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Anesthetic efficacy of intrathecal hyperbaric Bupivacaine with or without low dose Nalbuphine hydrochloride for abdominal hysterectomy - A randomized control study.

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Abstract

Background: Nalbuphine is a synthetic mixed ƙ agonist µ antagonist opioid, which produces analgesia without producing side effects, when intrathecally used with bupivacaine. We have designed our study to evaluate nalbuphine as adjuvant along with its pharmacodynamics, effective analgesia and side effects.

Methodology: A single blinded randomized control trial study was conducted on 30 American Society of Anesthesiologists I and II patients undergoing elective abdominal hysterectomy. These patients were randomly allocated to 2 groups. Group BD received Bupivacaine heavy 0.5 % 3cc (15mg) + 0.5 cc distilled water, Group BN received Bupivacaine heavy 0.5 % 3cc (15mg) + 0.5 cc (0.5mg) Nalbuphine. The onset and duration of the sensory and motor block, duration of effective analgesia, hemodynamic variables, and adverse effects intra/post T operatively were compared between these two groups.

Results: The mean onset of sensory block (T6) in Nalbuphine group was 115.133± 20.81 seconds where as in control group was179.533±32.67 seconds The mean onset of motor block in both the groups were 191.4 ± 28.08 & 283.87 ± 55.53seconds respectively. The statistical analysis has shown significant faster onset of sensory and motor block. The mean time of regression of sensory block up to T10 in Nalbuphine group was 202.73 ±1 8.25 minutes and in control group was 128.67 ± 23.21 minutes. Mean duration of motor blockage group was 230 ±35.97 minutes in nalbuphine group and

141.8 ±31.81minutes in control group and all these are statistically significant.

Conclusion: Intrathecal Nalbuphine as an adjuvant with bupivacaine prolongs the duration of the sensory and motor blockade and postoperative analgesia without increased side effects.

Keywords: Nalbuphine, Sensory block, Motor block, Analgesia, Bupivacaine Heavy

Introduction

Neuraxial block for lower abdominal surgeries have become popular as it has many advantages over general anaesthesia. Use of opioids as adjuvants increase the efficacy or potency of local anaesthetics. They increase the speed of the onset of neural blockade, improve the quality and prolong the duration of blockade.

Various Opioids (morphine, fentanyl, nalbuphine, buprenorphine) and alpha 2 agonist (clonidine, dexmedetomidine) are used as an adjuvant to spinal anaesthesia for lower abdominal surgeries to prolong post-operative analgesia.1,2

Nalbuphine is an adjuvant drug with mixed synthetic kappa agonist and a mu antagonist property. It is equal in potency as analgesic to morphine, and one fourth as potent as nalorphine as an antagonist. They have a short duration of action, property having consistent lipid solubility and rapid clearance. Due to mixed agonist antagonist action, it has very less opioid related side effects and when added with bupivacaine for intrathecal use it improved the quality of intra and post operative analgesia with minimum pruritis and respiratory depression[3.]

There is no documented report of neurotoxicity with nalbuphine. Morphine, fentanyl, and other μ-opioids come under Narcotic Act; thus their availability is a major apprehension while nalbuphine is easily available and with less side effects[4.]

So, we have designed our study to evaluate the effect of intrathecal nalbuphine added as an adjuvant to hyper baric bupivacaine and compare it with effect of plain hyperbaric bupivacaine for quality of block and post operative analgesia.

Review of literature

In a prospective randomized study in 2014 conducted by Shehla Shakooh et al in 60 patients using nalbuphine 0.8 mg as an adjuvant to intrathecal bupivacaine (0.5%) heavy for various lower abdominal and lower limb surgeries showed that the onset of sensory and motor block was faster and time taken to attain complete sensory and motor block to occur was shorter in the nalbuphine group as compared to only bupivacaine group.5

In another prospective, randomized, controlled study by Saad I et al compared the use of intrathecal hyperbaric bupivacaine 0.5% (B) without additives (control group) with the use of nalbuphine 0.5 mg(N), fentanyl 25 μg(F), and pethidine 10 mg(P) as different adjuvants to intra thecal heavy bupivacaine 0.5% for lower-limb surgeries in 100 patients showed onset of sensory block was significantly short in opioid additive groups F, N, and P compared with bupivacaine alone in group B, whereas the time for peak sensory block was not significantly different among the four groups.6 In (2011) Arghya Mukherjee et al observed that effective analgesia increased with increase in concentration of Nalbuphine and the ultimate observation of prolongation of analgesia was with 0.4mg of nalbuphine with 0.5% hyperbaric bupivacaine without any side effects[7.]

Similar study done by S Kumares an et al Raj in 2017 but with 0.4(A), 0.6(B), 0.8(C)mg nalbuphine made up

to 0.5 ml distilled water and last group 0.5 ml(D) distilled water added with 2.5 ml bupivacaine heavy which showed No difference in the onset of sensory and motor blockade among the four groups. Duration of two-segment regression time of sensory block, duration of motor blockade, and duration of analgesia time were prolonged in Groups B (0.6 mg) and C (0.8 mg) and found to be significant. The incidence of adverse effects was frequently higher in Group C compared to other groups[8.]

In 2017 Kanhya Lal Gupta et al did a study and found that the onset and duration of sensory blockade & motor blocked and duration of analgesia is higher in nalbuphine group. Two segment regression times for sensory blockage was prolonged in nalbuphine group[9] In contrast to these studies, Tiwari AK, Tomar GS, Agrawal J in their study in (2013) have shown that onset of sensory and motor blockade was not affected by adding nalbuphine intrathecally. Seventy-five patients posted for lower limb and lower abdominal surgeries received either 0.2mg or 0.4 mg nalbuphine or plain bupivacaine intrathecally. This disparity in the onset of blockade could be related to lower dose of nalbuphine used in this study[10]

Methodology

This is a single blinded randomized control study done at Gynae OT of AGMC & GBP Hospital, Agartala, Tripura. After approval from institutional ethical committee total 30 patients of ASA I & II, who had undergone abdominal hysterectomy were selected for the study after obtaining written informed consent. The patients who didn't give consent or who had bleeding disorder, psychological, neurological & musculoskeletal disorder were excluded from the study.

Patients were divided in two groups of 15 each equally by block randomization. Group BN patients received Nalbuphine as adjuvants whereas group BD was control group.

For Subarachnoid block patients of first group (BD) received Bupivacaine heavy (0.5%) 15mg mixed with 0.5ml distil water to make it 3.5ml and in patients in second group (BN) received Bupivacaine heavy (0.5%) 15mg with Nalbuphine 0.5mg. Sub- Arachnoid block was given in sitting position through L3-L4 interspaces. The onset, duration, quality of analgesia was calculated and hemodynamic changes and adverse effects was monitored.

Analgesic effect was calculated by visual analogue scale and the statistical analysis was done. The study also compared duration and regression of sensory and motor Block in the post-operative period till the time the regression of the block was complete up to desired level.

The comparison of normally distributed variables between these groups has been performed by t test. Nominal categorical data between the study groups was compared using chi square or fisher's exact test as appropriate. Statistical analysis has been done using SPSS software version 27.0.

Result & discussion

In this prospective randomized study, when used as adjuvant, intrathecal nalbuphine (0.5mg) caused early onset of sensory and motor blockage as well as extended post operative analgesia & early ambulation. Due to agonist antagonist action, it does not have any mu side effect.

The demographic profile like age, height, weight etc. and ASA status of the patients of both study groups where comparable p value was found to be not significant.

Table 1: Comparison of mean age and weight (N=30)

Variable	Group BD	Group BN	t value	P value	Remarks
Mean age	43.10 ± 5.5	43.50 ± 6.05	0.2	0.79	Not Significant
Mean weight	57.8 ± 5.08	56.26 ± 6.21	1.0	0.33	Not Significant

Table 2: Height comparison among the study group (N=30)

Variable	Group BD	Group BN	t value	P value	Remark
Mean height (cm)	157 ± 13	158 ± 60	6.4	0.51	Not Significant

Table 3: ASA grade comparison (N=30).

ASA	Study group		P Value
	Group BD	Group BN	
ASA 1	10	15	0.89
	40.0%	60.0%	
ASA 2	3	2	
	60.0%	40.0%	

The mean onset of sensory block (t6) in nalbuphine group was 115.133± 20.81 seconds where as in control group was179.533±32.67 seconds the mean onset of motor block in both the groups were 191.4±28.08 & 283.87±55.53seconds respectively. The statistical analysis has shown significant faster onset of sensory and motor block with p value 0.01 & 0.001 respectively in nalbuphine group.

Table 4: Time of onset of Sensory block / motor block (seconds) comparison (N=30)

Time of onset	Study group	N	Mean	Std. Deviation	P value	Remarks
Sensory block (seconds)	Group BN	15	115.133	20.8151	0.01	Significant value
	Group BD	15	179.533	32.6712		
Motor block (seconds)	Group BN	15	191.400	28.0785	0.001	
	Group BD	15	283.867	55.5272		

The mean time of regression of sensory block up to T10 in Nalbuphine group was 202.73±18.25 minutes and in control group was 128.67±23.21 minutes. Mean duration of motor blockage group was 230 ±35.97 minutes in nalbuphine group and 141.8 ± 31.81 minutes in control group and all these are statistically significant.

Table 5: Sensory block / motor block duration (mins) comparison (N=30)

Block duration	Study group	N	Mean	Std. Deviation	P value	Remarks
Sensory	Group BN	15	202.733	18.2525	0.020	Significant value
	Group BD	15	128.667	23.2007		
Motor	Group BN	15	230.467	35.9653	0.000	
	Group BD	15	141.800	31.8034		

Sheriff Abdulla et al in their double blinded randomized control trial demonstrated similar faster onset in sensory and motor block on addition of 0.8mg nalbuphine to 0.5% hyperbaric bupivacaine. They also shown the prolong duration prolong duration of analgesia using nalbuphine.

In our study mean duration of analgesia in nalbuphine group was 270.87±35.30 minutes and in control group was 160.2±28.31minutes.

Table 6:

Study group	N	Mean	Std. Deviation	P value	Remarks
Group BN	15	270.867	35.2981	0.001	Highly Significant
Group BD	15	160.200	28.3126		

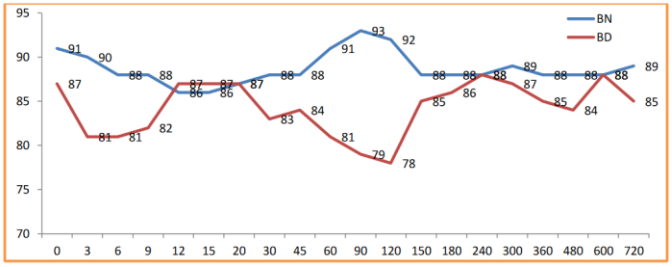
Athuwalia et al in 2015 demonstrated similar results in view of faster onset of sensory & motor block as well as prolong sensory & motor block duration[12] Shakooh et at in their study had demonstrated similar faster onset of sensory and motor block (1.43 ± 0.57 minutes and 3.47±1.01 minutes respectively)[5] Similar study done by Panigrahi et al in 2018 regarding intrathecal nalbuphine in different doses as adjuvant to SAB and found that nalbuphine when added to 0.5% hyperbaric bupivacaine for intrathecal administration prolong the duration of sensory blockage , provide excellent quality of analgesia and longer duration of post operative analgesia with minimal side effects[13]

The patients of nalbuphine group have very few side effects compared to control group. They maintained a steady hemodynamic status throughout the procedure.

Table 7: Comparison of side effects in the study group

Side effects	Study group N (%)		Total
	Group BD	Group BN	
Yes	3	1	3 patients out of 30 (In one patients both nausea hypotension occurred)
Nausea	1	1	
Vomiting	0	0	
Shivering	0	0	
Hypotension	2	0	
Bradycardia	0	0	
Respiratory depression	0	0	

Fig 1: Comparison of mean arterial pressure (MAP)



Summary

Combination of local anesthetic and opioid enables use of lower dose of spinal anesthetic and increases efficacy of anesthesia.

The study was intended to ascertain the effects of nalbuphine hydrochloride (opioid), given as adjuvant to low dose hyperbaric bupivacaine intrathecally in elective abdominal hysterectomy cases on the onset & duration of sensory and motor block, total duration of analgesia with observation of hemodynamic parameters and side effects.

The results obtained were as below

- Both the groups were comparable with regards to age, weight, height, religion, ASA grading.
- The mean onset of sensory and motor block was faster in nalbuphine group.
- The mean duration sensory and motor block in the nalbuphine group significantly more than control group.
- The mean duration of analgesia prolonged in the nalbuphine group was found to be 270.87±35.30 hrs and in the control group it was found to be 160.2±28.31hrs (Statistically significant).
- Fewer side effects noted in study group.

Limitations

Smaller sample size,

We have studied only with one feasible dose of intrathecal nalbuphine, different doses of intrathecal agents were not evaluated Some other parameters like maximum block height, two segment regression time etc have not covered in our study.

COVID -19 pandemic and imposed restrictions.

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