Journal of Advanced Zoology

ISSN: 0253-7214

Volume ***44*** *Issue* ***S-2 Year 2023*** *Page* ***481:490***

COMPARATIVE ANALYSIS OF NALBUPHINE AND BUPRENORPHINE AS ADJUVANTS TO BUPIVACAINE IN LOWER LIMB ORTHOPAEDIC SURGERIES

Dr.P.B.Patil

Assistant ProfessorDepartment of Anaesthesiology, Krishna Vishwa Vidyapeeth, Karad, Maharashtra, India, Email :drpradeeppatil11@ gmail.com

Dr. Mrs. N.V.

Kanase, ProfessorDepartment of Anaesthesiology, Krishna Vishwa Vidyapeeth, Karad, Maharashtra, India, Email : naseemakanase@ yahoo.co.in

Dr. Mrs. N.V.

Kanase, ProfessorDepartment of Anaesthesiology, Krishna Vishwa Vidyapeeth, Karad, Maharashtra, India, Email : naseemakanase@ yahoo.co.in

Article History

Received: 24 Aug 2023

Revised: 26 Sept 2023

Accepted: 05 Oct 2023

ABSTRACT

Studies have been proving that SB is popular due to its discrete endpoints and an anesthesiologist's ability to provide the block with a single injection. As a result, the goal of our study was to compare and contrast ITN against B for lower limb surgery under SA. The day prior to surgery, a full physical and systemic evaluation was performed on 30 patients. Patients were kept NPO for 6 hours prior to surgery and told about the SAT with lab tests. Patient groups N and B were randomly assigned. Group N received BV-heavy 0.5% in 3 ml + 0.5 ml (0.8 mg), and Group B received 60 ml. After turning the block and patient supine, a sterile gauge and micropore sealed the perforation. NIBP, HR, O2 saturation, sensory, and motor blocks were measured. NIBP, PR, C-ECG, PO, and UO were intraoperative.In our study, we found that the mean arterial pressures at different points in time showed no significant fall in B.P. among both groups. Peri-operative and PO PR variations were noted and found to be within normal parameters, and the DOA difference between the two groups is statistically significant (p value 0.0000).Thus, we conclude that ITN &B can increase DOA and reduce POA requirements.

Keywords: ITN**,** B**,** Peri-operative , PO PR**,** DOA, POA**,** SA**.**

INTRODUCTION

Studies have proven in the past that spinal anesthesia (SA) has the advantages of requiring a small amount of anesthetic medication and being straightforward to administer. It has a quick onset of effect, good surgical analgesia, and good muscular relaxation.[1] According to past studies, SB is popular due to its distinct endpoints and the ability of an anesthesiologist to administer the block with a single injection.[1] Furthermore, studies revealed that , a wide range of LA and additives that have the ability to control the depth, onset time, and duration

of spinal anesthesia enable SA's flexibility. Thus, the amount of NB that SA causes depends on how the LA solutions, which are spread out in the subarachnoid space. Hence, Due to its prolonged duration, reseachers through their studies revealed that, SA with HBV 0.5% is a common technique for longer procedures and DOPOA could be improved by increasing the intensity and DOSB.[2] As a result of this, according to researchers, one strategy that has been proposed to attain these goals is the utilization of opioids in the treatment process. Following a wide variety of surgical procedures, it has been shown to be highly effective in delivering pain relief through the introduction of opioids into the intrathecal space.

Thus, the purpose of this study was to evaluate and objectively quantify the effects of intrathecal nalbuphine (ITN) and V/S buprenorphine (B) as adjuvants to B in the lower limb following orthopaedic surgery.

AIM

To evaluate & compare the efficacy of intrathecal nalbuphine (ITN) V/S buprenorphine (B) as adjuvant to B in lower limb.

INCLUSION CRITERIA

1. Patients with age group between 18 to 60 years .
2. Patient with ASA grade I & II
3. Patients undergoing lower limb orthopaedic surgery.

EXCLUSION CRITERIA

1. Spine deformity or neurological disorder.
2. Local infection at the site of injection.
3. Coagulopathy
4. Allergy to study drug
5. Patient refusal

MATERIALS & METHOD

We have conducted a random, double-blind, hospital-based controlled study after approval from institutional ethics committee KH, Karad in the department of anesthesiology with a total of 30 patients in each group undergoing elective orthopaedic lower limb surgery. Furthermore,if inadequate spinal block is achieved, hemodynamic instability is observed, or marked side effects of the drug are seen, a procedure will be observed, and the case will be converted to general anesthesia following standard procedures and protocols.

Rescue Plan

Inj. Tramadol 50 mg IV bolus dose will be given if VAS score is 3 or more. A repeat inj. Tramadol 25mg IV bolus was given when there was no pain relief, even after 10 minutes.

Materials

1. Pre-sterilized equipment for spinal anaesthesia.
    a. Sponge holding forcep
    b. Guage piece
    c. Whole towel
    d. Qown
    e. Qallipot
2. Providine iodine & chlorhexidine
3. Disposable spinal needle 25Gor 23 G
4. 5ml Disposable syringe

5. IV cannula, IV infusion sets
6. Pair of sterile gloves
7. 18 guage sterile needle for testing pin prick
8. Anaesthesia work station, laryngoscope, cuffed endotracheal tubes (size 7 to 8.5) suction apparatus, section apparatus, suction cathether 14 & 12 FG defirillator
9. Sphygmomanometer
10. ECG electrodes

Drugs used

Study drugs:-

a. Inj.Bupivacaine(BV) 0.5% heavy (5mg/ml)
b. Inj. Nalbuphine 0.8 mg
c. Inj.B 60mcg

Other drugs:-

a. Inj. Midazolam (1mg/ml)
b. Inj. Pentazocine (30mg/ml)
c. Normal saline
d. Ringer lactate
e. Plasmalyte
f. Monitor: ECG monitor, pulse oximetery, non-invasive blood pressure instrument.

Methodology

Preanaesthetic evaluation

On the day prior to surgery, a detailed pre-anesthesia checkup was performed, including a general physical and systemic examination. After which, patients were explained about the SAT and kept NPO for at least 6 hours prior to surgery. All were given 0.25mg of Alprazolam orally the night before surgery and on the day of surgery with a few sips of water 2 hours prior to the scheduled time of surgery. In addition to this, lab investigations include CBC, FS, PPS, urine examination (routine and microscopic), X-ray chest PA view, ECG and LFT, KFT, ECHO, TSH, and coagulation profile (if indicated). Furthermore, patients were randomly allocated into two groups by computer as group N & group B.Where, group N recevied BV heavy 0.5% 3ml+0.5ml(0.8mg) whereas group B recevied BV haevy 0.5% 3ml + 0.5ml (60mg) B. In total, both groups received 3.5 mL of medicine after achieving free flow of CSF. The medications were prepared by the assistant so that the operator administering the block and doing the evaluation was blinded. Furthermore, the punctured site was sealed with a sterile gauge piece and micropore after the block and patient were turned into supine positions. Additionally,non–invasive blood pressure(NIBP), HR, O2 saturation, and level of sensory and motor block were checked. Intraoperative monitering(IOM) included NIBP,PR, C-ECG, PO,UO.

Grading of the block

Sensory block (SBG): The duration of it was defined by the time taken for it to regree up to the S1 dermatome (heel).

Motor block(MBG): It was assessed by modified broamage scale. Where,

0= Able to rise the whole lower limb at hip

1=Able to flex knee but unable to raise leg at hip

2=Able to plantar flex the ankle but unable to flex knee

3= No movement of lower limb

Post-operative assessment (POA)

It includes HR,NIBP,SBG,VAS, and MBG every 15 minutes for the first 2 hours, then hourly for 12 hours. Rescue analgesic (Inj.Tramadol 100mg IV) was administered at VAS score >3 and normal time, time of return of motor power, and time from IT INJ. The first request for analgesics was noted. Further total analgesic doses in the first 12 hours, along with incidences of symptoms such as nausea, vomiting, shivering, respiratory depression, and high BP, were recorded.

Visual Analogue Score (VAS): A scale used for grading the severity of pain from 0 to 10. Where 0 resembles no pain at all, whereas 10 resembles the worst imaginable pain ever.

Score	Criteria
0	No pain
1, 2, 3	Mild pain
4, 5, 6	Moderate pain
7, 8, 9	Severe pain
10	Worst imaginable pain

Table 1: VAS

RESULT

	GROUP B	GROUP N
18-29	9	6
30-39	6	4
40-49	4	6
50-59	11	14
TOTAL	30	30

Table 2: Age –wise distribution

In our study we found that, 36.6% of patients in group B and 46.6% of patients in group N belong to the age group between 50 and 59 years, and the mean age in group B was 39.8 ± 13.15 and the mean age in group N was 44 ± 13.59, which were comparable among the two groups. (p=0.169).

	GROUP B	GROUP N
MALE	22	22
FEMALE	8	8

Table 3: Gender-wise distribution

In our study, we found that male patients were more common in both groups, up to 22 in number, whereas females were 8 and 8 respectively.

	GROUP N	GROUP B
49-59	10	8
60-69	13	12
70-79	5	6
80-89	1	3
90-99	1	1

Table 4: Weight distribution

In our study, we found that patients maximum weight was seen in groups 60–69 in both groups respectively. Hence, the mean qweight in group B was 66.3±10.37 and in group N was 63.83±9.09, respectively (p = 0.33).

	GROUP N	GROUP B
140-149	0	3
150-159	9	8
160-169	13	13
170-179	6	2
180-189	2	4

Table 5: Height distribution

In our study, we found that the maximum number in height was seen in 160–169 in both groups, respectively. Hence, the mean height in group B was 162.76±10.10 and in group N was 164.06±8.56, respectively (p = 0.599).

MEAN DURATION(MIN)	GROUP B	GROUP N
60-90	7	2
91-120	10	11
121-150	6	7
151-180	3	5
181-210	2	5
211-240	2	0

Table 6: Duration of surgery (DOS)

In our study, we found that the mean DOS in group B was 130.9±41.87 min and in group N was 140.83±38.82 min, with the maximum D in group B being 230 min and in group N being 210 min. The DOS in both groups was found to be comparable (p > 0.05).

Group –B	Group -N	P Value
Mean ± SD	Mean ± SD	
2.741±0.817	2.80±0.80	0.774

Table 7: SB (min)

In our study, we found that the difference between both groups was not statistically significant.

Group –I	Group -II	P Value
Mean ± SD	Mean ± SD	
2.84±0.84	2.92±0.78	0.698

Table 8: MB

DURATION OF SENSORY BLOCK	GROUP B	GROUP N	P- value
MEAN	265.83 Min.	187.9 min.	0.00000
STD. DEV.	26.6	16.71	

Table 9: DSB

In our study, we found that the mean duration of sensory block in group B was 265.83 min±26.6 min and in group N was 187.9 min±16.71 min. The mean difference was 77.93 minutes(95% CI 66.4–89.5) between the two groups. The difference between the 2 groups is statistically significant (p value = 0.0000), with patients in group B achieving a much greater duration of sensory block compared to group N.

DURATION OF SENSORY BLOCK	GROUP B	GROUP N	P- value
MEAN	183.96 min	181.36 min.	0.55
STD. DEV.	22.56 min	8.41 min	

Table 10: DMB

In our study, we found that the mean duration of motor block for group B was calculated as 183.96±22.56 min, and group N was calculated as 181.36 ± 8.41 min. The difference between the two groups is statistically not significant (p value = 0.55).

TOTAL DURATIONOF ANALGESIA	GROUP B	GROUP N	P- value
MEAN	471.2Min.	371.56 min.	0.00000
STD. DEV.	76.29 min	33.14 min	

Table 11: D O Analgesia (A)

In our study, we found that the mean total DOA found in group B was 471.20±76.29 minutes, and in group N, it was found to be 371.56±33.14 minutes. The mean difference was calculated as 99.63333333 with a standard error of 30.67 min. (130.31–68.95 min) using a CI of 95%. The difference between the two groups is statistically significant (p value 0.0000), with patients in group B achieving a much greater DOA.

	GroupB	GroupN
HR 0	78.3	75.66
HR 2	75.03	74.3
HR 5	72.33	70.36
HR 10	70.13	68.96
HR 15	70.23	69.9
HR 30	69.76	69.8
HR 45	69.93	70.06
HR 60	70.13	70.6
HR 75	72.36	70.73
HR 90	72.3	70.93
HR 105	74.23	71.83
HR 120	75.16	72.1
HR 3	77.03	72.9
HR 4	78.46	73.23
HR 5	79.16	73.93
HR 6	79.53	74.66
HR 7	79.76	74.16
HR 8	79.63	74.26
HR 9	79.43	74.66
HR 10	80.93	75.13
HR 11	81.6	74.46
HR 12	80.03	75

Table 12: Pulse rate mointoring (PRM)

In our study, we found that peri-operativ and PO PR variations were noted and found to be within normal parameters. Thus, there is no significant fall or rise in PR.

	Group B	**Group N**
MAP 0(min)	96.52	92.78
MAP 2	92.6	91.75
MAP 5	88.73	85.1
MAP 10	83.37	84.02

MAP 15	84.23	84.77
MAP 30	85.6	85.17
MAP 45	86.72	85.66
MAP 60	88.44	87.35
MAP 75	89.11	87.77
MAP 90	90.95	89.18
MAP 105	91.95	91
MAP 120	93.62	92.1
MAP 3(hours)	93.72	91.23
MAP 4	95.6	92.78
MAP 5	96.91	93.18
MAP 6	97.84	92.78
MAP 7	99.95	93.48
MAP 8	98.91	94.21
MAP 9	99.04	91.44
MAP 10	99.42	93.16
MAP 11	98.22	93.61
MAP 12	96.65	93.26

Table 13: BP Mointoring (BPM)

In our study, we found the mean of mean arterial pressures at different points in time. There is no significant fall in B.P. among both groups.

DISCUSSION

Change in peri-op CV parameter

In the current study, there was no statistically significant decrease observed in BP and HR in either group throughout the entire IO and PO periods. A In a study conducted in 2000, the effects of varying doses of intrathecal nalbuphine with bupivacaine (10 mg) were assessed. The findings of the study indicated that there were no notable alterations in the hemodynamic status.[3]A subsequent study conducted in 1992 examined the impact of intrathecal nalbuphine or morphine with tetracaine on hemodynamic status. The results of this study indicated that there were no significant changes observed.[4]

Change in onset of S B & MB

There was no statistically significant difference between the two groups in this study regarding the time it took for SB to set in (2.741±0.817 min for group B versus 2.80±0.80 min for group N, p = 0.774). The 2.84±0.84 and 2.92±0.78 min difference between group-B

and group-N for the start of MB was not statistically significant (p = 0.69). Furthermore, the average time to SB for group N in a study was 1.68±0.21, while for group B it was 1.72±0.24. Thus, no significance was found (p = 0.4948). Additionally, Group N experienced MB 5.76±0.60 hours later than Group B (6.00±0.57) (p = 0.1176).[5] Another similar study found that the onset of SB took 2.74±0.659 min in group N and 2.69±0.672 0.74 min in group B, with a statistically significant association.[6]

VAS

The current study revealed a decrease in VAS in patients in group B compared to that in group N. The VAS was measured hourly during the PO period, up to 12 hours following the spinal injection.

DOA

The effective AD was found to be 471.40±76.29 min, which was significantly longer compared to the D of 371.56±33.14 min observed in group N (p< 0.001). This indicates a notable increase in DOA effects when using ITB. The DOA was significantly extended when LA was used in combination with other methods. A separate study demonstrated that the administration of 1.8 ml of BV combined with 60 mcg of B resulted in DOPO pain relief lasting 12.3 hours.[7] In another study, the average duration of effective postoperative analgesia was found to be 16.2 ± 6.66 hours in the B group, as compared to the control group.[8]

DOSB

The average DOSB in group B was 265.83 ±26.6 min, while in group N it was 187.9 ±16.71 minutes. The mean difference was 77.93 min. Thus, it was clinically significant, as the p-value was less than 0.00000. In another study, the DOSB in the B group was found to be 267±30.18 min when administered with a dosage of 60µg of B.[9]

DOMB

The average DOMB for group B was 183.96±22.56 min, while for group N it was 181.36±8.41 min. In another study, researchers evaluated different dosages of N with 2.5 mg of IT administered BV. Thus, they found that the N 0.2 mg produced the longest MB (138.8 min), while the N 0.8 mg produced the shortest B (139.45 min).[10]

CONCLUSION

IT administration of 3.0 ml of hyberbaric bupivacaine (HBV) 0.5% with B 60 mcg, when compared to HBV 0.5% with N at 0.8 mcg, produced greater DOSB, MB, and EA. Further, the incidence of side effects was minimal for both groups.Thus, we come to conclude that , it would increase DOA & reduce POA requirement.

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