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Comparative Study Of Intrathecal Nalbuphine Versus Intrathecal Fentanyl As Adjuvant To 0.5% Hyperbaric Bupivacaine In Intraoperative Haemodynamics And Postoperative Analgesia For Abdominal And Orthopaedic Surgeries

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I. Introduction:

Spinal anaesthesia is the most common regional anaesthesia technique. It is a simple procedure that is easier to conduct and provides appropriate analgesia due to the rapid onset of anaesthesia [1, 2].

August Bier first performed spinal anaesthesia on 16th August 1898 [3]. One of the most common concerns after surgery is pain.

A variety of local anaesthetics and additives can be used to provide spinal anaesthesia, allowing control over the onset and duration of anaesthesia [4].

The use of intrathecal opioids has a definitive place [5, 6]. They act in conjunction with local anaesthetics to enhance efficacy and provide better postoperative analgesia.

Fentanyl is an opioid that has agonistic action and operates on mu opioid receptors, which have a faster onset of action and fewer side effects (7).

Nalbuphine is a synthetic opioid that binds to kappa and mu opioid receptors, acting as an agonist at kappa and an antagonist at mu.

In the literature, only a few trials compare nalbuphine and fentanyl as adjuvants to bupivacaine in subarachnoid block.

Hence, a comparison of nalbuphine and fentanyl as adjuvants to hyperbaric bupivacaine in patients having abdominal and lower limb procedures is being made.

II. Methods:

Aim:

To assess, evaluate and compare the duration of the analgesic effect of nalbuphine and fentanyl when added to hyperbaric bupivacaine as adjuvants in subarachnoid block.

Objectives:

1. To study the duration of postoperative analgesia of nalbuphine and fentanyl.
2. To study the onset and duration of sensory and motor blockade.
3. To note any associated side effects of nalbuphine and fentanyl.

Materials and Methods:

Design of study:

- This observational study was conducted in Dr PSIMS & RF tertiary care centre teaching hospital from November 2019 to October 2021.
- Sixty patients who met the inclusion criteria were assigned to the study, i.e., intrathecal nalbuphine 0.5 mg (0.5 mL) versus intrathecal fentanyl 25 mcg (0.5 mL) as an adjuvant to 0.5% hyperbaric bupivacaine (3 mL) in intraoperative haemodynamics & postoperative analgesia

- Population and study subjects:

Inclusion criteria:

• ASA grade 1 and 2 patients.
• The age group is 18-60 years.
• Patients willing to give consent.
• Patients undergoing abdominal and lower limb surgeries.
• Patients are willing to follow up.

Exclusion criteria:
• Patients allergic to any anaesthetic drug.
• Bleeding disorders.
• ASA grade 3 and 4
• Patient not willing to consent and follow up.

Sample size: sixty, 2 groups of 30 people each.

Group distribution:
GROUP 1: 3 ml of 0.5% heavy bupivacaine with 25 micrograms of fentanyl
GROUP 2: 3 ml of 0.5% heavy bupivacaine with 0.5mg nalbuphine

Sampling: From the cases undergoing abdominal and lower limb surgeries.
Data collection: Using a pre-tested semi-structured questionnaire as a protocol.
Study variables: age, sex, height, weight, haemodynamics, and pain score as per VAS. Materials:
A. 23 G Quincke's needle
B. Inj. Nalbuphine.
C. Inj. Fentanyl.
D. Inj. Bupivacaine.
E. Spinal draping set

Methodology:

After obtaining approval from the ethics committee & written informed consent, a total of 60 patients undergoing abdominal and lower limb surgeries under spinal anaesthesia were included in the study.

Patients were kept nil per oral for 6 hours. Patients were randomly allocated to two groups by a computer-generated method.

An 18G IV line was secured. Patients were premedicated with Tab. Ranitidine 150 mg and Tab. Alprazolam 0.5 mg on the night before surgery and preloaded with 10 ml/kg of crystalloid solution. SpO2, NIBP, and ECG were recorded before the procedure. The study medication was prepared by a person who was not involved in the study to ensure blinding of the anaesthetist.

Under aseptic conditions, a subarachnoid block was performed using a 23-G Quincke's spinal needle at the L3-L4 level in a sitting position, and the study drug was injected. The assessments of the haemodynamic parameters like HR, BP, and SPO2 were noted.

The following observations were made:
• T0 – Time of spinal anaesthesia.
• T1- Time of onset of sensory block.
• T3 – Time of onset of motor block.
• T4- Duration of sensory block.
• T5- Time to the first dose of post-operative rescue analgesia.

Sensory block:

The sensory level is assessed by the pinprick method in the mid-clavicular line every 10 min., & the peak sensory level attained during the study was noted down.

Motor block: Using the modified Bromage scale.

The motor block was measured at 0, 10, 20, and 30 minutes post-injection until the patient returned to a score of 0 in both lower limbs.

Vital parameters were monitored every 5 min for 20 min, then every 10 min till the end of surgery. Perioperatively, patients were observed for side effects such as respiratory depression, nausea, vomiting, itching, etc.

The VAS score was calculated on a 10 cm long scale with '0' on one end, meaning 'no pain'. While '10' represents 'worst pain imaginable'.

Patients were rating the degree of pain by making a mark on the pain scale every 15 minutes. Thus, the pain score was obtained by measuring the distance from the '0' end to the indicated mark.

Postoperative analgesic drugs were given when the patient's VAS score reached > 3 (this time will be taken as the duration of postoperative analgesia). Inj. Diclofenac 75 mg in 100 ml saline was given as rescue analgesia.

By the following plan, a data management & statistical plan for evaluating the results was done.

Time of onset of sensory and motor block, duration of sensory and motor block, time of the first complaint of pain and rescue analgesia, and 24-hour VAS score were noted.

Intraoperative haemodynamics like SBP, DBP, MAP, PR, and SPO2 were recorded in both groups.

The above results were tabulated, & statistical analysis was made using mean & standard deviation.

The unpaired t-test and the chi-square test were used to compare different parameters in the two groups.

If the p-value was equal to or less than 0.05, the data were judged significant, and if the p-value was less than 0.01, the data were considered very significant.

STATISTICAL SOFTWARE: IBM SPSS 21 version 20. Windows was used to conduct the statistical analysis.

III. Results:

Table 1: Comparison of demographic data

VARIABLE	GROUP-FENTANYL	GROUP-NALBUPHINE	T-VALUE	P-VALUE
AGE (YEARS)	41.37±13.42	41.7±10.73	-0.1	0.9
WEIGHT (KG)	69.23±12.21	68.53±13.55	0.2	0.8
HEIGHT (CM)	163.07±5.88	164.13±6.91	-0.64	0.5
BMI	25.57±4.61	25.54±4.19	0.83	0.9
SEX (M:F)	16:14	20:10	1.11	0.3

Table 2: Comparison of Sensory And Motor Block

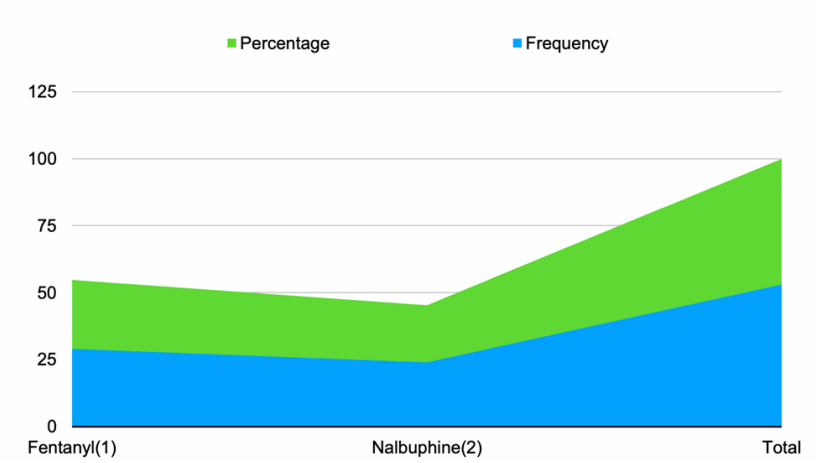
VARIABLE	GROUP-FENTANYL	GROUP-NALBUPHINE	T-VALUE	P-VALUE
TIME OF ONSET OF SENSORY BLOCK	4.5±2.56	4.72.56	-0.3	0.7
TIME OF ONSET OF MOTOR BLOCK	6.33±2.28	6.17±3.63	0.2	0.8
DURATION OF SENSORY BLOCK	192.3±76.61	324.4±59.67	-7.2	<0.0001
DURATION OF MOTOR TABLOCK	178.53±76.61	326.164.39	-8.08	<0.0001

TABLE 3: COMPARISON OF REQUIREMENT OF RESCUE ANALGESIA

Requirement of rescue analgesia	Frequency	Percentage
Fentanyl(1)	29	54.7
Nalbuphine(2)	24	45.3
Total	53	100.0

P-VALUE < 0.001

GRAPH 1: COMPARISON OF RESCUE ANALGESIA

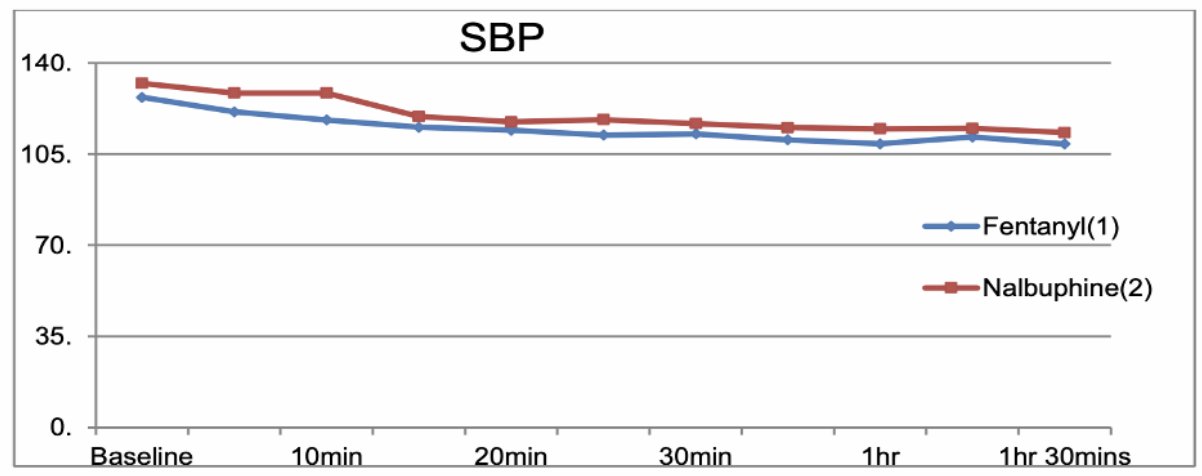


In group 1, the frequency of requiring rescue analgesia is 29, and the percentage is 54.7, while in group 2, the frequency is 24, and the percentage is 45.3. The rescue analgesia given is more in the fentanyl group when compared to the nalbuphine group.

HAEMODYNAMICS:
TABLE 4: COMPARISON OF SYSTOLIC BLOOD PRESSURE

SBP	Fentanyl(1)	Nalbuphine(2)	t value	P value
Baseline	126.77±12.38	132.167±13.19	-1.6	0.1
5min	121.2±14.49	128.4±10.54	-2.2	0.03
10min	118.07±12.4	128.4±10.54	-1.9	0.05
15min	115.27±12.4	119.43±8.38	-1.5	0.1
20min	114.13±11.54	117.33±8.96	-1.2	0.2
25min	112.27±10.94	118.17±8.96	-2.3	0.02
30min	112.73±11.09	116.7±9.05	-1.5	0.1
45min	110.47±9.69	115.17±9.03	-1.9	0.06
1hr	108.93±9.55	114.67±9.51	-2.3	0.02
1hr 15mins	111.53±10.48	114.83±10.75	-1.2	0.2
1hr 30mins	108.87±10.7	113.27±9.77	-1.7	0.1

GRAPH 2: COMPARISON OF SYSTOLIC BLOOD PRESSURE

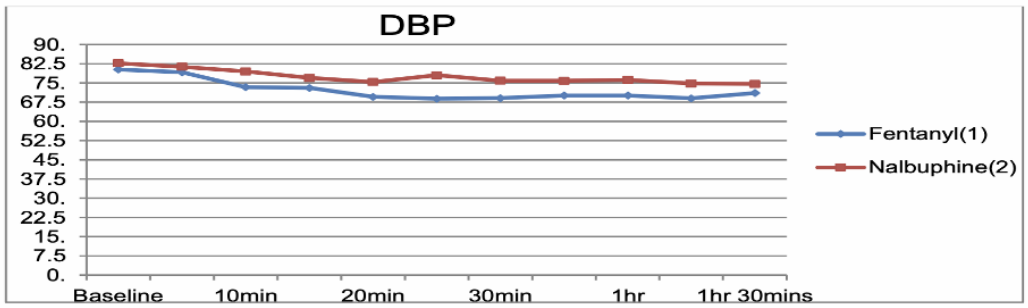


SBP at a specific time interval, comparing groups 1 and 2, with a p-value>0.01 indicating no statistical significance.

TABLE 5: COMPARISON OF DIASTOLIC BLOOD PRESSURE

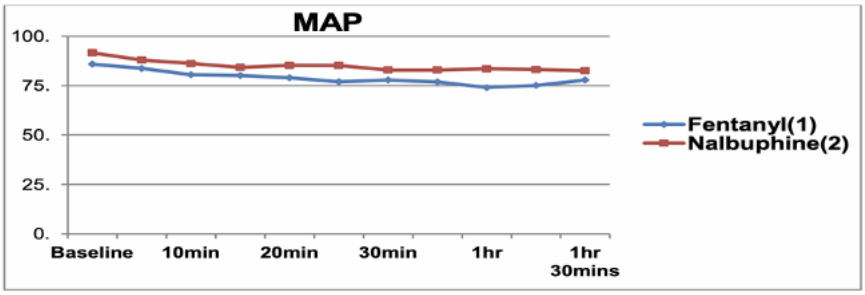
DBP	Fentanyl(1)	Nalbuphine(2)	t value	P value
Baseline	80.27±11.28	82.7±7.95	-0.9	0.3
5min	79.17±10.99	81.3±7.01	-0.8	0.3
10min	73.37±8.68	79.47±8.18	-2.8	0.01
15min	73.07±11.71	76.97±7.28	-1.5	0.1
20min	69.6±7.61	75.4±6.74	-3.1	0.003
25min	68.87±9.14	78.03±6.51	-4.5	**<0.0001**
30min	69.1±8.16	75.87±7.04	-3.4	**0.001**
45min	70.13±9.17	75.83±5.91	-2.9	**0.01**
1hr	70.13±9.58	76.2±7.04	-2.8	**0.01**
1hr 15mins	69±9.1	74.8±6.23	-2.9	**0.01**
1hr 30mins	71.1±9.64	74.6±7.38	-1.6	0.1

GRAPH 3: COMPARISON OF DIASTOLIC BLOOD PRESSURE



DBP at a specific time interval, comparing group 1 and group 2 with a p-value of 0.01 at 10 min and 45 min. 1 hr, 1 hr 15 min. The p-value is 0.01 at 25 and 30 min, exhibiting statistical significance.

GRAPH 4: COMPARISON OF MEAN ARTERIAL PRESSURE

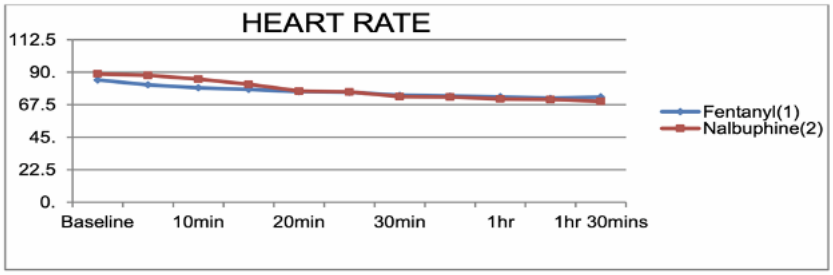


When the MAP of the 2 groups was compared at a specific time interval, the p-value was more than 0.01. At 1 hr 15 minutes, the p-value was 0.01, and at 30 minutes, it was 0.01.

TABLE 6: COMPARISON OF HEART RATE

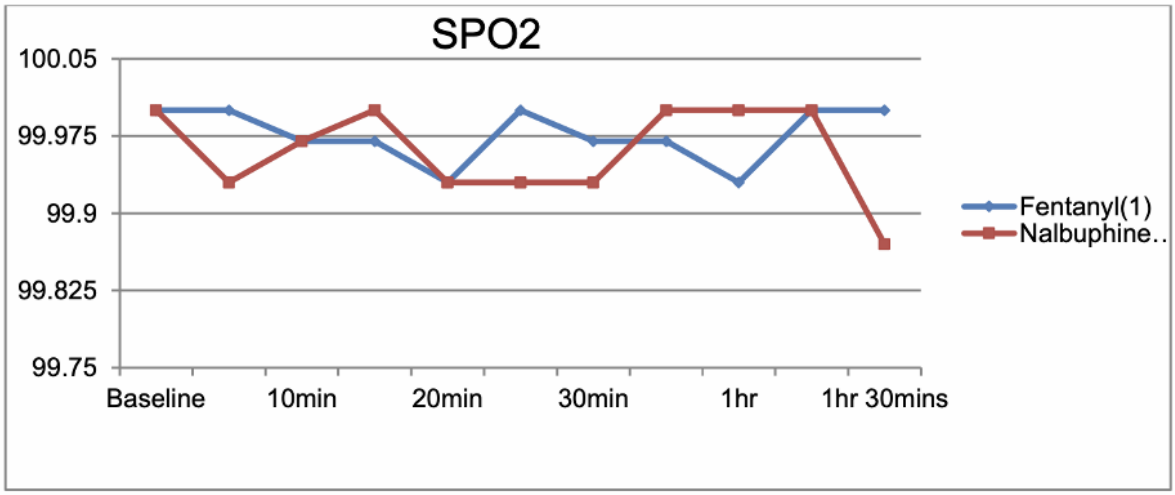
HR	Fentanyl(1)	Nalbuphine(2)	t value	P value
Baseline	84.63±11.79	88.83±13.11	-1.3	0.2
5min	81.31±1.34	87.83±14.31	-1.9	0.06
10min	79.23±10.51	85.23±11.54	-2.1	0.04
15min	78.13±10.98	81.6±11.85	-1.2	0.2
20min	76.63±10.35	76.93±10.74	-0.1	0.9
25min	76.13±10.67	76.37±11.29	-0.1	0.9
30min	74.06±10.17	73.17±10.51	0.3	0.7
45min	73.47±9.31	72.9±9.99	0.2	0.8
1hr	73.03±10.5	71.5±10.14	0.6	0.6
1hr 15mins	71.97±8.72	71.17±9.89	0.3	0.7
1hr 30mins	72.9±9.37	69.83±8.6	1.3	0.2

GRAPH 5: COMPARISON OF HEART RATE



HR at a given time interval was compared between the two groups with a p-value>0.01, indicating that there was no statistical significance.

GRAPH 6: COMPARISON OF SPO_2



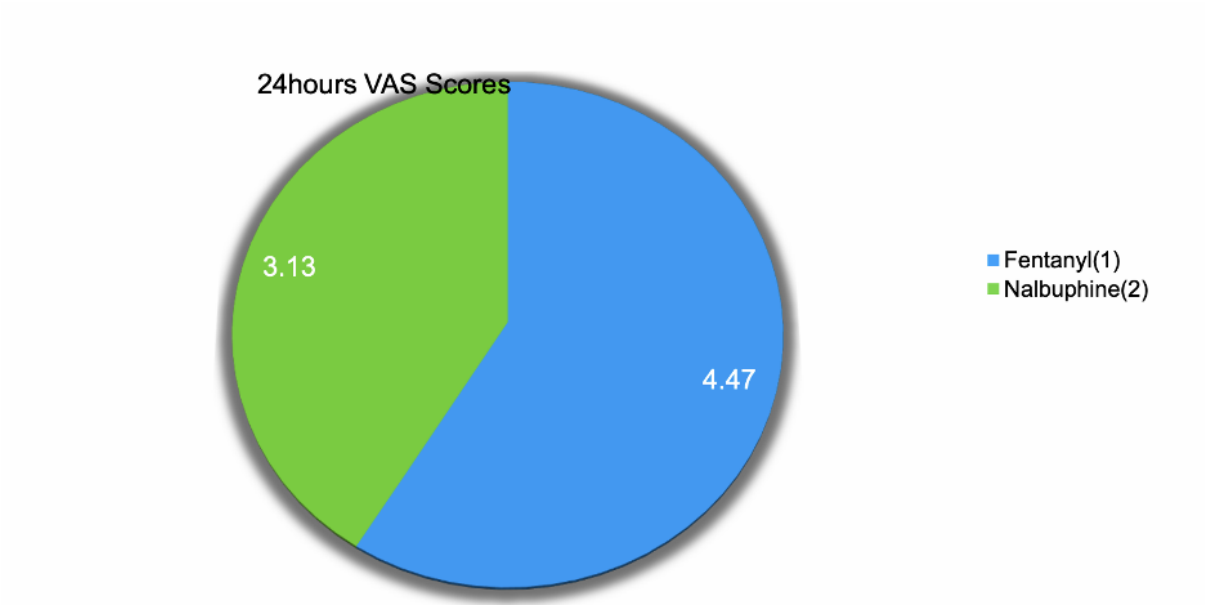
When SPO2 was compared between the two groups at a given time interval, the p-value was more than 0.01, indicating that there was no statistical significance.

TABLE 7: COMPARISON OF 24-HOUR VAS SCORE

24hours VAS Scores	Fentanyl(1)	Nalbuphine(2)	t value	P value
Mean	4.47	3.13	3.12	0.003
SD	1.99	1.22		

Using independent t-test

GRAPH 7: COMPARISON OF 24-HOUR VAS SCORE



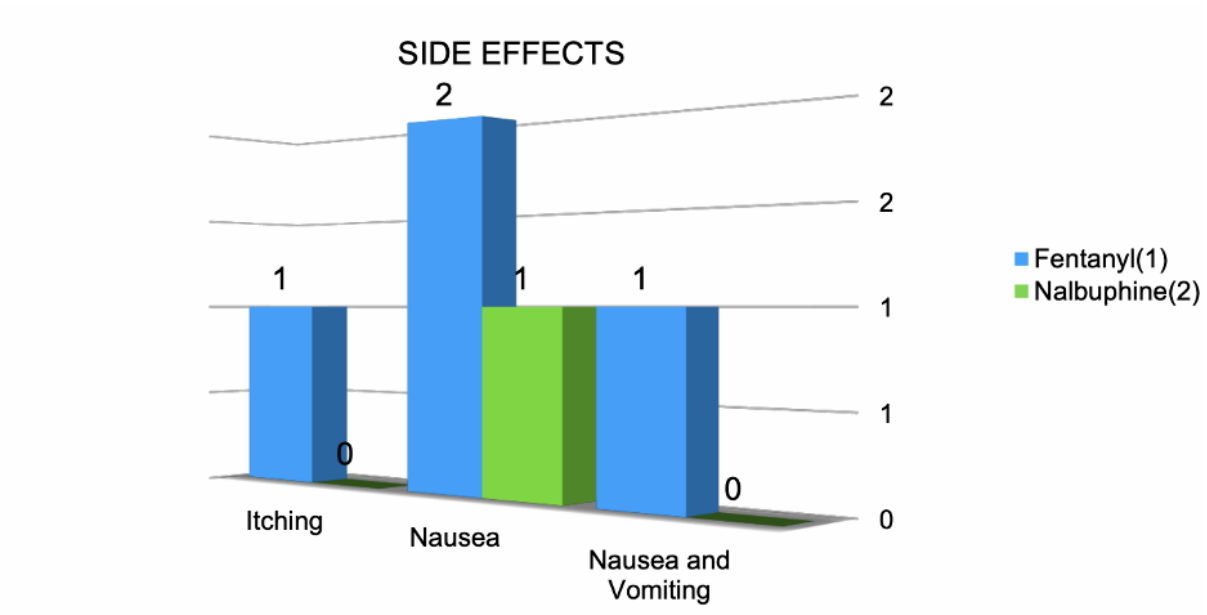
After 24 hours, the VAS score in Group 1 has a mean of 4.47 and an SD of 1.99, whereas Group 2 has a mean of 3.13 and an SD of 1.22, with a t value of 3.12. The VAS score was higher in the fentanyl group patients than in the nalbuphine group.

TABLE 8: COMPARISON OF SIDE EFFECTS

Side Effects	Fentanyl(1)	Nalbuphine(2)	Chi-Square value	P value
Itching	1	0	2.5	0.4
Nausea	2	1		
Nausea and Vomiting	1	0		

Using chi-square test

GRAPH 8: COMPARISON OF SIDE EFFECTS



In four cases in group 1, adverse symptoms such as itching, nausea, and vomiting were reported; one patient in group 2 experienced nausea. The chi-square value is 2.5, and the p-value is 0.4.

IV. Discussion

In comparison to general anaesthesia, regional anaesthesia is the most widely utilised technique. Several methods and pharmacological regimens have been used to improve the quality of spinal anaesthesia over the years [8].

Intrathecal local anaesthesia is used to provide an appropriate sensory and motor block. Because it combined properties of an acceptable onset, long duration of action, profound conduction blockade, and significant separation of sensory and motor blockade, bupivacaine, the most commonly used local anaesthetic, probably had the greatest influence on the practice of regional anaesthesia.

Adjuvants are typically mixed with 0.5% hyperbaric bupivacaine and injected intrathecally to prolong anaesthetic effect [9]. These adjuvants act on the dorsal horn level in the spinal cord and cause segmental blockade.

The opioid adjuvants allow early ambulation of the patient and prolonged postoperative analgesia due to their sympathetic and motor-sparing effect. They also lower the dose of local anaesthetics and decrease local anaesthetic toxicity. The commonest side effect of opioids is pruritus. Other side effects are nausea and vomiting, hypotension and shivering.

In our study, 60 patients were divided into two groups, and we have used 25 mcg fentanyl to 0.5% hyperbaric bupivacaine in one group and compared it with 0.5 mg nalbuphine to 0.5% hyperbaric bupivacaine in group 2 for assessing the intraoperative haemodynamics & postoperative analgesia as the primary endpoint and characteristics of sensory and motor blockade, intraoperative haemodynamic changes & side effects like nausea, vomiting, etc. as the secondary endpoints.

Culebras et al. [10] researched patients who were scheduled for elective caesarean births. A total of 90 healthy full-term patients were included. A comparison was made between intrathecal morphine (0.2 mg) and different doses of intrathecal nalbuphine (0.2 mg, 0.8 mg, and 1.6 mg) combined with hyperbaric bupivacaine. Intrathecal nalbuphine 0.8 mg gives good intraoperative and early postoperative analgesia with no side effects, according to this study.

In 2011, Mukherjee et al. [11] researched to determine the most effective dose of intrathecal nalbuphine as an adjuvant to subarachnoid block. Patients were assigned to one of four groups at random. Normal saline and 0.2 mg, 0.4 mg, and 0.8 mg of intrathecal nalbuphine, combined with 12.5 mg of hyperbaric bupivacaine 0.5%, were administered to each group. When administered as an adjuvant, intrathecal nalbuphine lengthens the duration of analgesia, with 0.4 mg being the most beneficial dose.

In our study, we have used 0.5 mg nalbuphine only, which was compared with 25 mcg fentanyl.

Alston et al. [12] conducted a double-blind trial and examined the effect of changing concentration and volume when delivered intrathecally to individuals in the sitting posture with solutions of 0.5 per cent or 0.75

per cent bupivacaine containing 8% dextrose. The smallest volumes (bupivacaine 10 mg) of both solutions had a significantly shorter duration of action than the higher volumes (15–20/22.5 mg), which demonstrated no significant differences.

In our study, we found that 0.5% hyperbaric bupivacaine 3 ml was used for a longer duration of action.

The present study revealed no statistically significant difference in the demographic data, which was comparable in both groups with respect to means of age, sex, height, weight and duration of surgery.

Padma et al. [13] conducted a study in 2015 to determine the efficacy of intrathecal nalbuphine as an adjuvant, as well as the efficacy and adverse effects of nalbuphine for postoperative analgesia. It was performed on 50 patients with ASA grades 1 and 2 who were scheduled for an elective lower limb surgery and were between the ages of 20 and 60. When used as an adjuvant intrathecally, it was discovered that nalbuphine gives a higher grade of blocking than hyperbaric bupivacaine alone, as well as extending postoperative analgesia.

The present study revealed no statistically significant difference in the demographic data, which was comparable in both groups with respect to means of age, sex, height, weight, and BMI (Table 1)

Jaideep Singh et al. [14] did a study in 2017 that compared 25 mcg of fentanyl and 0.8 mg of nalbuphine as an adjuvant to 0.5% hyperbaric bupivacaine and found that both groups had similar haemodynamic stability.

In our study, there was no significant change in SBP, DBP, MAP, or PR between the 2 groups of patients.

SPO2 was stable in both groups, and there was no significant hypoxia that occurred in either group. (graph 6)

Umesh N Prabhakaraiah et al. [15] conducted research comparing the postoperative analgesia & side effects of nalbuphine and fentanyl when used as an adjuvant to hyperbaric bupivacaine. Sixty patients with ASA I and II were divided into 2 groups of thirty patients each. Patients in the bupivacaine-nalbuphine group (Group BN) received 0.8 mg (0.3 ml) of nalbuphine mixed with 12.5 mg (2.5 ml) of 0.5% hyperbaric bupivacaine diluted to 3 ml, whereas those in the bupivacaine-fentanyl group (Group BF) got 25 mcg (0.5 ml) of fentanyl mixed with 12.5 mg. Haemodynamic alterations, sensory and motor block, early postoperative analgesia, and side effects were all evaluated in the patients. Both groups had similar onset, duration of sensory and motor block, and duration of effective analgesia. When administered as an adjuvant to hyperbaric bupivacaine, fentanyl was found to be more effective than nalbuphine in delivering early postoperative analgesia. The onset of motor block in Group BN was 2.53 +/- 1.28 minutes, but it was 2.40 +/- 1.22 minutes in Group BF, which was statistically insignificant (P = 0.688). Similarly, there was no significant difference between the 2 groups in terms of the highest motor block accomplished and the duration of the motor block; in Group BN, the maximum motor block was achieved in 5.80 +/- 2.48 minutes, whereas in Group BF, it was 5.40 +/- 2.42 minutes.

As per the above results in our study, the time of sensory and motor onset was similar in both groups. (Table 2)

The duration of the sensory block was significant, with the nalbuphine group having a p-value < 0.0001.

The duration of motor block is also prolonged, with the nalbuphine group having a p-value < 0.0001.

Singh N et al. (16) compared the duration of sensory and motor blockade, postoperative analgesia, and time of first rescue analgesia with intrathecal addition of nalbuphine and fentanyl with 0.5% bupivacaine heavy for lower abdominal surgeries, as well as the quality of perioperative anaesthesia and the incidence of side effects, complications, and sequelae. Group 1 received 0.6 mg of nalbuphine, group 2 received 30 mcg of fentanyl, and group 3 received 0.6 ml of normal saline as an adjuvant to 0.5% hyperbaric bupivacaine. In comparison to the control group, the duration of analgesia in both groups 1 and 2 was shown to be longer. However, group 1's analgesia lasted longer than group 2's. In both groups 1 and 2, the total number of rescue analgesics required in 24 hours was lower. The addition of nalbuphine to intrathecal bupivacaine results in a longer duration of sensory block and analgesia, as well as a lower need for analgesics in the postoperative period, with no increase in side effects or complications. Fentanyl, when added, provides all of these benefits, but to a lesser extent than nalbuphine.

In our study, group 1 participants required rescue analgesia 29 times, with a percentage of 54.7, while group 2 subjects required rescue analgesia 24 times, with a percentage of 45.3, indicating that the nalbuphine group patients required less rescue analgesia than the fentanyl group patients. (table 3, graph 1)

Rashmi Dubey et al. [17] compared the effects of intrathecal nalbuphine 0.5 mcg and normal saline 0.5 ml as adjuvants to hyperbaric 0.5% bupivacaine in a study published in 2014. In comparison to normal saline, it was discovered that nalbuphine gives a greater quality of block and prolongs postoperative analgesia

In our study, 24-hour VAS scores were better maintained in group 1 (fentanyl) patients when compared to group 2 (nalbuphine) patients.

Shraddha et al. [18] did a randomised clinical trial with a sample size of 60 adults in two groups of 30 each scheduled for lower abdominal & orthopaedic surgeries. Group 1 received 3 ml of hyperbaric bupivacaine 0.5% + 0.8 ml of nalbuphine (0.8 mg) intrathecally, whereas group 2 received 3 ml of hyperbaric bupivacaine 0.5% + 0.8 ml of normal saline intrathecally. The onset of sensory and motor blockade, regression time of sensory blockade, duration of motor blockade, analgesia, visual analogue scale (VAS) pain score & side effects were compared between the groups. Results showed the onset of sensory blockade was slower with an increased

duration of analgesia. Regression time of sensory blockade and duration of effective analgesia were prolonged in the study group with no significant side effects. It was concluded that improvement in the duration of sensory and motor blockade with minimal side effects was observed, thus proving that it is an effective intrathecal adjuvant for postoperative analgesia.

Our study also showed minimal side effects in the nalbuphine group. Though side effects like nausea and vomiting occurred in the fentanyl group, they were statistically insignificant, similar to a study done by Sharma et al. [19].

V. Conclusion

- The addition of nalbuphine as an adjuvant to bupivacaine provided a longer duration of sensory & motor blockade than fentanyl.
- The time of onset of the blockade was similar in both groups.
- The rescue analgesia time is longer with the nalbuphine group.
- Haemodynamics during the operative period were similar in both groups.
- The incidence of side effects was less in the nalbuphine group.

It was concluded that the addition of nalbuphine to bupivacaine for intrathecal anaesthesia has prolonged sensory and motor blockade, with increased duration for the requirement of rescue analgesia.

VI. Limitations Of The Study

- Our study sample is relatively small in size; hence, we cannot apply the results to the general population.
- Our study was conducted with a fixed-dose combination instead of a weight-based dosage.

There are no conflicts of interest regarding the current study.

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