Journal of Cardiovascular Disease Research

ISSN: 0975-3583, 0976-2833 VOL14, ISSUE10, 2023

TO COMPARE NALBUPHINE AND BUPRENORPHINE AS INTRATHECAL ADJUVANT TO HYPERBARIC BUPIVACAINE IN LOWER LIMB SURGERIES

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Abstract

Background and Aims: Intrathecal adjuvants are used to prolong the duration of block and provide post operative analgesia. Nalbuphine and Buprenorphine are mixed agonist-antagonist opioids which prolongs duration of block with fewer side effects. The study aimed to compare nalbuphine and buprenorphine as intrathecal adjuvant to hyperbaric bupivacaine in lower limb surgeries.

Materials and Methods: In a prospective, randomized, double blind study, forty-six patients of ASA class I and II scheduled for lower limb surgery were enrolled. Patients were randomly allocated into two groups of 23 each to receive 15mg hyperbaric bupivacaine with either 1mg nalbuphine (group N) or 60µg buprenorphine (group B) intrathecally.

Results: Patients who received intrathecal buprenorphine (group B) had significantly delayed onset of sensory block compared to patients who received nalbuphine (group N). The time to two segment regression was significantly prolonged in group B (93.91±17.19minutes) as compared to group N (85.65±9.33minutes) [*P* <0.05]. The onset and duration of motor block was comparable among two groups. Duration of spinal analgesia was significantly prolonged in group B (276.96±39.11minutes) as compared to group N (233.04±31.03minutes) [*P* <0.05]. The post operative analgesic requirement was significantly less in group B compared to group N [*P* <0.05]. Hemodynamic effects and incidence of side effects were comparable among two groups.

Conclusion: Intrathecal buprenorphine 60µg provides good post operative analgesia when used as an adjuvant to 0.5% hyperbaric bupivacaine in lower limb surgeries as compared to 1mg nalbuphine.

Keywords: Intrathecal buprenorphine, Lower limb surgeries, Hemodynamic effects

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1. INTRODUCTION

Lower limb surgeries form a major part of orthopaedic surgeries in the present health care scenario. Spinal anaesthesia is preferred mode of anaesthesia for lower limb surgeries as it causes less intra-operative blood loss, decreased cardiovascular, pulmonary side effects and allows early post-operative recovery. It has a major role in providing proper post-operative pain control. The attenuation of perioperative pain and optimisation of perioperative analgesia helps in decreasing complications.[1]

Hyperbaric Bupivacaine provides advantage of longer duration of effective blockade and pain relief with better control on the level of blockade achieved among conventional local anesthetics.[2] Adjuvants are added to local anaesthetics that help in prolonging the duration of sensory and motor block. A number of opioids like morphine, fentanyl and tramadol are used as intrathecal adjuvants.[3]

Nalbuphine is a semi synthetic agonist-antagonist opioid. It has μ receptor antagonist and κ receptor agonist properties. Nalbuphine used as an intrathecal adjuvant is found to be effective with minimal side effects. Intrathecal nalbuphine has been used in doses ranging from 0.2mg to 2.5mg.[4-6] Buprenorphine is a highly lipid soluble mixed agonist-antagonist narcotic. Buprenorphine has a partial agonist activity at the μ receptor and antagonist activity at κ receptor. Intrathecal buprenorphine has been used in doses ranging from 30μg to 150μg providing variable duration of analgesia and blockade.[6-8]

As per the available literature, there are not many studies comparing the effects of intrathecal nalbuphine versus buprenorphine as an adjuvant to bupivacaine. Limited studies were found to compare nalbuphine and buprenorphine as intrathecal adjuvant to 0.5% hyperbaric bupivacaine. However, no study has been found comparing 1mg nalbuphine and 60 μg buprenorphine as an intrathecal adjuvant. So, this study was planned to compare 1mg nalbuphine with 60 μg buprenorphine as an intrathecal adjuvant to hyperbaric bupivacaine.

The primary objective of the study was to compare the effective post-operative analgesia along with the side effects, sensory and motor characteristics following intrathecal nalbuphine and buprenorphine as an adjuvant to 0.5% hyperbaric bupivacaine in lower limb surgery.

2. MATERIALS AND METHODS

The study was performed after obtaining approval from the institutional ethics committee – human research (IEC-HR), University College of Medical Sciences, University of Delhi; IECHR/2020/PG/47/8-R1; December 22, 2020; Chairman – Prof. Siddarth Ramji. The study was prospectively registered with the Clinical Trials Registry of India (CTRI/2021/01/030672). The study was conducted from January 2021 to August 2022 in accordance with the Declaration of Helsinki of 1975, as revised in 2013, for experiments in human. Subjects were recruited into the study after obtaining written informed consent.

Forty-six patients of ASA physical status I and II in the age group of 18 to 60 years and height of 150 to 180 cm were included in the study. Patient with contraindication to neuraxial blockade, known allergy to drugs involved in this study, history of chronic pain or long-term use of opioids and patients with multiple fractures preventing proper assessment of pain were excluded from the study.

A routine pre-anaesthetic assessment was done and the procedure of spinal anaesthesia was explained to the patients. During the pre-anaesthetic assessment the concept of Visual Analogue Scale (VAS) for pain assessment was explained to the patient. The patients were

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kept fasting overnight. Premedication was done with tablet alprazolam 0.5mg night before the surgery. Using a computer-generated random number table, patients were randomly allocated into two groups. Concealment of randomization was done by sequentially numbered sealed opaque envelopes. Normal saline was used to dilute the study drug. Test solution was prepared by another anaesthesiologist not involved in the study. Subarachnoid block was performed and patients received 3.2 ml of the drug via intrathecal route according to the group allocated:

Group N – 15 mg of 0.5% hyperbaric Bupivacaine (3.0 ml) + 1 mg of Nalbuphine (0.2 ml)

Group B – 15 mg of 0.5% hyperbaric Bupivacaine (3.0 ml) + 60 µg of Buprenorphine (0.2 ml)

Patient were shifted to the operating table, monitors attached and baseline values of the heart rate, blood pressure (systolic, diastolic, mean), peripheral oxygen saturation and electrocardiograph (ECG) were noted. A fresh patent intravenous access was obtained using a 18G intravenous cannula and co-loading was done with 15 ml/kg of ringer's lactate. Under strict aseptic precautions spinal anaesthesia was performed, in sitting position and through mid-line approach, a 25G Quincke's needle was inserted into subarachnoid space at the level of L_3-L_4 or L_4-L_5 interspinous space till the loss of resistance was felt and free flow of CSF was confirmed at the hub of the spinal needle. Then, 3.2ml of study drug solution was injected intrathecally slowly over 10 seconds. The time of drug injection was noted and all the observations were made using this time as '0' minute. Immediately, the patient was placed in supine position and oxygen was administered by face mask. Ringer's lactate solution was used as maintenance and replacement fluid.

Sensory block characteristics were assessed and recorded at definite time intervals intra-operatively and post-operatively. The onset of sensory block was the time taken for the block to reach T10 segment. The time taken to achieve highest level of block was noted. The time taken for the initial two segment regression was noted as the duration of sensory block.

Motor block was assessed by using the Modified Bromage Scale (0-3).[9] The onset of motor block was taken as Modified Bromage grade 3 and time taken for it was noted. The time taken for complete recovery (Modified Bromage grade 0) was taken as the duration of motor block. Heart rate, Systolic, diastolic and mean blood pressure values, and SpO_2 was recorded every 5 minutes for the first 15 minutes and then every 15 minutes for the rest of the operative period and then every 30 minutes till 2 hours of post-operative phase and then each hourly till complete recovery. Sedation scoring was done every 30 minutes intra-operatively and then hourly for 2 hours in the post-operative period using 6-point Ramsay Sedation Score.[10]

Pain was evaluated using a standard 10cm linear Visual Analogue Scale (VAS). [(11)] Pain score was recorded post-operatively every 30 minutes for first 2 hours, at 3rd, 4th, 8th, 12th, and after 24 hours respectively. Duration of complete analgesia was defined as time from intrathecal analgesia to the time of first rescue analgesia. Rescue analgesia was given when VAS score was ≥ 3. Injection diclofenac 75mg intravenously was given as rescue analgesia and if VAS was persistently ≥3 even after half hour of injection diclofenac then injection paracetamol 1g intravenously was given. Patients were monitored for the side effects like pruritus, bradycardia, hypotension, nausea, vomiting, headache, respiratory depression or any other complication.

Statistical Analysis

Considering the variability in duration of effective analgesia based on the previous study which showed the duration of analgesia as 285±94.46 and 383.67±79.20 with nalbuphine and

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buprenorphine respectively, to estimate the difference at α = 5% and power = 90% a sample size of 23 patients was required in each group. [6]
All statistical analysis were done using SPSS version 20. One time measured parameters like age, height, weight and duration of surgery were compared by unpaired t test and repeatedly measured parameters such as heart rate, blood pressure by repeated measure ANOVA followed by TUKEY'S test and others like mean VAS by one way ANOVA. P value <0.05 was taken as significant.

3. RESULTS

A total of 53 patients undergoing orthopaedic lower limb surgery under subarachnoid block were assessed for the eligibility for the study. Four patients did not give the consent and three patients did not meet the inclusion criteria. Forty-six patients fulfilling the inclusion criteria were finalized and allocated into two groups of 23 each. The age, weight, height and gender ratio of the patients were comparable among the three groups [Table 1]. The duration of surgery was comparable among the groups and was not statistically significant [Table 2].
The mean time of onset of sensory block in group N was 6.09 ± 1.76 min and in group B was 7.15 ± 1.69 min. The mean time of onset was significantly decreased in group N when compared to group B (p-value 0.044). The mean time to achieve maximum block height in group N was 10.03 ± 1.17 min and that in group B was 12.44 ± 2.42 min. The mean time to achieve maximum block was statistically significant among group B and group N (p-value <0.001). The mean time for two segment regression was prolonged in group B (93.91 ± 17.19 min) when compared with group N (85.65 ± 9.33 min) which was found to have marginal statistical significance (p-value 0.049) [Table 3]. The maximum level of sensory block achieved in both the groups were comparable [Figure 2].
The time of onset of motor block in group N was 3.44 ± 0.89 min and that in group B was 3.99 ± 1.10 min. Both the groups showed no significant difference in onset of motor block. The duration of motor block was comparable among the group N (207.57 ± 28.03 min) and group B (215.43 ± 24.12 min) [Table 4].
The duration of spinal analgesia in group N was 233.04 ± 31.03 min and in group B was 276.96 ± 39.11 min. It was found to be significantly prolonged in group B as compared to group N (p-value 0.001). The requirement of rescue analgesia in 24 hours was statistically significant among both groups and was found to be less in group B (p-value 0.015). [Table 5]. The mean VAS at 1.5 hours post operatively was 3.08 ± 2.10 in group N and 1.39 ± 1.67 in group B which was statistically significant. No other time intervals showed statistically significant VAS post operatively among the two groups [Figure 3].
There was no incidence of pruritus, respiratory depression, bradycardia, hypotension, nausea and vomiting in group N. In group B, 1 out of 23 patients had nausea, vomiting and hypotension. The incidence of side effects among the two groups were comparable. None of the patients in our study had undesirable sedation. The mean sedation score in two groups was 2. The patients were monitored for hemodynamic changes intra-operatively every 5 minutes for first 15 minutes and then every 15 minutes till the end of surgery. The mean intra-operative blood pressure and heart rate at various time intervals were comparable among the two groups. [Figure 4 to 7]

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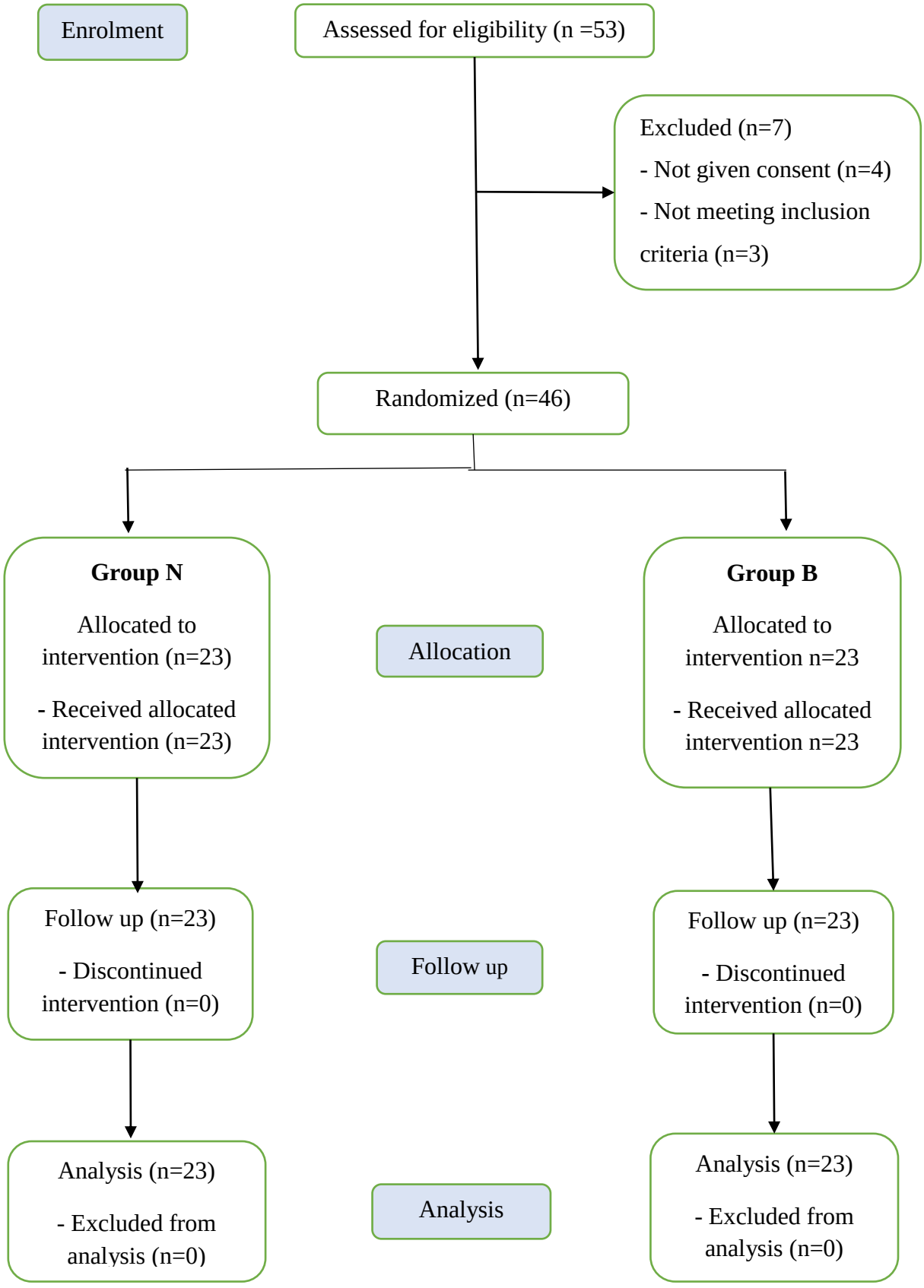

Figure 1. Consolidated Standards of Reporting Trials (CONSORT) Flow diagram

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Table 1: Demographic profile in two groups

Parameter		**Group N (n=23)**	**Group B (n=23)**	**p- value**
Age (years)	Mean ± SD	36.78 ± 12.90	34.96 ± 10.30	0.598
	Range	18-60	18-60	
Weight (kg)	Mean ± SD	63.74 ± 9.19	63.74 ± 9.86	1.000
	Range	55-90	50-95	
Height (cm)	Mean ± SD	165.43 ± 2.83	166.35 ± 3.26	0.315
	Range	160-170	158-172	
Gender ratio	Male	18	20	0.437
	Female	5	3	

p<0.05 significant
p>0.05 Not Significant.

Table 2: Duration of surgery in two groups

Parameter	**Mean ± SD**		**p- value**
	Group N (n=23)	**Group B (n=23)**	
Duration of surgery (min)	134.57 ± 34.61	131.04 ± 29.82	0.713

p<0.05 significant
p>0.05 Not Significant.

Table 3: Comparison of Sensory Block Characteristics in two groups

Parameter	**Mean ± SD**		**p-value**
	Group N (n = 23)	**Group B (n = 23)**	
Time of onset of sensory block (min)	6.09 ± 1.76	7.15 ± 1.69	0.044*
Time to achieve maximum level (min)	10.03 ± 1.17	12.44 ± 2.42	<0.001*
Time to two segment regression (min)	85.65 ±9.33	93.91 ± 17.19	0.049*

*p<0.05 significant

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p>0.05 Not Significant.

Figure 2: Maximum block height achieved

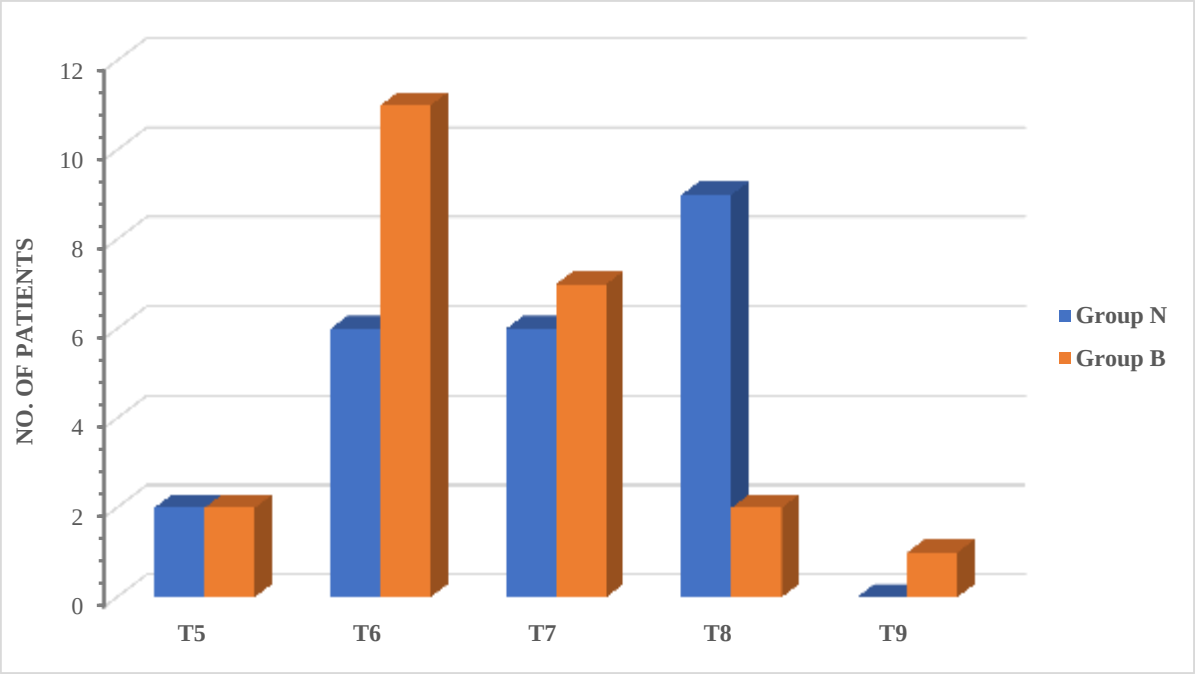

Table 4: Comparison of motor block characteristics

Parameter	Mean ± SD		p-value
	Group N (n = 23)	Group B (n = 23)	
Time of onset of motor block (min)	3.44 ± 0.89	3.99 ± 1.10	0.071
Duration of motor block (min)	207.57 ± 28.03	215.43 ± 24.12	0.313

p<0.05 significant
p>0.05 Not Significant.

Table 5: Duration of spinal analgesia and rescue analgesics required in 24 hours post-operatively

Parameter	Mean ± SD		p-value
	Group N (n = 23)	Group B (n = 23)	
Duration of spinal	233.04 ± 31.03	276.96 ± 39.11	0.001*

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analgesia (min)			
Total post-operative analgesic requirement in 24 hours	4.30 ± 0.70	3.83 ± 0.58	0.015*

*p<0.05 significant
p>0.05 Not Significant

Fig 3: VAS at various time intervals

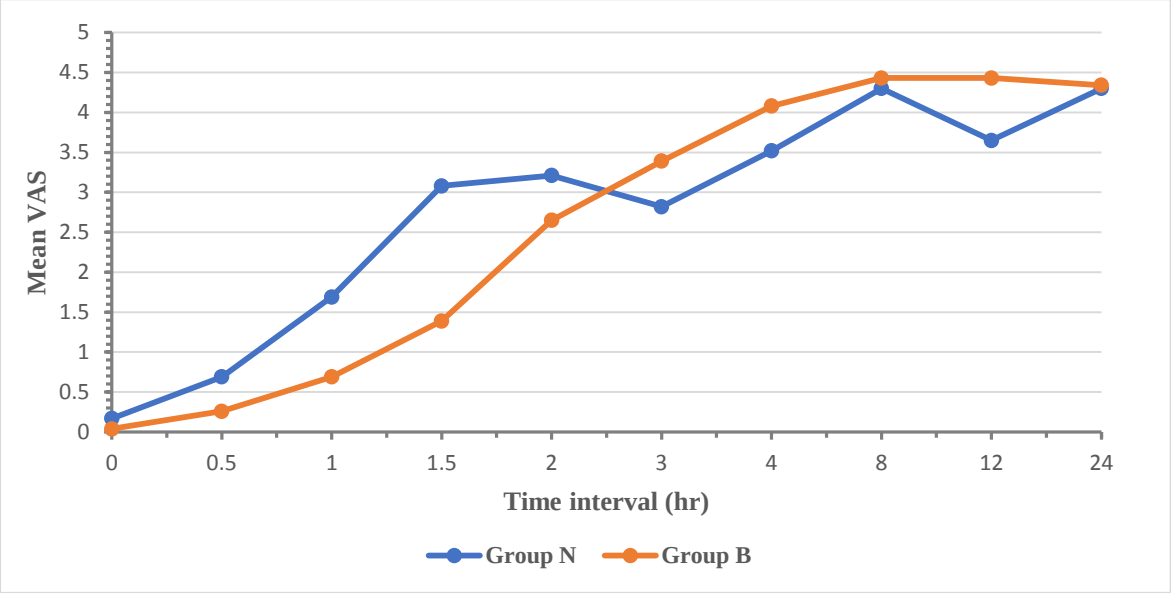

Fig. 4: Trend of intra-operative systolic blood pressure (mmHg)

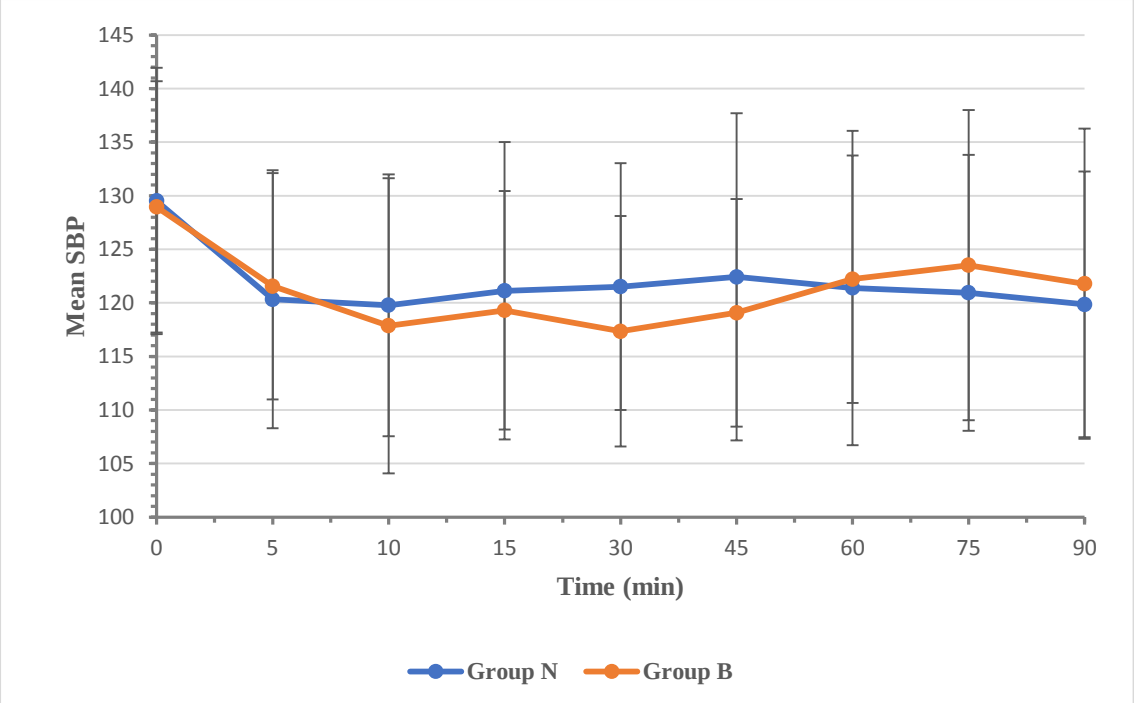

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Fig. 5: Trend of intra-operative diastolic blood pressure (mmHg)

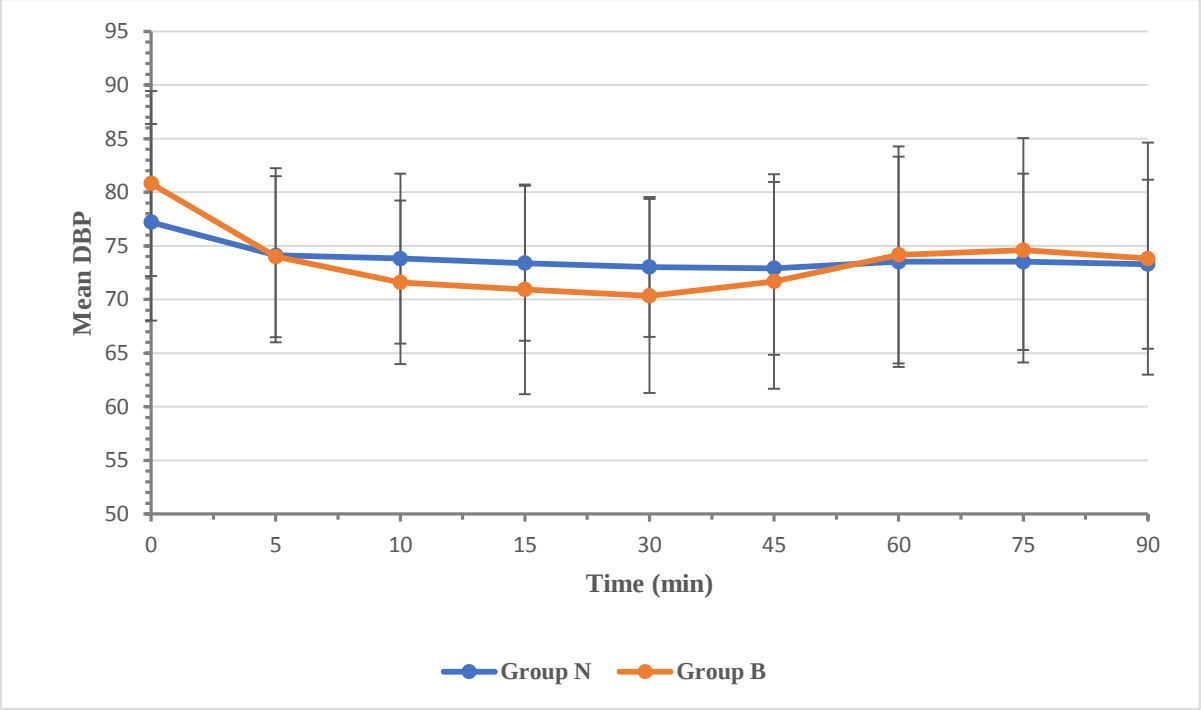

Fig. 6: Trend of intra-operative mean arterial pressure (mmHg)

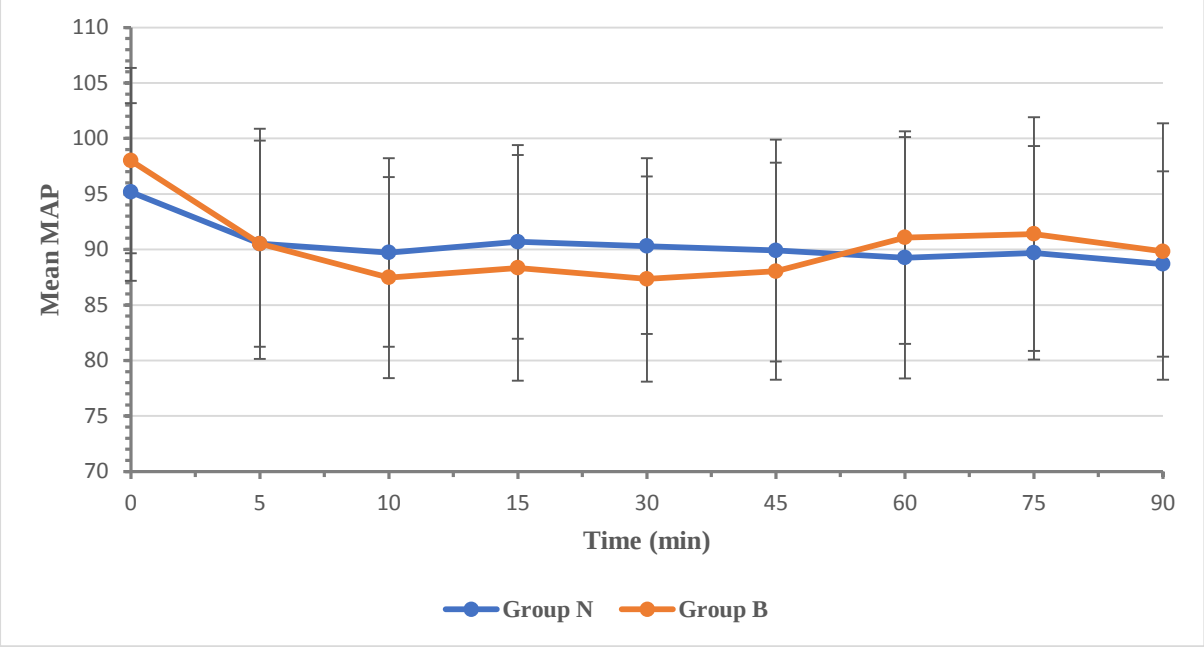

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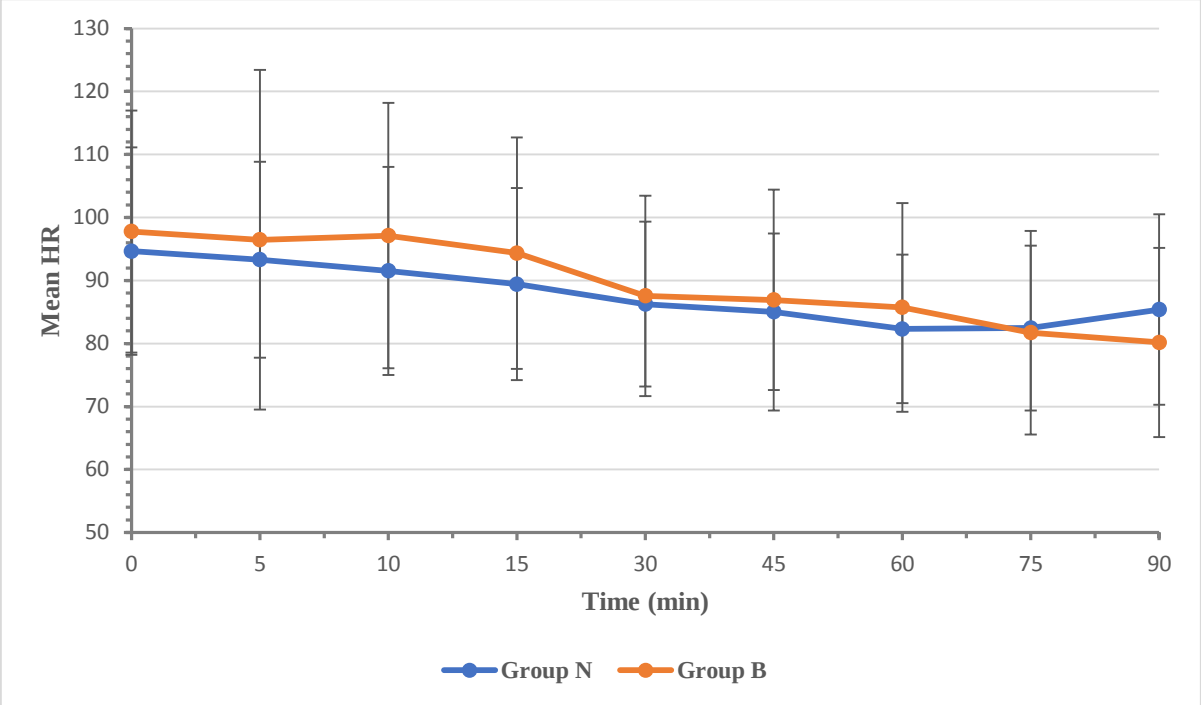
Fig. 7: Trend of intra-operative heart rate (bpm)



4. DISCUSSION

Subarachnoid blockade is the first choice of anaesthesia for the orthopaedic lower limb surgeries. Limited duration of block and post operative analgesia are the major limitations of this technique. To overcome this, various drugs have been used as intrathecal adjuvants which increases the duration of block and provide effective post operative analgesia. Opioids like morphine, fentanyl, sufentanil and tramadol, alpha-2 adrenergic agonists like clonidine and dexmedetomidine, other drugs like dexamethasone and ketamine have also been used successfully as intrathecal adjuvants. The relatively newer opioids like nalbuphine and buprenorphine has been studied as an intrathecal adjuvant and documented to have minimal or no adverse effects.

Present study was conducted to compare the efficacy of intrathecal nalbuphine versus buprenorphine as an adjuvant to 0.5% hyperbaric bupivacaine in orthopaedic lower limb surgery. We compared the efficacy and safety of 1 mg intrathecal nalbuphine with 60 µg buprenorphine as an adjuvant to 15 mg of hyperbaric bupivacaine for orthopaedic lower limb surgeries. The characteristics of subarachnoid block like onset, duration, quality of sensory and motor block and the duration of post-operative analgesia were studied. Patients in both the groups were also observed for any significant side effects.

In the present study, the onset of sensory block was significantly delayed in patients receiving intrathecal buprenorphine as an adjuvant to hyperbaric bupivacaine in patients undergoing orthopaedic lower limb surgeries (7.15 ± 1.69 min) as compared to patients receiving intrathecal nalbuphine (6.09 ± 1.76 min).

Prabhu R. *et al*, reported similar results which showed significant prolongation of onset of sensory block in patients who received 60 µg of intrathecal buprenorphine (2.66 ± 0.46 min) as compared to patients who received 0.8 mg of intrathecal nalbuphine (1.51 ± 0.36 min).[(12)]

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However, many previous authors have reported no significant difference in the onset of sensory block. There was no significant difference in the onset of sensory block in a study by Pratap D. *et al,* done among patients who received 0.8 mg of intrathecal nalbuphine and 60 µg of intrathecal buprenorphine.[6] Kumar K. *et al* found no significant difference in the onset of sensory block on comparing 1 mg nalbuphine and 150 µg buprenorphine as an adjuvant to 3 ml of 0.5% hyperbaric bupivacaine.[13] In a study by Kaushal S. *et al,* no significant difference was found in the onset of sensory block among patients who received 0.8 mg nalbuphine and 60 µg buprenorphine as an intrathecal adjuvant to 3 ml of hyperbaric bupivacaine.[14]

In the present study, duration of sensory block was defined as the time to two segment regression and was found to be significantly prolonged in patients who received intrathecal buprenorphine (93.91 ± 17.19 min) when compared with patients who received intrathecal nalbuphine as adjuvant (85.65 ± 9.33 min).

The results of the present study were in accordance the study by Prabhu R. *et al,* in which the duration of sensory block was found to be significantly prolonged in group of patients who received intrathecal buprenorphine (237.93 ± 16.43 min) as compared to patients who received intrathecal nalbuphine (170.60 ± 24.42 min).[12] Similar results were seen in a study by Kaushal S. *et al,* where patients receiving intrathecal buprenorphine (265.63 ± 26.33 min) showed increased duration of sensory block than with patients who received intrathecal nalbuphine (187.90 ± 16.99 min).[14] In a study by Kumar K. *et al,* and Pratap D. *et al,* no significant difference in the duration of sensory block was observed among the patients receiving intrathecal nalbuphine and buprenorphine.[5,6]

In the present study, the onset of motor block is defined as time taken to reach full motor block (modified bromage grade 3). There was no significant difference in the onset of motor block among the patients who received intrathecal nalbuphine and buprenorphine respectively as an adjuvant to 0.5% hyperbaric bupivacaine. These results were in concurrence with the study conducted by Kumar K. *et al and* Kaushal S. *et al*. No significant difference was found in the onset of motor block among the patients receiving intrathecal nalbuphine and buprenorphine as an adjuvant to 3 ml 0.5% hyperbaric bupivacaine.[5,14]

The results of the present study are in contrast with the results of the study by Prabhu R. *et al,* which found statistically significant difference in the onset of motor block among patients receiving intrathecal nalbuphine and buprenorphine. The onset of motor block was much earlier in patients who received intrathecal buprenorphine (3.686 ± 0.373 min) when compared to patients who received intrathecal nalbuphine (4.639 ± 0.976 min) as an adjuvant to hyperbaric bupivacaine.[12]

Present study showed no significant difference in the duration of motor block among the patients receiving intrathecal nalbuphine and buprenorphine as an adjuvant to hyperbaric bupivacaine. Similar results were shown in the study conducted by Kumar K. *et al* and Kaushal S. *et al*..[5,14]

In contrast to the results of the present study, Prabhu R. *et al,* found significant prolongation in duration of motor block among patients receiving intrathecal buprenorphine (410.93 ± 17.79 min) when compared to patients receiving nalbuphine (257.17 ± 27.74 min) as an adjuvant to 3 ml of hyperbaric bupivacaine.[12]

Present study defined duration of spinal analgesia as the time from subarachnoid block to the time to first rescue analgesic dose given at VAS score $\geq$ 3 for the first time. The duration of spinal analgesia was significantly prolonged among patients receiving buprenorphine (276.96 ± 39.11 min) as compared to nalbuphine (233.04 ± 31.03 min). Results similar to the present study were also reported by Pratap D. *et al*, Prabhu R. *et al*, Kumar K. *et al* and Kaushal S. *et*

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al. There was significant prolongation in the duration of spinal analgesia with intrathecal buprenorphine as compared to nalbuphine.[5,6,12,14]

In terms of mean number of rescue analgesic dose requirement in the 24 hours, in present study it was significantly less with buprenorphine (3.83 ± 0.58) as compared to nalbuphine (4.30 ± 0.70). In a study by Pratap D. *et al*, rescue analgesia was given once VAS > 3. The mean duration of requirement of first rescue analgesia was significantly prolonged with buprenorphine (425 ± 81.53 min) when compared with nalbuphine (354 ± 106.69 min).[9] In another study by Kaushal S. *et al*, nalbuphine group achieved a VAS >3 at an earlier time when compared to buprenorphine suggesting that intrathecal buprenorphine provided longer pain free period as compared to intrathecal nalbuphine.[14]

Hemodynamic profile and vitals were monitored at regular intervals both intra-operatively and post-operatively in the present study. There were no significant changes in the heart rate and blood pressure in either group and similar results were reported in studies done by Kumar K. *et al*, Prabhu R. *et al* and Kaushal S. *et al*.[5,12,14]

Comparison of side effects like pruritis, respiratory depression, bradycardia, hypotension, nausea, vomiting and headache were found to be comparable in both the groups in the present study. Only 1 patient (4.34%) who received buprenorphine had nausea, vomiting and hypotension. The hypotension responded well to intravenous fluids. Nausea and vomiting was managed with anti-emetics. In a study by Prabhu R. *et al*, three patients in group nalbuphine and five patients in group buprenorphine had nausea and vomiting (out of 35 each).[12] The study by Kaushal S. *et al*, reported minimal side effects with both intrathecal nalbuphine and buprenorphine. Patients who received intrathecal nalbuphine has 3.2% incidence of nausea. No other side effects were reported in this group. In buprenorphine group there was 10% incidence of nausea and 3.2% incidence of vomiting. No other clinically significant side effects were observed in either group.[14] Limitations of the present study is that further studies are required to extrapolate the results into larger population and other surgeries. Nalbuphine and buprenorphine are both opioid drugs and further studies are required to compare these with other drugs like non-opioid drug.

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