Journal of Cardiovascular Disease Research

ISSN: 0975-3583, 0976-2833 VOL14, ISSUE 12, 2023

Original Research Paper

"A COMPARATIVE STUDY TO ASSESS THE EFFICACY OF INTRATHECAL NALBUPHINE 1MG VERSUS INTRATHECAL FENTANYL 25MCG AS AN ADJUVANT TO 0.5% HYPERBARIC BUPIVACAINE FOR LOWER ABDOMINAL SURGERIES"

Dr. Shivanand K Madanagondi[1], Dr. Avinash Muniratna[2], Dr. Haridaveeseeran P K[3], Dr. Pradeep Kumar S[4]

[1,2] Assistant Professor, Department of Anaesthesia, Akash Institute of Medical Science & Research Centre, Bengaluru

[3]Senior Resident, Department of Anaesthesia, ESIC Medical College & PGIMSR & Model Hospital,
Rajaji Nagar, Bangalore

[4]Assistant Professor, Department of Anaesthesia, Rajarajeswari Medical College and Hospital, Bangalore

Corresponding Author: Dr. Haridaveeseeran P K

ABSTRACT:

Background: Subarachnoid block/spinal anaesthesia is the most commonly used method for lower abdominal and lower leg procedures [1]. It offers various advantages over general anesthesia, such being less expensive, having a speedier onset of anaesthesia with less intraoperative blood loss, and providing good postoperative analgesia [2].

AIM: To evaluate the effect of intrathecal hyperbaric bupivacaine 0.5% 3ml plus nalbuphine 1mg compared to hyperbaric bupivacaine 0.5% 3ml plus fentanyl 25 mcg in lower abdominal surgical procedures regarding,

OBJECTIVES: • Onset and the duration of sensory block • Onset and the duration of motor block • Hemodynamic changes • Side effects • Time to rescue analgesia

MATERIAL & METHODS: Study Design: Prospective, randomized open-label study. **Study area:** The study was conducted in the Department of Anaesthesia, Akash Institute of Medical Science & Research Centre, Bengaluru from January 2023 to October 2023. **Study Period:** 1 year. **Study population:** The study group comprised of patients admitted to hospital for lower abdominal surgeries. **Sample size**: Study consisted a total of 80 subjects. **Sampling Technique:** Simple Random technique. **Study tools and Data collection**

ISSN: 0975-3583, 0976-2833 VOL14, ISSUE 12, 2023

procedure: Eighty patients aged between 20 years and 60 years of physical status ASA grade 1 and ASA grade 2 scheduled for lower abdominal operations will be included in the study after receiving approval from the institutional ethical committee. A detailed preoperative evaluation will be done for all the patients. All routine investigations required will be done. The procedure will be explained and written informed consent will be obtained. Patients will be pre-medicated with tablet Alprazolam 0.5 mg overnight. Patients will be allowed for a period of absolute fasting of 8 hours. On arrival in the operating room, monitors –ECG, NIBP, SPO2 will be connected and baseline readings will be recorded. An intravenous line will be secured with an 18G Intravenous cannula and Ringer's lactate will be started. Patients were randomized to 2 groups of 40 each based on a sealed envelope technique for the intrathecal injection: 1. Group N (n=40) - 15mg of 0.5 percent hyperbaric bupivacaine and nalbuphine 1mg plus 0.4 ml NS. Total volume 3.5ml, 2. Group F (n=40) - 15mg of 0.5 percent hyperbaric bupivacaine and Fentanyl 25mcg (0.5ml). Total volume 3.5ml
Results: In this study, mean ±SD time to rescue analgesia (hours) in the nalbuphine group was 5.94±0.34 hours, and the mean ± SD time to rescue analgesia (hours) in the fentanyl group was 4.14±0.32 hours. The mean difference between nalbuphine and fentanyl groups for time to rescue analgesia (hours) was shown statistically significant (P<0.0001).

CONCLUSION: In this study, we found that nalbuphine plus bupivacaine significantly prolonged analgesia duration compared to fentanyl plus bupivacaine in lower abdominal surgeries.

Keywords: nalbuphine, bupivacaine, lower abdominal surgeries, rescue analgesia

INTRODUCTION:

ISSN: 0975-3583, 0976-2833 VOL14, ISSUE 12, 2023

Subarachnoid block/spinal anaesthesia is the most commonly used method for lower abdominal and lower leg procedures [1]. It offers various advantages over general anesthesia, such being less expensive, having a speedier onset of anaesthesia with less intraoperative blood loss, and providing good postoperative analgesia [2]. Bupivacaine is the most often used local anesthetic in spinal anesthesia because it produces long-lasting, severe sensory and motor blockade, as well as significant sympathetic blockade and effective operative relaxation [(3,4)]. The duration of spinal anesthesia with hyperbaric bupivacaine is typically 2 to 2.5 hours [(5)].

As a result, to lengthen the duration of spinal anesthesia, numerous intrathecal adjuvants are added to local anesthetics. Intrathecal opioids have gained appeal as adjuvants because they prolong postoperative analgesia, reduce the requirement for local anaesthesia, and improve hemodynamic stability. Various opioids, including "morphine, fentanyl, buprenorphine, and nalbuphine," have been given intravenously(intrathecally) to speed up the onset and lengthen the duration of sensory and motor blockage.

Nalbuphine [(6)] is a synthetic opioid that functions as an agonist as well as an antagonist. When injected intravenously, it binds to kappa receptors in the spinal cord and brain. Because it causes analgesia and sedation via kappa receptors, there are no side effects mediated by mu receptors such as shivering, nausea, vomiting, and urine retention. Furthermore, while Nalbuphine is freely available, other opioids such as morphine and fentanyl are uncommon and require Narcotic Act licensing.

Fentanyl [(2)] is a highly lipid-soluble opioid agonist that promotes supraspinal and spinal analgesia principally by acting on the (mu) receptor. Despite several studies showing that it improves sensory anaesthesia and lengthens post-operative analgesia, fentanyl produces nausea, vomiting, pruritus, sleepiness, and respiratory depression due to its activity on the "mu receptor."

ISSN: 0975-3583, 0976-2833 VOL14, ISSUE 12, 2023

The purpose of this study is to investigate the effects of two adjuvants, nalbuphine and fentanyl, delivered to 0.5% hyperbaric bupivacaine in two groups of patients undergoing lower abdominal surgeries, Group N and Group F.

AIM: To evaluate the effect of intrathecal hyperbaric bupivacaine 0.5% 3ml plus nalbuphine 1mg compared to hyperbaric bupivacaine 0.5% 3ml plus fentanyl 25 mcg in lower abdominal surgical procedures regarding,

OBJECTIVES:

• Onset and the duration of sensory block

• Onset and the duration of motor block

• Hemodynamic changes

• Side effects

• Time to rescue analgesia

MATERIAL & METHODS:

Study Design: Prospective, randomized open-label study.

Study area: The study was conducted in the Department of Anaesthesia, Akash Institute of Medical Science & Research Centre, Bengaluru.

Study Period: From January 2023 to October 2023.

.

Study population: The study group comprised of patients admitted to hospital for lower abdominal surgeries.

Sample size: Study consisted a total of 80 subjects.

ISSN: 0975-3583, 0976-2833 VOL14, ISSUE 12, 2023

Sampling Technique: Simple Random technique.

Inclusion Criteria:

• 20-60 years of age

• ASA physical status of I or II

• Informed written consent

• Elective lower abdominal surgeries

Exclusion criteria:

• Patient refusal

• Allergy history to local anesthetics

• Contraindications to spinal anesthesia like infection at the injection Site

• Neurological and Musculoskeletal diseases,

• bleeding disorders, patients on anticoagulants

• Cardiovascular, Renal or liver disorders

• Morbid obese

Ethical consideration: Institutional Ethical committee permission was taken prior to the commencement of the study.

Study tools and Data collection procedure: Eighty patients aged between 20 years and 60 years of physical status ASA grade 1 and ASA grade 2 scheduled for lower abdominal operations will be included in the study after receiving approval from the institutional ethical committee. A detailed preoperative evaluation will be done for all the patients. All routine investigations required will be done. The procedure will be explained and written informed

ISSN: 0975-3583, 0976-2833 VOL14, ISSUE 12, 2023

consent will be obtained. Patients will be pre-medicated with tablet Alprazolam 0.5 mg overnight. Patients will be allowed for a period of absolute fasting of 8 hours.

On arrival in the operating room, monitors –ECG, NIBP, SPO2 will be connected and baseline readings will be recorded. An intravenous line will be secured with an 18G Intravenous cannula and Ringer's lactate will be started. Patients were randomized to 2 groups of
40 each based on a sealed envelope technique for the intrathecal injection:

1. Group N (n=40) - 15mg of 0.5 percent hyperbaric bupivacaine and nalbuphine 1mg plus 0.4 ml NS. Total volume 3.5ml
2. Group F (n=40) - 15mg of 0.5 percent hyperbaric bupivacaine and Fentanyl 25mcg (0.5ml). Total volume 3.5ml

Procedure:

Patient will be positioned in supine or lateral position. Under all aseptic precautions L3-L4 space will be pierced with 25G Quincke's spinal needle by midline approach and the study drug will be deposited intrathecally. After completion of block, patients will be laid to rest in supine position. Oxygen will be administrated through a mask if the pulse oximetry reading decreased below 95%. Hypotension defined as a decrease in SBP by greater than 20% from baseline or less than 90 mm Hg will be treated with incremental intravenous doses of Ephedrine 6 mg and further intravenous fluid as required. Bradycardia demarcated as a heart rate less than 50 beats per minute will be treated with intravenous Atropine 0.6 mg. Intraoperative monitoring will be done using automated multi parameter monitor. Vital parameters like HR, NIBP, Spo2 will be documented every 5 mins for first 15 mins and then every 15 mins till end of surgery. Sensory block evaluated via pinprick method in the mid clavicular line by means of 25G pointer every minute, until maximum sensory block is attained. The modified bromage scale will be used to determine the onset of the motor block.

Following parameters are observed:

ISSN: 0975-3583, 0976-2833 VOL14, ISSUE 12, 2023

• Onset & duration of sensory block

• Onset & duration of motor block

• Hemodynamic parameters

• Side effects

• Time to rescue analgesia

After the surgery, patients will be shifted to the post-anesthesia care unit where they will remain until there is complete recovery of sensory and motor blockade. Postoperatively hemodynamic parameters will be recorded every 30 minutes till full sensory & motor recovery. Adverse effects like nausea, hypotension, vomiting, pruritus, shivering, etc will be noted. Time for recovery of sensory & motor blocks will be noted. Time of rescue analgesia is noted, inj.Tramadol 50mg i.v will be given slowly as rescue analgesia when vas score is 4 or more.

VISUAL ANALOGUE SCALE:

0-10 VAS Numeric Pain Distress Scale

score 0-2 =no pain

score 2-4= mild pain

score 4-6= moderate pain

score 6-8 =severe pain

score 8-10 =unbearable pain

Statistical analysis:

The data has been entered into MS-Excel and statistical analysis has been done by using IBM SPSS Version 25.0. For categorical variables, the data values are represented in terms of numbers and percentages. The chi-square test was used to assess group association. For continuous variables, mean and standard deviation of the data are displayed. The student's t-test was used to compare the mean differences between the two groups. All p values less than 0.05 are regarded as statistically significant.

ISSN: 0975-3583, 0976-2833 VOL14, ISSUE 12, 2023

OBSERVATIONS & RESULTS:

Table 1. Between group comparison of age and weight distribution parameters

Variable	Nalbuphine (n=40)		Fentanyl (n=40)				
	Mean	SD	Mean	SD	Difference	95% CI	P-value
AGE	39.25	9.48	39.13	9.55	-0.13	-4.36 to 4.11	0.9533
WEIGHT	62.08	4.97	62.53	5.05	0.45	-1.78 to 2.68	0.6891

In this study, mean±SD age in the nalbuphine group was 39.25±9.48 years, and the mean±SD age in the fentanyl group was 39.13± 9.55 years. The mean difference between nalbuphine and fentanyl groups for age was shown statistically not significant (P=0.9533).

In this study, mean ±SD weight (kgs) in the nalbuphine group was 62.08±4.97 kgs, and the mean±SD weight (kgs) in the fentanyl group was 62.53±5.05 kgs. The mean difference between nalbuphine and fentanyl groups for weight (kgs) was shown statistically not significant (P=0.6891).

Table 2: Sex distribution

			GROUP		Total
			Nalbuphine	Fentanyl	
SEX	FEMALE	Count	16	16	32
		% WithinSex	50.0%	50.0%	100.0%
		% Within Group	40.0%	40.0%	40.0%
	MALE	Count	24	24	48
		% Within Sex	50.0%	50.0%	100.0%
		% within Group	60.0%	60.0%	60.0%
Total		Count	40	40	80
		% within Sex	50.0%	50.0%	100.0%

ISSN: 0975-3583, 0976-2833 VOL14, ISSUE 12, 2023

	% within Group	100.0%	100.0%	100.0%

In nalbuphine group (n=40), 24 (60.0%) patients were males, and 16 (40.0%) patients were females. In fentanyl group (n=40), 24 (60.0%) patients were males, and 16 (40.0%) patients were females. The association between sex of both groups shown statistically not significant (P = 1.00).

In nalbuphine group (n=40), 26 (65.0%) patients were ASA-1, and 14 (35.0%) patients were ASA-2. In fentanyl group (n=40), 25 (62.5%) patients were ASA-1, and 15 (37.5%) patients were ASA-2. The association between ASA in both the groups was shown statistically not significant (P = 0.816).

Table 3: Between group comparison of various variables

Variable	nalbuphine (n=40)		fentanyl (n=40)				
	Mean	SD	Mean	SD	Difference	95% CI	P-value
onset of sensory block (min)	3.58	0.65	3.53	0.63	-0.05	-0.33 to 0.23	0.7269 (NS)
onset of motor block (min)	4.73	0.66	4.75	0.76	0.03	-0.29 to 0.34	0.8755 (NS)
duration of sensory block (hours)	4.30	0.48	3.09	0.36	-1.21	-1.4 to -1.03	<0.0001 (S)
duration of motor block (hours)	4.94	0.36	3.59	0.36	-1.35	-1.51 to -1.19	<0.0001 (S)
Time to rescue analgesia (hours)	5.94	0.34	4.14	0.32	-1.80	-1.95 to -1.65	<0.0001 (S)

ISSN: 0975-3583, 0976-2833 VOL14, ISSUE 12, 2023

In this study, mean ±SD onset of sensory block (mins) in the nalbuphine group was 3.58±0.65 mins, and the mean±SD onset of sensory block (mins) in the fentanyl group was 3.53±0.63 mins. The mean difference between nalbuphine and fentanyl groups for the onset of sensory block (mins) was shown statistically not significantt (P=0.7269).

In this study, the mean ±SD onset of motor block (mins) in the nalbuphine group was 4.73±0.66 mins, and the mean ±SD onset of motor block (mins) in the fentanyl group was 4.75±0.76 mins. The mean difference between nalbuphine and fentanyl groups for onset of motor block (mins) was shown statistically not significant (P=0.8755).

In this study, mean±SD of duration of sensory block in the nalbuphine group was 4.30±0.48 hours, and the mean±SD of duration of sensory block in the fentanyl group was 3.09±0.36 hours. The mean difference between nalbuphine and fentanyl groups for the duration of sensory block was shown statistically significant (P<0.0001).

In this study, the mean±SD of duration of motor block in the nalbuphine group remained 4.94±0.36 hours, and the mean±SD of length of motor block in the fentanyl group remained 3.59± 0.36 hours. The mean difference between nalbuphine and fentanyl groups for duration of motor block was shown statistically significant (P<0.0001).

In this study, mean ±SD time to rescue analgesia (hours) in the nalbuphine group was 5.94±0.34 hours, and the mean ± SD time to rescue analgesia (hours) in the fentanyl group was 4.14±0.32 hours. The mean difference between nalbuphine and fentanyl groups for time to rescue analgesia (hours) was shown statistically significant (P<0.0001).

Table 4: Mean heart rate

Variable	Nalbuphine (n=40)		Fentanyl (n=40)				
	Mean	SD	Mean	SD	Difference	95% CI	P-value
HR_BASE	80.40	5.50	79.70	6.22	-0.70	-3.31 to 1.91	0.5952

ISSN: 0975-3583, 0976-2833 VOL14, ISSUE 12, 2023

HR_5_MIN	83.50	5.65	83.75	6.13	0.25	-2.37 to 2.87	0.8501
HR_10_MIN	77.15	5.22	76.30	5.43	-0.85	-3.22 to 1.52	0.4774
HR_15_MIN	73.10	4.20	73.50	4.70	0.40	-1.58 to 2.38	0.6893
HR_30_MIN	72.20	3.73	71.45	3.45	-0.75	-2.35 to 0.85	0.3533
HR_45_MIN	71.10	3.45	69.95	3.25	-1.15	-2.64 to 0.34	0.1288
HR_60_MIN	69.80	3.23	69.50	3.16	-0.30	-1.72 to 1.12	0.6757
HR_75_MIN	68.65	2.77	68.95	2.93	0.30	-0.97 to 1.57	0.6395
HR_90_MIN	69.00	3.07	68.90	2.56	-0.10	-1.36 to 1.16	0.8747
HR_105_MIN	68.95	2.72	69.75	1.88	0.80	-0.24 to 1.84	0.1296
HR_120_MIN	71.40	2.32	71.85	1.99	0.45	-0.51 to 1.41	0.3549
HR_150_MIN	75.95	3.46	75.00	2.79	-0.95	-2.35 to 0.45	0.1808

In this study, mean±SD difference between nalbuphine and fentanyl for heart rate (HR) at different time intervals was shown statistically not significant (P>0.05).

Table 5. Mean SBP at variable intervals

Variable	**Nalbuphine (n=40)**		**Fentanyl (n=40)**				
	Mean	**SD**	**Mean**	**SD**	**Difference**	**95% CI**	**P-value**
SBP_BASE	122.75	13.16	123.13	14.60	0.38	-5.81 to 6.56	0.9043
SBP_5_MIN	118.95	12.15	119.20	13.43	0.25	-5.45 to 5.95	0.9307
SBP_10_MIN	115.95	13.06	115.68	13.96	-0.28	-6.29 to 5.74	0.9277

ISSN: 0975-3583, 0976-2833 VOL14, ISSUE 12, 2023

SBP_15_MIN	114.15	11.00	113.90	12.07	-0.25	-5.39 to 4.89	0.9231
SBP_30_MIN	114.43	9.97	114.23	10.56	-0.20	-4.77 to 4.37	0.9308
SBP_45_MIN	114.35	8.69	113.20	9.22	-1.15	-5.14 to 2.84	0.5675
SBP_60_MIN	112.75	7.55	111.88	8.37	-0.88	-4.42 to 2.67	0.6248
SBP_75_MIN	111.80	6.90	112.60	7.47	0.80	-2.4 to 4	0.6202
SBP_90_MIN	111.90	6.51	113.70	7.09	1.80	-1.23 to 4.83	0.2404
SBP_105_MI N	113.33	6.41	114.98	6.72	1.65	-1.27 to 4.57	0.2647
SBP_120_MI N	114.88	6.12	116.05	6.54	1.18	-1.64 to 3.99	0.4089
SBP_150_MI N	116.60	5.76	117.78	6.49	1.18	-1.56 to 3.91	0.3946

In this study, mean±SD difference between nalbuphine and fentanyl groups for Systolic Blood Pressure (SBP) at different time intervals was shown statistically not significant (P>0.05).

Table 6. Mean DBP at variable intervals

Variable	Nalbuphine **(n=40)**		Fentanyl **(n=40)**				
	Mean	**SD**	**Mean**	**SD**	**Difference**	**95% CI**	**P-value**
DBP_BASE	75.80	9.24	76.35	9.47	0.55	-3.62 to 4.72	0.7934
DBP_5_MIN	68.10	8.73	67.30	9.01	-0.80	-4.75 to 3.15	0.6879
DBP_10_MIN	65.95	7.98	64.78	8.77	-1.18	-4.91 to 2.56	0.5328

ISSN: 0975-3583, 0976-2833 VOL14, ISSUE 12, 2023

DBP_15_MIN	64.43	7.56	63.53	7.92	-0.90	-4.35 to 2.55	0.6045
DBP_30_MIN	63.30	7.38	62.43	7.58	-0.88	-4.21 to 2.46	0.6024
DBP_45_MIN	62.90	7.20	62.15	7.11	-0.75	-3.94 to 2.44	0.6407
DBP_60_MIN	64.10	6.90	63.48	6.90	-0.63	-3.7 to 2.45	0.6864
DBP_75_MIN	65.25	6.99	64.63	6.85	-0.63	-3.71 to 2.46	0.6874
DBP_90_MIN	66.48	6.82	65.78	6.72	-0.70	-3.71 to 2.31	0.6451
DBP_105_MI N	67.80	6.76	66.93	6.67	-0.88	-3.86 to 2.11	0.5618
DBP_120_MI N	68.55	6.41	67.73	6.35	-0.83	-3.67 to 2.02	0.5648
DBP_150_MI N	69.43	6.24	68.43	6.40	-1.00	-3.82 to 1.82	0.4816

In this study, mean±SD difference between nalbuphine and fentanyl groups for diastolic blood pressure (DBP) at different time intervals was shown statistically not significant (P>0.05).

Table 7. MAP at variable intervals

Variable	**Nalbuphine (n=40)**		**Fentanyl (n=40)**				
	Mean	**SD**	**Mean**	**SD**	**Difference**	**95% CI**	**Pvalue**
MAP_BASE	91.40	10.43	91.85	11.04	0.45	-4.33 to 5.23	0.8519
MAP_5_MIN	85.05	9.63	84.55	9.84	-0.50	-4.83 to 3.83	0.8190
MAP_10_MIN	82.65	9.42	81.73	10.01	-0.93	-5.25 to 3.4	0.6715
MAP_15_MIN	81.03	8.41	80.33	8.79	-0.70	-4.53 to 3.13	0.7169
MAP_30_MIN	80.45	7.88	79.75	8.02	-0.70	-4.24 to 2.84	0.6949
MAP_45_MIN	80.10	7.44	79.15	7.30	-0.95	-4.23 to 2.33	0.5662

ISSN: 0975-3583, 0976-2833 VOL14, ISSUE 12, 2023

MAP_60_MIN	80.30	6.78	79.60	6.96	-0.70	-3.76 to 2.36	0.6497
MAP_75_MIN	80.75	6.48	80.65	6.66	-0.10	-3.02 to 2.82	0.9459
MAP_90_MIN	81.60	6.32	81.75	6.46	0.15	-2.69 to 2.99	0.9167
MAP_105_MI N	82.95	6.27	83.00	6.25	0.05	-2.74 to 2.84	0.9716
MAP_120_MI N	83.98	5.95	83.80	6.06	-0.18	-2.85 to 2.5	0.8966
MAP_150_MI N	85.10	5.57	84.85	6.04	-0.25	-2.84 to 2.34	0.8478

In this study, mean±SD difference between nalbuphine and fentanyl groups for Mean Arterial Pressure (MAP) at different time intervals was shown statistically not significant (P>0.05).

Table 8. Between group comparison of side effects

side effects	Group N	Group F
Shivering	**4**	**5**
Hypotension	**3**	**3**
Nausea & vomiting	**4**	**4**
Urinary retention	**3**	**3**
pruritis	**0**	**4**
Nil	**26**	**21**
Total	**40**	**40**

All the above side effects were comparable between the nalbuphine and fentanyl group which are statistically not significant except pruritis, only side effect seen in fentanyl group which is significant.

ISSN: 0975-3583, 0976-2833 VOL14, ISSUE 12, 2023

DISCUSSION:

In this study, we examined Nalbuphine 1 mg and Fentanyl 25 mcg as adjuvants in spinal anesthesia for lower abdomen procedures with 0.5 percent hyperbaric bupivacaine. There have been relatively few trials comparing similar dosages of both medications as adjuvants with hyperbaric bupivacaine.

Mukherjee [7] et al in his study to determine the safety of intrathecal nalbuphine and its action to prolong analgesia, and to determine the optimum dose of intrathecal Nalbuphine, study examined different doses of nalbuphine, namely 0.2mg, 0.4 mg, and 0.8 mg, with the control group and discovered that 0.4mg of nalbuphine, when added as an adjuvant to 0.5 percent hyperbaric bupivacaine, prolongs period of postoperative analgesia without any side effects. Hence, we used 1mg of nalbuphine intrathecally to see the effects.

Sensory Block: Onset of sensory block is defined as period from delivery of medication intrathecally to the moment the patient loses feeling to pinprick at level of T10 is referred to as onset of sensory block. Mean time of, onset of sensory blockage in our study was, Group N-3.58±0.65 mins, Group F-3.53±0.63 mins P value- 0.7269. In both groups, there was no statistically significant difference in the onset of sensory block.

In concordance to our study DN Sharma [2] et al., who compared similar doses of nalbuphine and fentanyl as in our study in subarachnoid block for lower limb orthopedic procedures, the onset of sensory blockage (Time to attain T10 sensory blockade) was found to be 3.2± 0.35 min in nalbuphine group and 3.5± 0.97 min in fentanyl group, with no significant difference statistically (P = 0.12).

Similarly, HM Gomaa [8] et al., concluded, there is no significant difference in the onset of sensory blockage between intrathecal nalbuphine and intrathecal fentanyl

ISSN: 0975-3583, 0976-2833 VOL14, ISSUE 12, 2023

Also K Garg [9] et al,. reported that there is no significant difference in the onset of sensory blockage between intrathecal nalbuphine and intrathecal fentanyl. But in contrast to our results Gurunath BB [1] et al., in their study comparing nalbuphine 300μg with fentanyl 25 μg as adjuvants to hyperbaric bupivacaine when used in spinal anesthesia for lower abdominal procedures, the onset of sensory block was faster in the fentanyl group (3.09 ± 0.47 min) than in Nalbuphine group (4.20± 0.52 min). These disparities may be due to fact that they compared 0.3 mg Nalbuphine to 25mcg Fentanyl, whereas we compared 1 mg Nalbuphine to 25mcg Fentanyl in our study. In our investigation, the duration of sensory block was shown to be longer in nalbuphine group (4.30±0.48 hrs) as compared to fentanyl group (3.09± 0.36 hrs), with a statistically significant P value of 0.0001.

This is similar to the study conducted by DN sharma [2] et al; who compared similar doses of nalbuphine and fentanyl as in our study in subarachnoid block for lower limb orthopaedic surgeries and found that duration of sensory blockage was significantly longer in the nalbuphine group when compared to the Fentanyl group with a P value of <0.001, which is statistically significant.

Similarly, in a study conducted by K Garg [9] et al., who compared 0.8 mg of intrathecal nalbuphine with 25 mcg of intrathecal fentanyl as adjuvants to 0.5 percent hyperbaric bupivacaine in spinal anesthesia for urological procedures and found that duration of sensory blockade remained significantly lengthy in patients of the nalbuphine group when compared to fentanyl group, with a P value of <0.001 being statistically significant.

Motor blockade:Onset of motor block is defined as the period elapsed between the injection of the medication intrathecally and the patient developing bromage 3 on the modified bromage scale. Mean time of onset of motor blockage in our study was, Group N-4.73±0.66 mins. Group

ISSN: 0975-3583, 0976-2833 VOL14, ISSUE 12, 2023

F-4.75±0.76 mins. P value-0.8755. With a p value of 0.8755, there was no significant difference in the onset of motor block between Group N and Group F.

This is similar to a study conducted by DN sharma [2] et al; who compared similar doses of nalbuphine and fentanyl as in our study in subarachnoid block for lower limb procedures, observed that mean time required for onset of motor block was similar between the two groups, although there was no statistical significance. Similarly, in a study conducted by K Garg [9] et al., who compared 0.8 mg of intrathecal nalbuphine with 25 mcg of intrathecal fentanyl as adjuvants to 0.5 percent hyperbaric bupivacaine in spinal anesthesia for urological procedures and found that onset of motor blockade was 3.38±0.88 mins in nalbuphine group and 4.10 ±1.91 mins in the fentanyl group, with no statistical difference between the groups.

Similarly, Bindra T K [10] et al. found that when intrathecal nalbuphine (0.8 mg) and intrathecal fentanyl (20mcg) were used as adjuvants to 0.5 percent hyperbaric bupivacaine, mean onset of motor block was not significantly different between the two groups but comparable.

However, in a study comparing intrathecal fentanyl and intrathecal nalbuphine as adjuvants to bupivacaine in lower limb procedures, Ravikiran J Thote [11] et al. found that onset of motor blockade was much earlier in fentanyl group when compared to nalbuphine group due to high lipophilic nature of fentanyl.

In our study, duration of motor block is defined as period between administration of a drug into the intrathecal space to the time when the patient attains complete motor recovery. It is more prolonged in nalbuphine group compared to fentanyl group which is 4.94±0.36 hours, and 3.59± 0.36 hours respectively, P-value is <0.0001 which is statistically significant.

This is similar to a study conducted by DN Sharma [2] et al., in lower limb procedures where they compared nalbuphine and fentanyl as intrathecal adjuvants to 0.5 percent hyperbaric bupivacaine with the same doses as in our study and found that mean duration of motor block was prolonged in patients of the nalbuphine group compared to patients of the fentanyl group

ISSN: 0975-3583, 0976-2833 VOL14, ISSUE 12, 2023

with a statistically significant difference between two groups. Hala Mostafa [8] Gomaa et al., they found no significant difference in onset of motor block between intrathecal fentanyl (25mcg) and intrathecal nalbuphine (0.8 mg) as adjuvants to bupivacaine in caesarean delivery. A study conducted by K Garg [9] et al, where they compared nalbuphine vs fentanyl as intrathecal adjuvants to bupivacaine for urological procedures disclosed that patients in nalbuphine group exhibited longer motor block when compared to fentanyl group ($P < 0.001$)., which is statistically significant. However, Hala Mostafa [8] Gomaa et al. determined that there was no statistically significant difference in duration of motor blockage between intrathecal nalbuphine and fentanyl groups when used as adjuvants to bupivacaine in spinal anaesthesia for caesarean patients.

Time to rescue analgesia: It is the time when rescue analgesia is needed for the patient with a Vas score of 4 or more. Mean duration of time to rescue analgesia in our study is Group N-5.94±0.34 hours. Group F-4.14±0.32 hours. P-value-<0.0001. The duration of time to rescue analgesia in Group N is prolonged than Group F which is statistically significant. The results obtained in our study reveal that length of analgesia is much prolonged by intrathecal nalbuphine compared to fentanyl.

This is similar to a study conducted by DN Sharma [2] et al; where they compared nalbuphine and fentanyl as intrathecal adjuvants to 0,5 percent hyperbaric bupivacaine with the same doses as in our study in lower limb procedures showed that duration of analgesia in Nalbuphine group is 263.4 ± 20.8 mins and 228.7 ± 19.8 mins in fentanyl group with p value 0.0001 which is statistically significant.

Our results are in concordance with the study conducted by Ravikiran J Thote [11] et al., who compared fentanyl and nalbuphine as intrathecal adjuvants to 0.5 percent bupivacaine in lower limb procedures and stated that intrathecal nalbuphine prolongs the duration of analgesia than intrathecal fentanyl. Similarly, a study conducted by Shehla shakooh [12], et al., who did a study

ISSN: 0975-3583, 0976-2833 VOL14, ISSUE 12, 2023

on nalbuphine as intrathecal adjuvant to bupivacaine versus plain bupivacaine also observed that sensory blockade, motor blockade and post-operative analgesia was much prolonged with the intrathecal nalbuphine group than plain bupivacaine group. similarly, Mukherjee [7] et al., in their study showed that 0.4mg nalbuphine is most effective intrathecal dose that increases postoperative analgesia with no side effects.

Hemodynamic parameters: Hemodynamic parameters such as HR, NIBP, and Spo2 were measured every 5 minutes for first 15 minutes and subsequently every 15 minutes until the procedure was completed. In our study, overall hemodynamic variables in both groups were comparable. In our study, there was a slight decrease in heart rate initially from baseline values in both groups which then stabilized and came to near baseline value by end of surgery. No statistically significant changes were seen during the intraoperative period. The mean difference of heart rate between nalbuphine and fentanyl were comparable.

In our study SBP, DBP, MAP of both groups found to be in a decreasing trend from the baseline up to 1 hr after which they came back to near baseline values. There are no periods of significant hypotension in both groups and the fall in BP was manageable with fluids only.

Our findings are consistent with those of Prabhakaraiah [6] UN et al., who investigated nalbuphine and fentanyl as adjuvants to Bupivacaine for spinal anesthesia in lower abdomen operations and discovered that intraoperative hemodynamic parameters were equivalent between the two groups. Similarly, K Garg [9] et al. discovered that intraoperative hemodynamic variables were comparable in both groups in their study, comparative analysis of intrathecal nalbuphine vs fentanyl as an adjuvant to bupivacaine for urological procedures.

Side effects: The side effects compared were shivering, hypotension, nausea & vomiting, pruritis and urinary retention.

Hypotension: Hypotension was considered when the systolic arterial pressure decreases by 20% from the base line or less than 90mmHg.

ISSN: 0975-3583, 0976-2833 VOL14, ISSUE 12, 2023

In our study hypotension was observed in 3 patients of Group N and 3 patients in Group F. There is no statistically significant difference between two groups. Hypotension was treated with fluids only and none of the patients required medical interference. This is similar to study conducted by UN prabhakaraiah [6] et al., who compared nalbuphine and fentanyl as intrathecal adjuvants to bupivacaine for spinal anesthesia in lower abdomen procedures found that hypotension was seen in four patients in Group nalbuphine and seven patients in Group fentanyl with no statistical significance.

Shivering: Shivering was observed in four patients in nalbuphine group and five patients in fentanyl group in our study, with no statistical difference between the two groups.

Similarly, in a study conducted by K Garg [9] et al, who compared nalbuphine vs fentanyl as intrathecal adjuvants to bupivacaine for urological procedures and discovered that shivering was observed in both groups despite the fact that there was no statistical difference

Nausea and vomiting: In our study, four patients in nalbuphine group and four patients in fentanyl group experienced nausea and vomiting, with no statistical difference between the two groups. Bindra T K[10] et al, in their study, postoperative analgesia with nalbuphine versus fentanyl as intrathecal adjuvants to bupivacaine in caesarean section, observed nausea and vomiting in both groups with no statistical difference.

Urinary retention: Urinary retention was observed in three patients in nalbuphine group and three patients in fentanyl group in our study, with no statistical difference between the two groups. This is similar to a study conducted by Bindra T K [10] et al, who compared nalbuphine and fentanyl as intathecal additives to bupivacaine for spinal anaesthesia in caesarean section and discovered that urinary retention was observed in both the nalbuphine and fentanyl groups, though not statistically significant.

Pruritis: In our study pruritis was seen in 4 patients of the fentanyl group and not seen in the patients of nalbuphine group with statistically significant difference (p-value 0.04) found

ISSN: 0975-3583, 0976-2833 VOL14, ISSUE 12, 2023

between both the two groups. Our findings are consistent with those of UN prabakaraiah [6] et al, who compared nalbuphine and fentanyl as intrathecal adjuvants to bupivacaine for spinal anaesthesia in lower abdomen procedures and discovered that pruritus was found in four patients in fentanyl group and none in nalbuphine group, despite the fact that the difference was statistically insignificant. In our study, we found that when nalbuphine was added to bupivacaine as an adjuvant, it increased duration of sensory & motor block and time to rescue analgesia when compared to fentanyl. Onset of sensory & motor block, hemodynamics, and side effects were not significantly different between two groups.

CONCLUSION:

In this study, we found that nalbuphine plus bupivacaine significantly prolonged analgesia duration compared to fentanyl plus bupivacaine in lower abdominal surgeries.

REFERENCES:

1) Gurunath BB, Madhusudhana R. Postoperative analgesic efficacy of intrathecal fentanyl compared to nalbuphine with bupivacaine in spinal anesthesia for lower abdominal surgeries. Anesthesia, essays and researches. 2018 Apr;12(2):535.

2) Sharma DN, Padhy M, Kar M. A randomized comparative study to assess the effect of intrathecal nalbuphine versus intrathecal fentanyl as an adjuvant to bupivacaine for lower limb orthopedic surgery. J Evolution Med Dent Sci.,(12). 2019 Mar 25:830-4.

3) Bandi E, Weeks S, Carli F. Spinal block levels and cardiovascular changes during post-cesarean transport. Can J Anaesth 1999;46(8):736–40.

4) Parpaglioni R, Frigo MG, Lemma A, Sebastiani M, Barbati G, Celleno D. Minimum local anaesthetic dose (MLAD) of intrathecal levobupivacaine and ropivacaine for caesarean section. Anaesth 2006;61(2):110–115

ISSN: 0975-3583, 0976-2833 VOL14, ISSUE 12, 2023

5) Brown DL. Spinal epidural and caudal anaesthesia. In: Miller RD, Eriksson LI, Fleisher LA, Wiener-Kronish GP, Young WL, editors. Millers' Anaesthesia. 7th ed. Philadelphia, PA: Elsevier Churchill Livingstone; 2010.p. 1624.

6) Pabhakaraiah UN, Narayanappa AB, Gurulingaswamy S, Kempegowda K, Vijaynagar KA, Hanumantharayappa NB, Ramegowda DS. "Comparison of nalbuphine hydrochloride and fentanyl as an adjuvant to bupivacaine for spinal anesthesia in lower abdominal surgeries:" A randomized, double-blind study. Anesthesia, essays and researches. 2017 Oct;11(4):859.

7) Mukherjee A, Pal A, Agrawal J, Mehrotra A, Dawar N. Intrathecal nalbuphine as an adjuvant to subarachnoid block: What is the most effective dose?. Anesthesia, essays and researches. 2011 Jul;5(2):171.

8) Gomaa HM, Mohamed NN, Zoheir HA, Ali MS. A comparison between post-operative analgesia after intrathecal nalbuphine with bupivacaine and intrathecal fentanyl with bupivacaine after cesarean section. Egyptian Journal of Anaesthesia. 2014 Oct 1;30(4):405-10.

9) Garg K, Garg P, Katyal S. Comparative analysis of intrathecal nalbuphine vs fentanyl as an adjuvant to bupivacaine for urological procedures. MGM Journal of Medical Sciences. 2020 Oct 1;7(4):203.

10) Bindra TK, Kumar P, Jindal G. Postoperative analgesia with intrathecal nalbuphine versus intrathecal fentanyl in cesarean section: A double-blind randomized comparative study. Anesthesia, essays and researches. 2018 Apr;12(2):561.

11) Thote RJ, Lomate P, Gaikwad S, Paranjpe JS, Mane M. Comparison among intrathecal fentanyl and nalbuphine in combination with bupivacaine and plain bupivacaine for lower limb surgeries. Int J Recent Trends Sci Technol. 2015; 14:361-6.

12) Shakooh S, Bhosle P. Intrathecal nalbuphine: An effective adjuvant for post-operative analgesia. Age (years). 2014;40(14.09):46-90.