

Comparative Analysis of Efficacy & Post-Operative Analgesia with Hyperbaric Bupivacaine and Nalbuphine Combination Versus Hyperbaric Bupivacaine and Fentanyl Combination in Infraumbilical Surgeries

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Abstract

Spinal anaesthesia is one of the most commonly used technique for lower abdominal and lower limbs surgeries. However its short duration of action and early arising post-operative pain moves the focus towards the use of adjuvant to it. So numbers of adjuvant from different groups were used and evaluated. Out of which opioids are the most commonly used family as an intrathecal adjuvant to local anaesthetics. Our aim of the study to evaluate the analgesic efficacy of hyperbaric Bupivacaine & Nalbuphine versus hyperbaric Bupivacaine & Fentanyl in infraumbilical surgeries. The study was conducted during period of 2020 to 2022 at tertiary care center. Total 100 patients were participated in study each group includes 50. Demographic data, onset of sensory & motor block, duration of sensory and motor block, two segment regression time and first rescue analgesia time were noted. The onset of sensory and motor block was earlier in Bupivacaine plus Nalbuphine (BN) combination as compared to Fentanyl plus Bupivacaine (BF) combination. Two segment regression time was longer with BN group. Nalbuphine also shows good hemodynamic stability. Rescue analgesia time with Nalbuphine was much longer than Fentanyl. The adverse effect was also much less with Nalbuphine. Nalbuphine could be a better and settle alternative to the Fentanyl and other opioids as adjuvant to intrathecal local anaesthetics.

Keywords: Bupivacaine; Nalbuphine; Fentanyl; Infraumbilical surgeries; Rescue analgesia.

INTRODUCTION

Spinal anaesthesia is one of the most commonly used anaesthesia techniques for lower abdominal

and lower limb surgeries due to its well-known advantages.¹

Intrathecal administration of adjuvant drugs to local anesthetics improves quality and duration of the spinal blockade, and prolongs post-operative analgesia. More over, the dose and amount of local anesthetic drugs are also reduced during the subarachnoid block.^{2,3}

Intrathecal opioid administration has been demonstrated to provide effective post operative analgesia & they have synergistic effect in augmenting the block without prolonging the motor recovery.⁴

The common problems encountered with the

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use of intraspinal opioids are their side effects that include nausea/ emesis, pruritis, constipation, undesirable sedation, respiratory depression and the development of tolerance/ dependence.

However, Nalbuphine (a mixed opioid agonist-antagonist) can prove to be particularly advantageous because of the potential to maintain or even enhance opioid based analgesia while simultaneously eliminating the common μ -opioid side effects.^{3,4} Kappa receptors are distributed throughout the brain and spinal cord involved in nociception. Nalbuphine binds avidly to kappa receptors in these areas to produce analgesia.⁹

Intrathecal Nalbuphine added to Bupivacaine (0.5% Hyperbaric) has the potential to provide good intraoperative analgesia & prolongs early post operative analgesia with decreased incidence & severity of mu-agonist side effects such as pruritis, nausea, vomiting & respiratory depression.¹⁰

Thus, the study was undertaken in an attempt to compare and evaluate efficacy & post-operative analgesia with the minimum adverse effect between combination of nalbuphine plus hyperbaric bupivacaine with combination of fentanyl plus hyperbaric bupivacaine.

Aim and Objective

Comparative Analysis of Efficacy & Post-operative Analgesia with Hyperbaric Bupivacaine and Nalbuphine Combination versus Hyperbaric Bupivacaine and Fentanyl Combination in Infraumbilical Surgeries.

Objectives

The aim and objective of this study to compare:

1. Efficacy.

2. Quality, duration of anesthesia.
3. Effect on the onset of sensory and motor blockade and post-operative analgesia.
4. Adverse drugs reactions.

MATERIALS AND METHOD

Group BN: Patients receiving injection nalbuphine 1mg with injection hyperbaric bupivacaine 17.5mg.

Group BF: patients receiving injection fentanyl 25 micg with injection hyperbaric bupivacaine 17.5mg.

All patients had under gone pre anesthetic checkup, thorough examination for any systemic illness and laboratory investigation as per existing protocol one day prior to surgery. All patients were educated about the procedure of spinal anesthesia and visual analogue scale for pain. Inclusion criteria Patients undergoing elective in fraumbilical surgeries, ASA Grade I & II, Patients willing for study, age group 18 to 60 years. Exclusion criteria Patients age below 18 or above 60 years. 2. Contraindications of spinal anesthesia, Morbid obesity, ASA grade III & above and Emergency surgeries.

Procedure

Standard procedure was followed and spinal anesthesia was given in n the L3-L4 intervertebral space using 23G Quincke's needle.

RESULTS

There was no significant difference in age distribution in all two groups. ($p > 0.05$).

Table 1: Showing demographic profile among various groups

Characteristics		Group BN (n=50) (%)	Group BF (n=50) (%)	P Value
Mean age (years)		35.84 ± 12.24	36.02 ± 12.44	>0.05
Sex	Male	33 (66)	34 (68)	>0.05
	Female	17 (34)	16 (32)	
ASA	I	28 (56)	25 (50)	>0.05
	II	22 (44)	25 (50)	
Anthropometry	Weight	62.52 ± 7.13	64.36 ± 6.54	>0.05
	Height	168.32 ± 11.12	166.38 ± 10.36	>0.05
	BMI	21.73 ± 5.18	22.84 ± 5.43	>0.05

($P > 0.05$ Statistically Not Significant)

There was no gender difference when two groups were compared statistically. ($p > 0.05$)

There was no significant statistical difference

in ASA grade distribution amongst two groups. i.e. matching in ASA grading was done during selection of subjects.

There was no significant statistical difference in type of surgery distribution amongst two groups.

This difference in duration of surgery in patients in two groups was statistically not significant. (P

>0.05). There is no statistically significant difference amongst the baseline characteristics of mean heart rate, systolic and diastolic blood pressure, O₂ Saturation, respiratory rate in two study groups. The First Rescue analgesia (min) was found to be

Table 2: Showing time of onset of sensory and motor block

Parameters	Group BN	Group BF	P value
Onset of Sensory block (min)	3.12 ±1.53	3.18 ±1.63	>0.05
Onset of Motor block (sec)	2.38 ±1.03	2.73 ±1.63	>0.05

(P>0.05 Statistically Not Significant)

Table 3: Showing quality of sensory and motor block

Parameters	Group BN	Group BF	P value
Sensory block (Hollmen scale)	3.81 ±0.85	2.93 ±0.92	>0.05
Motor block (Bromage scale)	2.89 ±0.81	1.98 ±0.78	>0.05

(P>0.05 Statistically Not Significant)

Table 4: Showing duration of sensory and motor block

Parameters	Group BN	Group BF	P value
Maximum Sensory block (min)	8.31 ±2.19	7.23 ±2.18	>0.05
Maximum Motor block (min)	5.35 ±1.34	5.85 ±1.63	>0.05

(P<0.05 Statistically Significant)

Table 5: Showing duration of sensory and motor block

Parameters	Group BN	Group BF	P value
2 segment regression (min)	219.31 ±32.19	122.23 ±21.18	<0.05
Motor block (min)	242.35 ±51.34	149.12 ±19.63	<0.05

(P<0.05 Statistically Significant)

Table 6: Showing total duration of analgesia

Parameters	Group BN	Group BF	P value
First Rescue analgesia (min)	189.12 ±49.18	161.33 ±23.21	<0.05
Median Ramsay Sedation score	3	2	<0.05

(P<0.05 Statistically Significant)

189.12 \pm 49.18 minutes in group BN while 161.33 \pm 23.21 minutes in group BF. The difference in First Rescue analgesia (min) was statistically significant. (P <0.05)

The Median Ramsay Sedation score was found to be 3 in group BN while 2 in group BF. The difference in Median Ramsay Sedation score was statistically significant. (P <0.05)

The mean VAS score of patients from Group BN was less compared to Group BF at different time intervals with statistical significance. (P<0.05)

The overall incidence of intraoperative complications was 13%. Group BN had the least complications (6%). Bradycardia was the major intra-operative complication in group BF (8%). In BF group respiratory depression (any other complication) was observed in one patient.

Bradycardia was the major intra-operative complication in group BF. (4%) Pruritis was observed in one patient in Group BN.

DISCUSSION

The present prospective study was conducted to evaluate the analgesic efficacy of Hyperbaric Bupivacaine and Nalbuphine Combination Versus Hyperbaric Bupivacaine and Fentanyl Combination in Infraumbilical Surgeries.

The study was conducted during the period of November 2020 to October 2022 at Department of Anesthesiology, in tertiary care hospital.

All the patients presenting to the Department of Anesthesiology undergoing Infraumbilical Surgeries were included as study population.

A total sample size of 100 patients was included in the study. The computer assisted randomisation of patients were done and divided into 2 groups of 50 subjects each. Group BN (bupivacaine+nalbuphine); 50 patients and Group BF (bupivacaine hydrochloride + fentanyl); 50 patients.

All the subjects included in the study volunteered after proper consent. The study was conducted after obtaining clearance from the ethical committee of the institute.

The data collection was done by using predesigned pretested questionnaire. The questionnaire consisted socio-demographic details and complete medical and surgical history along with outcome measures of drugs.

Surgical Characteristics

Out of total 100 patients, appendicectomy

procedures were done in majority in Group BN (32%) and Group BF (36%). There was no significant statistical difference in type of surgery distribution amongst two groups. The mean duration of surgery in patients in Group BN was 120.72 \pm 34.73 minutes and in Group BF was 124.17 \pm 42.83 minutes. This difference in duration of surgery in patients in two groups was statistically not significant. (P > 0.05)

Sensory and Motor Block

The mean time for onset of sensory block was found to be 3.12 \pm 1.53 minutes in group BN while 3.18 \pm 1.63 minutes in group BF. The difference in mean time for onset of sensory block was statistically not significant. (P >0.05)

The mean time for onset of motor block was found to be in 2.38 \pm 1.03 seconds group BN while 2.73 \pm 1.63 seconds in group BF. The difference in mean time for onset of motor block was statistically not significant. (P >0.5)

The quality of mean sensory block (Hollmen scale) was found to be 3.81 \pm 0.85 in group BN while 2.93 \pm 0.92 in group BF. The difference in mean sensory block quality was statistically not significant. (P>0.05)

The quality of mean motor block was found to be 2.89 \pm 0.81 in group BN while 1.98 \pm 0.78 in group BF. The difference in mean motor block quality was statistically not significant. (P >0.05)

The mean maximum duration to attain the sensory block was found to be 8.31 \pm 2.19 minutes in group BN while 7.23 \pm 2.18 minutes in group BF. The difference in mean duration of sensory block was statistically not significant. (P >0.05)

Bhavana B. Gurunath et al. compare the effects of intrathecal nalbuphine and fentanyl as adjuvants to hyperbaric bupivacaine observed duration of onset of sensory blockade was 3.9 \pm 0.35 min in Group C and 3.1 \pm 0.18 min in Group F.

UN Prabhakaraiah et al. in a study on post-operative analgesia and adverse effects of nalbuphine and fentanyl when used as an adjuvant to hyperbaric bupivacaine during spinal anesthesia observed onset of sensory and motor block, duration of sensory and motor block, and effective analgesia were similar in both groups. This can be explained that both fentanyl and nalbuphine are lipophilic which can result in rapid uptake of the drugs resulting in similar onset.^{9,10}

The present study result was in agreement with the studies performed by Thote et al., where onset of sensory and motor block with 25 μ g of fentanyl and 1 mg of nalbuphine were similar.¹¹ While study

done by Gomaa et al. in cesarean section patients showed the faster onset of motor block in fentanyl group when compared to nalbuphine group which contradicted our study results.¹³ This can be explained that the study population was different.

The 2 segment regression was found to be 219.31 \pm 32.19 minutes in group BN while 122.23 \pm 21.18 minutes in group BF. The difference in 2-segment regression was statistically significant. (P < 0.05)

The mean motor block was found to be 242.35 \pm 51.34 minutes in group BN while 149.12 \pm 19.63 minutes in group BF. The difference in mean duration of motor block was statistically significant. (P < 0.05)

The First Rescue analgesia (min) was found to be 189.12 \pm 49.18 minutes in group BN while 161.33 \pm 23.21 minutes in group BF. The difference in First Rescue analgesia (min) was statistically significant. (P < 0.05)

Bhavana B. Gurunath et al compare the effects of intrathecal nalbuphine and fentanyl as adjuvants to hyperbaric bupivacaine observed Two segment sensory regression time was prolonged in Group C (193.16 \pm 39.55) compared to Group F (167.41 \pm 30.17 min). Rescue analgesia was given at 268.33 \pm 44.44 min in nalbuphine group which was significantly prolonged as compared to fentanyl group in which rescue analgesia was given at 220.91 \pm 24.36 min.

UN Prabhakaraiah et al in a study on post-operative analgesia and adverse effects of nalbuphine and fentanyl when used as an adjuvant to hyperbaric bupivacaine during spinal anesthesia observed fentanyl had lower VAS scores and was more efficient in providing better quality of analgesia in the early post-operative period than compared to nalbuphine.

The Median Ramsay Sedation score was found to be 3 in group BN while 2 in group BF. Patients are more comfortable with BN group as compare to BF and when we compare it statistically Median Ramsay Sedation score was statistically significant. (P < 0.05).

Similar results were seen by the studies done by Gomaa et al. The study showed that fentanyl 25 μ g and nalbuphine 0.8 mg as an adjuvant to 10 mg of 0.5% bupivacaine in cesarean section patients produced similar block characteristics.¹³ Although duration of analgesia was prolonged when compared to fentanyl, the results were not statistically significant. Contradict to our study, the study done by Thote et al. in patients undergoing lower abdominal surgeries using 25 μ g of fentanyl and 0.5 mg of nalbuphine with 12.5 mg of 0.5%

bupivacaine observed longer duration of analgesia with nalbuphine group when compared to fentanyl group.¹² The study also showed the greater intensity of analgesia with nalbuphine group. Similarly, a study done by Fournier et al. comparing morphine and nalbuphine in patients under going total hip replacement using continuous spinal anesthesia showed that duration of analgesia was shorter in nalbuphine group when compared to morphine group. This shows nalbuphine though has a similar potency to morphine, the duration of analgesia is much shorter.¹⁴

Studies done by Jyothi et al., Culebras et al., and Gomaa et al. have shown lesser VAS scores with prolongation of analgesia with nalbuphine group.^{4,11,13} This potency of nalbuphine might be because of its agonist and antagonist property and this might be the cause for its efficacy when compared to fentanyl. This pharmacodynamic property of nalbuphine needs further study involving larger sample group.

Ankit Sharma et al in their of Comparison of nalbuphine versus fentanyl as intrathecal adjuvant to bupivacaine for orthopedic surgeries Intrathecal nalbuphine in a dose of 1 mg is an equally useful alternative to fentanyl in a dose 25 μ g when used as an intrathecal adjuvant to bupivacaine for lower limb surgeries. The prolonged duration of analgesia and no adverse effects makes it a good choice. This study support the our findings.^{18,19}

Hemodynamic Parameters

The mean intraoperative and post operative heart rates, systolic blood pressure, diastolic blood pressure, SPO2 and respiratory rate of patients from Group BN were more stable as compared to Group BF at different time intervals with no statistical significance. (P > 0.05)

Similarly, UN Prabhakaraiah et al in a study on post-operative analgesia and adverse effects of nalbuphine and fentanyl when used as an adjuvant to hyperbaric bupivacaine during spinal anesthesia observed no statistical difference in hemodynamic parameters.

Bhavana B. Gurunath et al compare the effects of intrathecal nalbuphine and fentanyl as adjuvants to hyperbaric bupivacaine observed on statistical difference in hemodynamic parameters.

Complications

The over all incidence of intra-operative complications was 13%. Group BN had the least complications (6%). Bradycardia was the major intra-operative complication in group BF (8%). In

BF group respiratory depression was observed in one patient. Which was not significant.

The overall incidence of post-operative complications was 12%. Group BN had the least complications (10%). Bradycardia was the major intra-operative complication in group BF. (4%) Pruritis was observed in one patient in Group BN.

UN Prabhakaraiah et al, in a study on post-operative analgesia and adverse effects of nalbuphine and fentanyl when used as an adjuvant to hyperbaric bupivacaine during spinal anesthesia observed incidence of hypotension and bradycardia was not statistically significant between the groups in our study. This shows that both the opioids did not have any significant sympatholytic activity and rather enhanced the antinociception in the spinal cord.

A study done by Tiwari et al., where combination of bupivacaine with nalbuphine was compared with plain bupivacaine and a study done by Singh et al., where fentanyl was compared to plain bupivacaine group. Both these studies have shown that the incidence of hypotension and bradycardia were lesser in adjuvant groups than compared to plain bupivacaine. The opioids did not have any significant sympatholytic activity and rather they enhances the antinociception in the spinal cord might be the reason.^{15,16}

The effective relief of pain during the intra and post-operative period is of principal importance for anesthesiologist as it has significant physiological benefit by means of smoother post-operative course. Nalbuphine, a part from its potent analgesic property, shows antagonizing morphine induced side effects. It might be particularly considered, especially if the patient has history of μ side effects.

CONCLUSION

In our study of intrathecal use of Nalbuphine 1mg and Fentanyl 25 μ g as adjuvant to 0.5% Hyperbaric Bupivacaine in infraumbilical surgeries increase efficacy in term of increase in total duration of action of sensory and motor block with insignificant adverse events. Intrathecal use of Nalbuphine as adjuvant to hyperbaric Bupivacaine was clinically more efficient than fentanyl for enhancing the post-operative analgesia. It could be a good alternative to Fentanyl and other opioids as adjuvant.

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