaine was clinically more efficient than fentanyl for enhancing postoperative analgesia.25mcg of fentanyl was selected as the dose based on the studies conducted by Bishat *et al*, Gurunath *et al*, Naaz *et al*, Gupta *et al*

In current study 50 patients undergoing elective lower limb surgeries were included. The demographic data in terms of age, gender, weight ASA physical status, and surgical characteristics showed no statistical difference.

The haemodynamic characteristic of mean HR, SBP DBP at baseline with intraoperative changes were comparable and there was no statistically significant difference in HR, SBP DBP and SPO2

NO patients suffered from postspinal shivering, nausea, vomiting or respiratory depression.

None of the patients needed supplemented analgesia during surgery

Conclusion

Our study Reveled that 0.4mg nalbuphine when added to 2.5ml of 0.5% hyperbaric bupivacaine for subarachanoid block prolongs the duration of sensory and motor block and also duration of analgesia compared to 25mcg fentanyl when added to 2.5ml of 0.5% hyperbaric bupivacaine.

And we concluded that intrathecal nalbuphine is better compared to intrathecal fentanyl when used as adjuvant to 0.5% hyperbaric bupivacaine for lower limb orthopedic surgery under subarachanoid block

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