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Original Research Article
To compare effect of Fentanyl and Nalbuphine as adjuvant to Bupivacaine in below umbilical surgeries in spinal anaesthesia: A randomised control trial

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ABSTRACT-

BACKGROUND- In spinal anaesthesia, opioids have been preferred as adjuvants to local anaesthetics. An effective adjuvant to local anaesthetics appears to be nalbuphine, a receptor agonist and antagonist. This study compared the effects of nalbuphine and fentanyl when administered as an adjuvant to bupivacaine during spinal anaesthesia in below umbilical surgeries in terms of postoperative analgesia and side effects.

MATERIALS AND METHODS- 100 patients belonging to the American Society of Anaesthesiologists Physical Status I and II were allocated into two groups of fifty each according to systematic sampling method, patient was allocated into 2 groups according to their IPD number in which Group A includes (odd IPD number) and were receiving fentanyl while Group B includes (even IPD number) and were receiving nalbuphine. Each group was given drug 0.5% Bupivacaine Heavy 3.5 ml along with adjuvant fentanyl 25 mcg to Group A and adjuvant nalbuphine 1 mg to Group B. Patients were assessed for hemodynamic changes, sensory and motor block, early postoperative analgesia, and adverse effects.

RESULTS- There are no significant differences in PR, SBP, DBP, MAP and SpO_2 of Fentanyl and Nalbuphine groups. Post SAB motor recovery shows no significant difference in both the groups using modified bromage scale. It was found that no significant difference was noted in adverse effect in both the groups. Both intrathecal nalbuphine and fentanyl are found to be effective adjuvants to bupivacaine in subarachnoid block. However, Nalbuphine has the longer duration of sensory recovery as compared to fentanyl.

CONCLUSION- Nalbuphine has the longer duration of sensory recovery as compared to fentanyl.

KEY WORDS- Bupivacaine, fentanyl, nalbuphine, spinal anaesthesia
STUDY DESIGN: Observational Study

1. INTRODUCTION

For the surgeries below umbilicus, subarachnoid block is considered the method of choice for its being a method which is easy to execute as well faster acting. Addition of other drugs to anesthetic agent for sub-arachnoid block improves quality and duration of sensory blockade and prolongs postoperative analgesia. Intrathecal opioids are synergistic with local anesthetics, thereby intensifying the sensory block without increasing sympathetic block.[1]
Spinal anesthesia is widely used in general orthopedic and general surgery and it has several benefits noted in the literature, including rapid onset, less intraoperative blood loss,

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thrombotic events, pulmonary complications, and postoperative cognitive dysfunction. [2-4] It also allows the patient to breathe spontaneously and reposition themselves to avoid compression injuries during the course of the procedure.[5]

Spinal anesthesia has the definitive advantage that profound nerve block can be produced in a large part of the body by the relatively simple injection of a small amount of local anesthetic.[6] Spinal anesthesia has the advantage of simplicity of technique, rapid onset of action and reliability in producing uniform sensory and motor blockade. Its main disadvantage relates to its limited duration of action and hence, lack of long lasting post-operative analgesia. To overcome this problem, administration of local anesthetics in combination with different adjuvants is an excellent technique which not only relieves postoperative pain but also refines the quality of sensory and motor blockade of subarachnoid block.

Recently, a growing body of evidence has suggested a beneficial role of different adjuvants in the analgesic efficacy of intrathecal anesthesia. [7,8] Neuraxial opioids provide equipotent analgesia to that of systemically administered opioids with smaller doses and concentrations; thus, it carries less risk of serious side effects. [9,10] Subarachnoid anesthesia is commonly employed for below umbilical surgeries, but it has the drawbacks of fixed duration of block. In recent years the use of intrathecal adjuvants has gained popularity with the aim of prolonging the duration of block and better success rate.

Longer duration of surgeries under spinal anesthesia needs adjuvant drugs to increase the duration of anesthesia. This study compares "Fentanyl and Nalbuphine" the two adjuvant drugs which can increase the duration of anesthesia with hemodynamic stability.

Fentanyl is an opioid which is soluble in lipid which is responsible for the rapid onset of action of the drug during the intrathecal injection. There have been multiple studies which have shown that fentanyl improves the duration of sensory anesthesia and postoperative analgesia without producing significant side effects.[11]

Nalbuphine when used as adjuvant to hyperbaric bupivacaine has also improved the quality of perioperative analgesia with fewer side effects. It is a mixed synthetic agonist antagonist which attenuates the μ-opioid effects and enhances the κ-opioid effects.[12] There is no documented report of neurotoxicity with nalbuphine.

2. MATERIAL AND METHODS

There are very few large studies that have compared intrathecal nalbuphine with intrathecal fentanyl added to hyperbaric bupivacaine in cesarean section. This led to design a randomized controlled study to compare the effects of intrathecal nalbuphine or fentanyl as adjuvants to bupivacaine in comparison to bupivacaine in 100 patients.

The aim of the present study is to compare effect of fentanyl and nalbuphine in prolonging the duration of spinal anesthesia as adjuvant to bupivacaine. Also, to assess the duration of spinal anesthesia when fentanyl is used as adjuvant and when nalbuphine is used as adjuvant and to compare the duration of spinal anesthesia of both drugs.

After obtaining clearance from the Institutional Ethical Committee, 100 patients of either gender undergoing elective lower abdominal surgeries, aged between 21 to 60 years, and patients' physical status American Society of Anaesthesiologists (ASA) Classes I and II were enrolled in this prospective, double-blind, randomized control study. The study was carried out from December 2018 to May 2020. Patients with known history of allergy to study drugs, who had infection at the site of subarachnoid block (SAB), bleeding disorder, patients on tranquilizers, hypnotics, sedatives, and other psychotropic drugs, and patients who fall under physical status ASA Grade III and above were excluded from this study. According to systematic sampling method, patient was allocated into 2 groups according to their IPD

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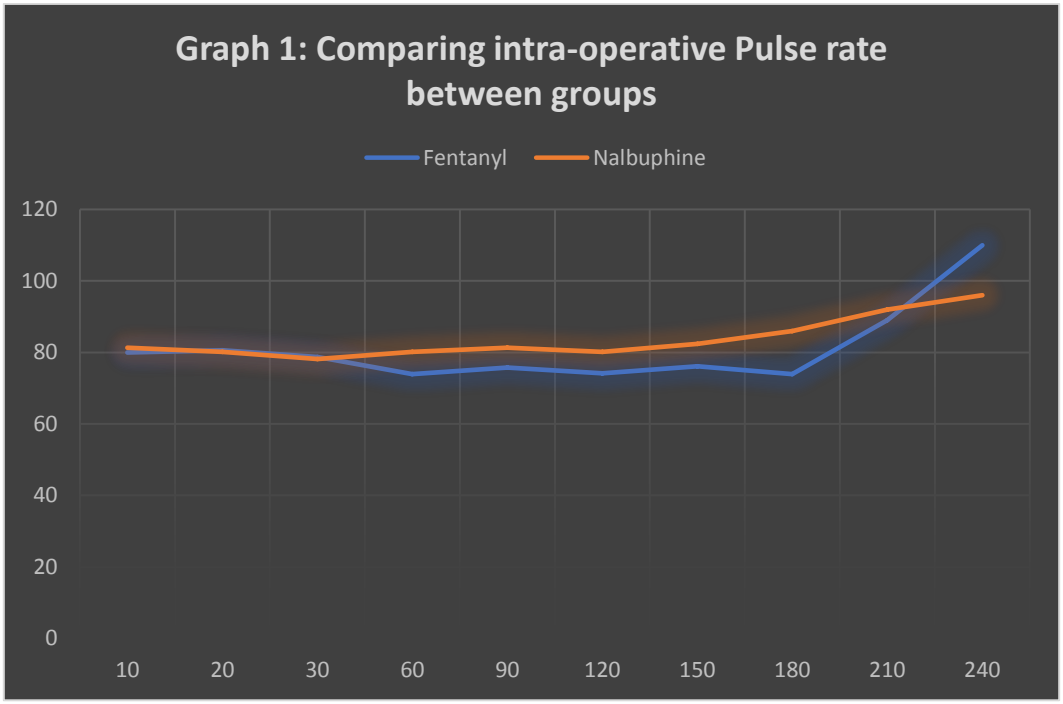
number in which Group A includes (odd IPD number) and were receiving fentanyl while Group B includes (even IPD number) and were receiving nalbuphine.
Premedication of patient was carried out with IV Ondansetron 0.06 mg/kg and IV Ranitidine 0.2 mg/kg and then preloaded with Ringer's lactate 10ml/kg over 15-20 minutes prior to procedure. Under aseptic precautions spinal anesthesia was administered at L3 – L4 interspace with 25-gauge Quincke's spinal needle. After free flow of CSF was obtained, each group was given drug 0.5% Bupivacaine Heavy 3.5 ml along with adjuvant fentanyl 25 mcg to Group A and adjuvant nalbuphine 1 mg to Group B.
The main aim of this study was to compare effect of fentanyl and nalbuphine in prolonging the duration of spinal anesthesia as adjuvant to bupivacaine.

3. RESULTS

In current study, majority of the patients in Fentanyl group had age between 31-40 years (n=23/50) and 41-50 years (n=10/50) whereas in Nalbuphine group majority had age between 41-50 years (n=20/50) followed by 51-60 years (n=15/50). Also, majority of patients in Fentanyl group were females (n=35/50) similarly in Nalbuphine group majority were females (n=31/50). In Fentanyl group, most common diagnosis was Fracture NOF (R) (n=8/50) followed by AUB (n=7/50), AVN Head of femur B/L (n=4/35) and 3^0 UV Prolapse with Cystocele with Polyp (n=6/50) whereas in Nalbuphine group most common diagnosis was AUB with Adenomyosis (n=7/50) followed by 2^0 UV Prolapse (n=6/50) and PCL Tear (R) Knee (n=6/50).
Most common procedure planned in Fentanyl group was TAH (n=22/50) followed by Bipolar hemiarthroplasty (n=10/50), similarly in Nalbuphine group most common procedure planed was TAH (n=16/50) followed by VH (n=8/50). Graph 1 shows the comparison of pulse between groups. It was found that there was no significant difference in pulse between both Fentanyl and Nalbuphine till 30 min, however a significant higher pulse rate was reported in Nalbuphine group as compared to Fentanyl at 60 (80.16±5.30 vs 74.04±12.12; p=0.001), 90 (81.32±6.95 vs 75.78±12.29; p=0.002), 120 (80.14±3.01 vs 74.16±13.13; p<0.001), 150 min (82.42±3.85 vs 76.16±10.23;p<0.001) and 180 min (85.94±6.48 vs 73.94±11.79;p<0.001).



Graph 2 shows the comparison of SBP between groups. It was found that there was no significant difference in SBP between both Fentanyl and Nalbuphine till 90 mins, however, at

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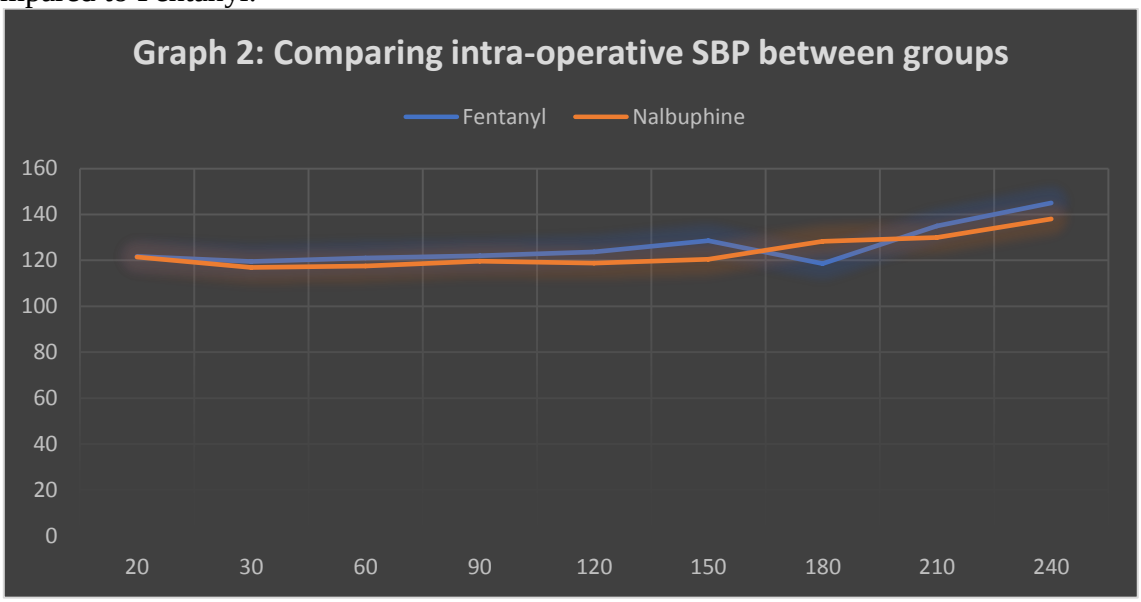
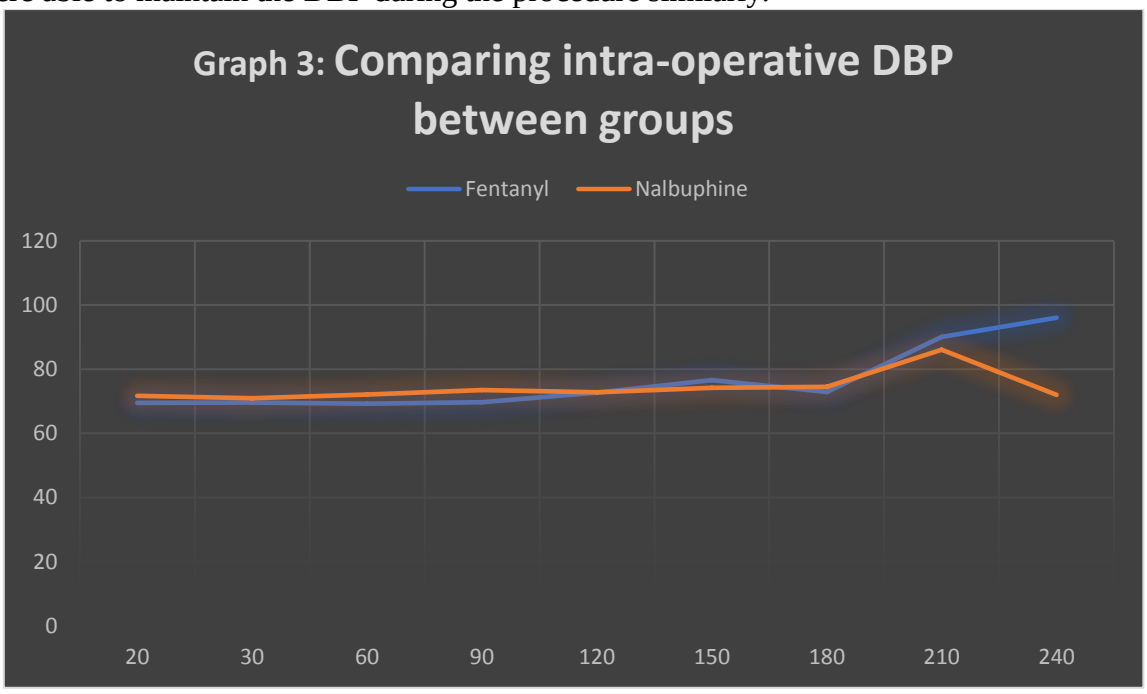
120 (123.70±7.95 vs 118.82±6.79;p=0.001) and 150 (128.63±11.38 vs 120.42±9.48;p<0.001) SBP was significantly higher in Fentanyl as compared to Nalbuphine group. However, at 150 min (118.59±8.71 vs 128.31±5.63;p<0.001) higher SBP was recorded in Nalbuphine group as compared to Fentanyl.



Graph 3 shows the comparison of DBP between groups. It was found that there was no significant difference in DBP between both Fentanyl and Nalbuphine across all the time line as revealed by the insignificant p value of >0.05. It can be concluded that both the drugs were able to maintain the DBP during the procedure similarly.



Graph 4 shows the comparing MAP between groups. It was found that there was no significant difference in MAP between both Fentanyl and Nalbuphine across all the time line as revealed by the insignificant p value of >0.05. It can be concluded that both the drugs were able to maintain the MAP during the procedure similarly.

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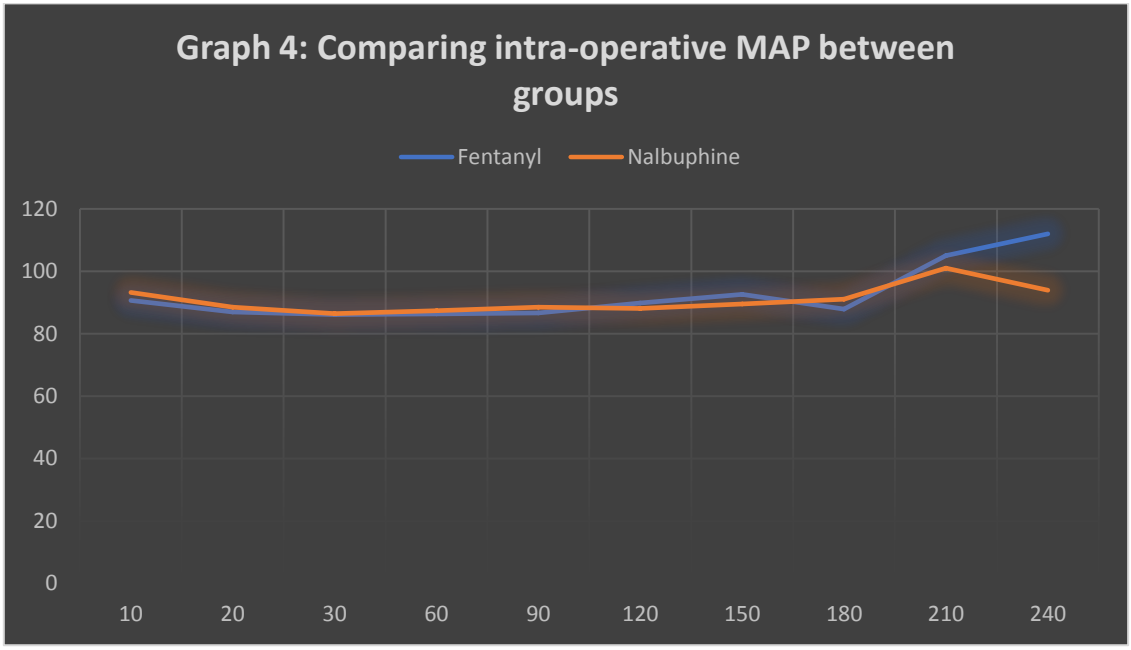

Table 1: Post SAB Sensory evaluation Response to pin prick-

Time (min)	Group		P value
	Fentanyl	Nalbuphine	
60	0	0	NA
120	0	0	NA
150	4	0	0.041
180	19	2	<0.001
210	43	34	0.032
240	45	40	0.248
270	47	42	0.442
300	50	50	NA

Table 1 shows the findings of post SAB sensory evaluation using pin prick. It was found that response to pin prick was started at 180 min in Nalbuphine group which was at 150 min in fentanyl group. Means Nalbuphine has the longer duration of sensory loss as compared to fentanyl.

Table 2: Post SAB motor evaluation Modified Bromage scale

		Group			
		Fentanyl	Nalbuphine	Total	P value
60	Mean	3.00	3.00	3.00	NA
	Std. Deviation	.000	.000	.000	
120	Mean	3.00	3.00	3.00	NA
	Std. Deviation	.000	.000	.000	
150	Mean	3.00	2.92	2.96	0.053
	Std. Deviation	.000	.274	.202	

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180	Mean	2.60	2.80	2.71	0.096
	Std. Deviation	.709	.404	.566	
210	Mean	2.08	2.00	2.03	0.672
	Std. Deviation	1.071	.571	.827	
240	Mean	.88	1.10	1.00	0.220
	Std. Deviation	.822	.886	.861	
270	Mean	.17	.32	.26	0.280
	Std. Deviation	.382	.741	.620	
300	Mean	.00	.16	.09	0.013
	Std. Deviation	.000	.370	.294	

Table 2 shows the post SAB motor evaluation using modified bromage scale. It was found that no significant difference was noted in motor nerve response in both the groups using modified bromage scale.

4. DISCUSSION

Intra and post-operative analgesia is one of the primary concerns for patients undergoing surgeries. It can cause distress to patients, hamper their well-being, and finally prolong their hospital stay. While for surgeons, it can result in a poor clinical outcome. There are myriad choices of pharmacological agents and techniques to choose for postoperative pain management. Following a surgery, approximately 10% of patients develop chronic post-surgical pain. Proper intraoperative pain control may improve their outcome. Based on the multimodal analgesia principle, the use of local anesthetic, regional anesthesia, and opioids are at the forefront of current intraoperative pain control.[13]

Local anesthetic like bupivacaine is commonly used in spinal anesthesia, but the duration of spinal anesthesia may be short and limited, and higher doses of rescue analgesics may be required in the postoperative period. This can be avoided by using higher doses of bupivacaine which again can produce cardiac toxicity. Studies have shown that duration of analgesia due to bupivacaine in spinal anesthesia can be prolonged by using adjuvants such as midazolam, opioids, neostigmine, dexmedetomidine, and clonidine. Almost all opioids have been used as adjuvants intrathecally.

Fentanyl and morphine have been the most preferred opioids. When used intrathecally along with local anesthetics, they prolong postoperative analgesic-sparing sympathetic action. Fentanyl is more lipid soluble than morphine which is more rapidly eliminated from cerebrospinal fluid. It provides dense blockade with complete intra- and postoperative analgesia without causing hemodynamic instability. It has relatively fewer side effects which are manageable and very well tolerated by the patients.

Nalbuphine has also been a part of anesthetic armamentarium as an adjuvant to local anesthetics. Nalbuphine is opioid μ-receptor antagonist and κ-receptor agonist. It has the potential to provide better intra- and postoperative analgesia with decreased incidence and severity of μ-receptor side effects.[14]

This randomised controlled trial was conducted to compare the effect of fentanyl and nalbuphine as adjuvant to bupivacaine in below umbilical surgeries in spinal anaesthesia.

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In present study, patients in Fentanyl group were aged between 31-40 years (n=23/50) and 41-50 years (n=10/50), whereas in Nalbuphine group majority were aged between 41-50 years (n=20/50) followed by 51-60 years (n=15/50). In both Fentanyl group (n=35/50) and in Nalbuphine group (n=31/50) majority were females. Deshmukh et al (2020) also recruited similar cohort of subjects where maximum numbers of patients were between the age group of 31 – 50 years. Male preponderance was observed, M: F in group Fentanyl group was 1.27: 1, and in Nalbuphine group it was 2.84: 1.[15]

In present study, no significant difference was found in pulse rate between both Fentanyl and Nalbuphine till 30 min, however a significant higher pulse rate was reported in Nalbuphine group as compared to Fentanyl at 60 (80.16±5.30 vs 74.04±12.12; p=0.001), 90 (81.32±6.95 vs 75.78±12.29; p=0.002), 120 (80.14±3.01 vs 74.16±13.13; p<0.001), 150 min (82.42±3.85 vs 76.16±10.23;p<0.001) and 180 min (85.94±6.48 vs 73.94±11.79;p<0.001). Similar study by Gomaa HM et al (2014) reported higher pulse rate at 30 min. Fentanyl (86) compared to Nalbuphine (83), but it got reversed at 60 mins where Fentanyl group average heart rate was 85, significantly lower than pulse rate of Nalbuphine group i.e. 89. Overall, there was no significant difference in the heart rate between group F and group N. [16] Deshmukh P et al in similar comparative study recorded that during the intra and postoperative period, there was no significant difference observed in the mean pulse rate and mean arterial pressure at various intervals in two groups [16]. Banerjee, et al. in similar comparative study did not found change in pulse rate in fentanyl and nalorphine groups.[17]

Kumar R et al, in similar study, compared Fentanyl and Nalbuphine. In their study, mean heart rate was not significantly different in between Group Fentanyl and Group Nalbuphine at baseline. The heart rates were comparable between the groups intraoperatively and post-operatively except 15 minutes and 300 minutes.[18]

Blood Pressure monitoring showed that there was no significant difference in SBP between both Fentanyl and Nalbuphine till 90 mins, however, at 120 (123.70±7.95 vs 118.82±6.79;p=0.001) and 150 (128.63±11.38 vs 120.42±9.48;p<0.001) SBP was significantly higher in Fentanyl as compared to Nalbuphine group. However, at 150 min (118.59±8.71 vs 128.31±5.63;p<0.001) higher SBP was recorded in Nalbuphine group as compared to Fentanyl.

Deshmukh P et al (2020) in similar comparative study of postoperative efficacy of Fentanyl and Nalbuphine also recorded no significant difference in mean preoperative systolic blood pressure (SBP), but the difference in mean SBP was statistically significant at the intervals of 20, 30, 50 and 60 minutes. At these occasions, the mean SBP was comparable in group Fentanyl and Nalbuphine. Observations at other intervals and an immediate postoperative period no significant differences were observed in mean SBP in two groups.[15] Kumar R et al also recoded that the mean SBP was comparable in between Group Fentanyl (127.30±12.67 mmHg) and Group Nalbuphine (121.87±13.18 mmHg) at baseline. The mean SBP were not significantly different in between the groups intraoperatively and postoperatively except at 2 hours, 3 hours and 330 minutes (p<0.05). [18] All the above-mentioned studies are line with the present findings.

Gupta K, et al (2016) reported that the mean HR and SBP at baseline with intraoperative changes were comparable and there was no statistically significant difference in HR, SBP, and SPO2 during intra- and post-operative periods between Fentanyl and Nalbuphine groups (P > 0.05). [19]

Present study found that there was no significant difference in DBP between both Fentanyl and Nalbuphine across all the time line as revealed by the insignificant p value of >0.05. It can be concluded that both the drugs were able to maintain the DBP during the procedure similarly. Kumar R et al observed that the mean DBP was comparable in between Group Fentanyl (74.87±10.03 mmHg) and Group Nalbuphine (72.97±8.34 mmHg) at baseline. The

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mean DBP were not significantly different in between the groups intraoperatively and postoperatively except 5 minutes, 10 minutes 90 minutes and 210 minutes ($p<0.05$). [18]
Mean arterial pressure (MAP) is the average arterial pressure throughout one cardiac cycle, systole and diastole. MAP is influenced by cardiac output and systemic vascular resistance, each of which is under the influence of several variables. MAP is a derived value and is important in relation to the auto regulatory responses of the heart, brain, and kidneys. In present study there was no significant difference in MAP between both Fentanyl and Nalbuphine across all the time line as revealed by the insignificant p value of >0.05. It can be concluded that both the drugs similarly affected the MAP during the procedure.
In present study sensory block was assessed by pinprick method and motor block by Modified Bromage Scale. The duration of sensory blockade was recorded in each patient. Post subarachnoid block (SAB) sensory evaluation using pin prick shows that response to pin prick was started at 180 min in Nalbuphine group which was at 150 min in fentanyl group. Means Nalbuphine has the longer duration of sensory loss as compared to fentanyl. Also, mean pin prick time was significantly lower in Nalbuphine group as compared to fentanyl as revealed by the highly significant p values. Similar observations were made by Karthick K et al (2017) where SAB sensory evaluation was done using pinprick. [20]
Duration of motor blockade (time required for motor blockade to return to Bromage's Grade 1 from the time of onset of motor blockade) was also noted.
On post SAB motor evaluation using modified bromage scale, present study found that no significant difference was noted in motor nerve response in both the groups using modified bromage scale. Similar comparative study by Bindra TK et al (2018) observed that the difference in the time of onset of sensory and motor block was statistically no significant (NS) among the groups ($P > 0.05$). The mean duration of sensory block was 108.46 ± 5.51 min in Group I (nalbuphine), 111.46 ± 6.49 min in Group II (fentanyl). The mean duration of sensory block was significantly higher ($P< 0.001$) in patients receiving nalbuphine than fentanyl group. The mean duration of motor block (time required for motor block to return to Bromage's Grade 1 from the time of onset of motor block) was 154.72 ± 5.89 min in Group I and 154.44 ± 5.24 min in Group II. The mean duration of motor block was significantly higher ($P< 0.001$) in Group I than group II patients. [21] Gomaa et al. compared intrathecal nalbuphine 0.8 mg and fentanyl 25 μg and found that there was no statistically significant difference in onset of sensory block between fentanyl (1.64 min) and nalbuphine (1.60 min) group. [16] Similar results were Naaz S et al (2017) where the duration of analgesia (in minute) was 441±119.69 in NL (0.8 mg of 0.5 ml nalbuphine) Group, 450±103.38 in NH (1.6 mg of 0.5 ml nalbuphine) Group and 300.0±88.53 in Group F (25 μg of 0.5 ml fentanyl). There was no significant difference regarding block characteristics and hemodynamic parameters. Total 24 hours analgesic requirement was titrated by analgesic score which was 2.25±0.7 (NH Group), 1.875±0.83 (NL Group) and 3.375±1.77 (F Group). The adverse effects of NL Group were least. [22] All these studies are in line with present study findings.
In medical college hospitals fentanyl is commonly used as spinal adjuvant. On comparing nalbuphine with fentanyl, the latter is costlier and needs narcotic licensing. Nalbuphine doesn't need narcotic licensing. This study have compared the analgesic efficacy of nalbuphine with fentanyl as well as the associated adverse effects. Hence, we have compared whether fentanyl or nalbuphine is a better additive for bupivacaine and it is nalbuphine.
There were few limitations of present study such as no control group and smaller sample size. There is need of large randomized clinical trial to provide strength to present study findings.

5. CONCLUSION

From the observations of present study, we conclude that there are no significant differences in PR, SBP, DBP, MAP and SpO_2 of Fentanyl and Nalbuphine groups. Post SAB motor

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recovery shows no significant difference in both the groups using modified bromage scale. It was found that no significant difference was noted in adverse effect in both the groups.
Both intrathecal nalbuphine and fentanyl are found to be effective adjuvants to bupivacaine in subarachnoid block. However, Nalbuphine has the longer duration of sensory recovery as compared to fentanyl.

CONFLICTS OF INTEREST-
There is no conflict of interest.

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