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Comparison among Intra-Thecal Fentanyl and Nalbuphine in Combination with Bupivacaine for Lower-Limb Surgeries.

Dr Deepti N Anandani (Assistant Professor), Dr Shahin S Pathan (Ex resident)
Dr Sejal D Shelat (Assistant Professor), Dr Manisha A Sharma (Resident)
Dr Swapnali S Suryawanshi Resident), Dr Kushal A Shah (Resident)
Dr Jaimin M Joshi (Resident), Dr Namrata Mehta (Resident)
Department of Anaesthesiology , NHL MUNICIPAL MEDICAL COLLEGE , VS HOSPITAL, AHMEDABAD, GUJARAT, INDIA

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I. Introduction

"For all the happiness mankind can gain, is not in pleasure, but in rest from pain."
-John Dryden

Alleviation of pain is one of the most fundamental goals in anesthesiology. Postoperative pain, apart from patient's suffering, has many other adverse physiological and psychological effects like respiratory depression, circulatory disturbances and metabolic stress responses induced by anesthesia and surgery.Thus, postoperative pain management plays a vital role in deciding the overall outcome of any surgery.

Subarachnoid block was introduced in 1885 by J. Leonard Corning. It was first used by Bier in 1898.

The concept of post-operative analgesia is gaining importance in recent times. Many adjuvants like opioids, adrenaline, ketamine, benzodiazepines, neostigmine have been used along local anaesthetic agents.[1,2,3,4,5]

Neuraxial administration of opioids in conjunction with local anaesthetics improves the quality of intraoperative analgesia and prolongs the duration of postoperative analgesia with minimal hemodynamic instability.

FENTANYL is a synthetic lipophilic opioid with a rapid onset of action. It acts on**μ**(mu) receptor (agonist) at supraspinal siteleading to analgesia.

NALBUPHINE, is a mixed agonist-antagonist opioid, has a potential to attenuate the μ-opioid effect and to enhance the **κ effects.** It was synthesized in an attempt to produce analgesia without the undesirable side effects of μ agonist like respiratory depression, pruritus,nausea, vomiting.

The purpose of this study was to compare potency of fentanyl and nalbuphine administered along with bupivacaine in the subarachnoid space to improve perioperative analgesia in patients undergoing lower limb surgeries.

II. Aims And Objectives:

The present study was designed to compare the effect of intrathecal bupivacaine 0.5% heavy 3.0 ml (15 mg) with fentanyl 0.5 ml (25μg) and bupivacaine 0.5% heavy 3.0 ml (15 mg) with 0.5 mL (0.8) mg nalbuphine with 0.9% normal saline to a total volume of 3.5mL in various lower limb surgeries (30 patient in each group).

- To compare the onset of sensory and motor block
- To compare the duration of sensory and motor block.
- To compare the duration of post operative analgesia.
- To compare peri-operative hemodynamic changes.
- To compare the peri-operative side effects and complications if any.

III. Material & Methods:

After obtaining consent from the ethical committee ,we conducted a study on 60 patients of ASA grade -I and II, age group between 20-60 years, who were admitted for lower limb surgeries. Patients were divided into two groups.

GROUP A: received 3 mL of 0.5% heavy bupivacaine (15 mg) + 0.5ml ofFentanyl(25 µg) to a total volume of 3.5mL.
GROUP B : received 3 mL of 0.5% heavy bupivacaine (15 mg)+ 0.5 mL of 0.8 mg Nalbuphine with 0.9% normal saline to a total volume of 3.5mL.

EXCLUSION CRITERIA:
- Patient refusal
- Patients with ASA III or IV
- Pre existing medical condition
- Pre existing neurological disease
- Patients with coagulopathy or on anti-coagulation.
- Uncooperative patient
- Local site infection
- Allergy to local anesthetic
- Patient having spine deformity.

STUDY PROTOCOL
PRE ANAESTHETIC ASSESSMENT:
• Detailed preoperative history and physical examination was done on the previous day of surgery.
• Procedure explained to the patient and explained about VAS score.
• Written informed consent was taken from the patients and his/her relatives.
• All routine pre-operative investigations were done.
• Patients advised to remain NBM for 6 hours prior to surgery.

IN THE OPERATION THEATRE:
• Intravenous line taken by large gauge intravenous canula and preloaded with10ml/ kg of Ringer's lactate solution before procedure.
• vital parameters were noted.
• No narcotic or sedative premedication was given to any patient.

TECHNIQUE:
• Under all strict aseptic and antiseptic precaution, with patient in sittingposition, lumbar puncture was performed at L2-L3 intervertebral space with23G Quincke needle and selected drug was given slowly. After completion ofprocedure, patient was immediately turned to supine position and time ofinjection of drug was noted.
• Pulse, BP and SpO2 were recorded at 2, 4, 6, 10, 15, 20, 30, 45 and 60 minutesafter giving spinal anaesthesia and then every 30 minutes till 240 minutes andthen frequently upto 720 minutes.

EVALUATION:
1. Sensory block was assessed by the loss of sensation to pinprick.Time for onset of sensory block was noted. Time to achieve sensory block at T10 dermatome and time for regression of sensory block to S2 dermatome were recorded.
2. Onset of grade 4 motor block and time for regression of motor blockade to grade 1 were noted.

Motor blockade was measured by bromage criteria

TABLE 1: Bromage Criteria[6]

Scale	Criteria	Degree of block
1	Free movement of legs and feet	Nil (0%)
2	Just able to flex knees with free movement of feet	Partial (33%)
3	Unable to flex knees with free movement of feet	Almost complete (66%)
4	Unable to move legs or feet	Complete (100%)

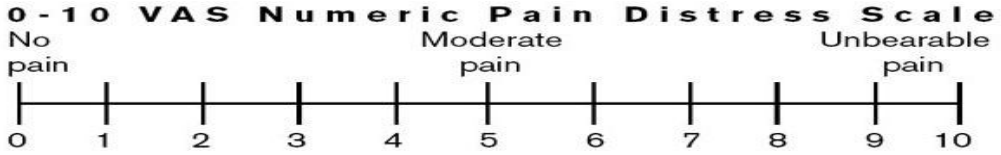
TABLE 2: Sedation Score- was measured by Ramsay Sedation Score(RSS)[7].

Grade 1	Anxious and agitated or restless, or both
Grade 2	Co-operative, oriented and tranquil
Grade 3	Responds only to verbal commands but awake
Grade 4	Asleep with brisk response to commands (light glabellar tap or loud auditory stimulus
Grade 5	Asleep with sluggish response to commands (light glabellar tap or loud auditory stimulus)
Grade 6	No response to auditory stimulus

After establishment of adequate level of block, surgery was started and duration of surgery was noted.

• No sedative or analgesic medication was used during perioperative period.
• Patients were observed for any intraoperative complications.
• Hypotension was defined as systolic blood pressure >20% decrease in baseline value and treated with an intravenous bolus of 6 mg of mephentermine and intravenous fluid.
• Bradycardia was defined as HR <60/mins and treated with 0.6 mg of intravenous atropine.
• Patients were inquired for the degree of pain they felt with the helpof visual analogue scale (VAS) and total duration of analgesia was noted.

LINEAR VISUAL ANALOG SCALE



Rescue analgesia was given in form of Inj. Diclofenac sodium 75 mg iv. When VAS score reached≥4.

STATISTICAL ANALYSIS

Statistical analysis was done. Data was expressed as mean, mean± SD and percentage. Data were compared using t test. The level of significance used was $p<0.05$.

IV. Observation &Results

TABLE 3: DEMOGRAPHIC DATA (MEAN ±SD).

		GROUP A	GROUP B
NO. OF PATIENTS		30	30
AGE (Years)		34.06±5.8	33.9±7.1
SEX (MALE /FEMALE)		17/13	14/16
ASA GRADE	1	18	20
	2	12	10
DURATION OF SURGERY		120.83±23.56	118.43±22.95

Table 3 shows There was insignificant difference between two groupswith regardsto age,sex ,ASA grade and duration of surgery.(P >0.05).

TABLE 4: PRE-OPERATIVE VITAL PARAMETERS

PARAMETERS	GROUP A	GROUP B
PULSE (BPM)	85.6±4.23	85.46±6.08
SYSTOLIC BLOOD PRESSURE (mm Hg)	129.93±4.50	130.2±3.25
DIASTOLIC BLOOD PRESSURE (mm Hg)	79.73±5.23	80.2±4.02
MEAN BLOOD PRESSURE (mm Hg)	96.86±5.24	96.9±3.10
SpO_2 %	98.93±0.444	98.73±0.58
RESPIRATORY RATE (/MIN)	13.8±0.92	13.9±1.28

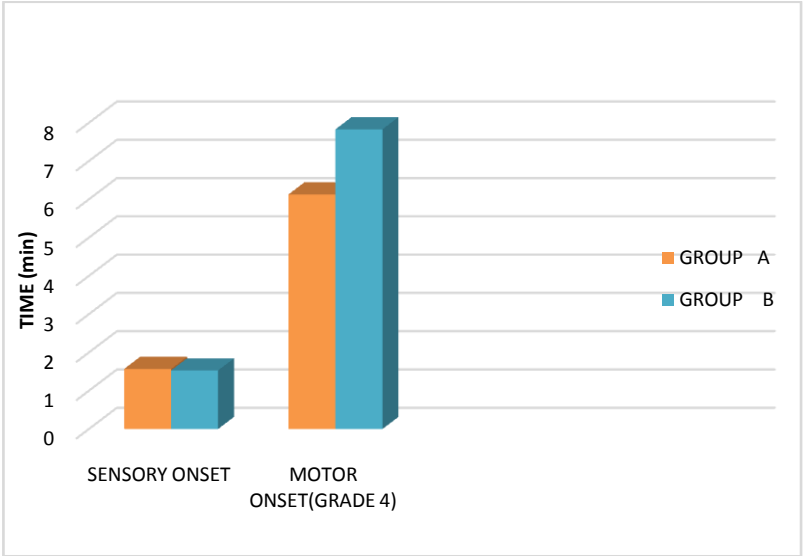
Table 4 shows that there was statistically insignificant difference between two groups with regards to preoperative hemodyanamic parameters (P > 0.05).

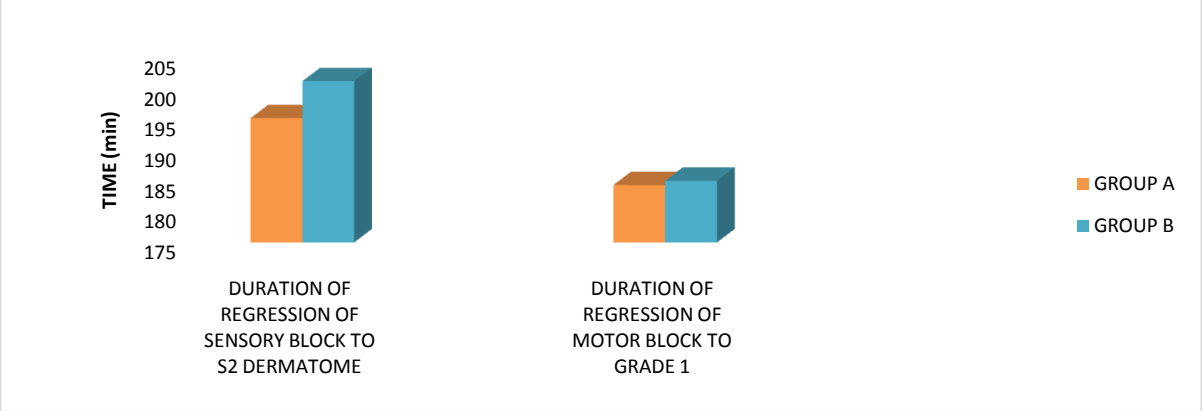
TABLE 5: CHARACTERISTIC OF SENSORY AND MOTOR BLOCKADE

PARAMETERS (MEAN±SD) (MIN)	GROUP A	GROUP B
ONSET OF SENSORY BLOCK	1.57±0.08	1.53±0.12
TIME TO ACHIEVE LEVEL OF SENSORY BLOCK AT T10 DERMATOME	4.36±0.41	4.55±0.46
DURATION OF REGRESSION OF SENSORY BLOCK	195.16±7.82	201.16±11.42

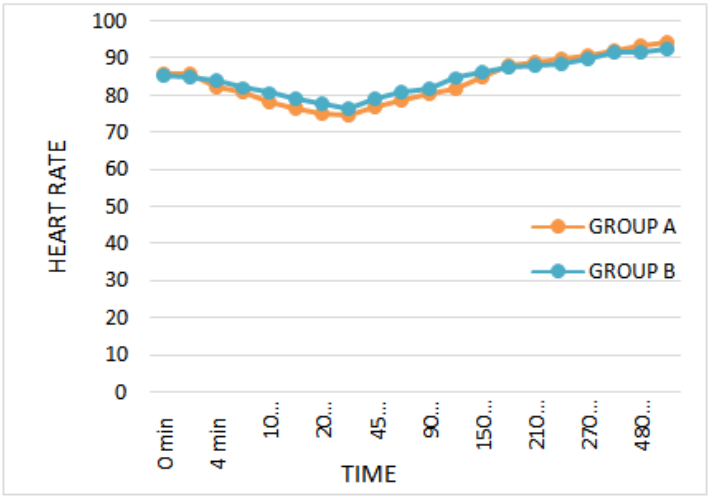
TO S2 DERMATOME		
ONSET OF GRADE 4 MOTOR BLOCK	6.13±0.58	7.83±0.53
DURATION OF REGRESSION OF MOTOR BLOCK TO GRADE 1	184.3±19.7	185±15.86

No statistically significant difference was found between both groups as regards to the onset of sensory block, Time to achieve sensory block at T10 dermatome and duration of regression of motor block to grade 1.($p > 0.05$)
There was statistically significant difference found in regression of sensory block to S2 dermatome, which was prolonged in GROUP B as compared to GROUP A.($p<0.05$)
There was statistically significant difference found in onset of grade 4 motor block, which was rapid in GROUP A as compared to GROUP B.($p<0.05$)



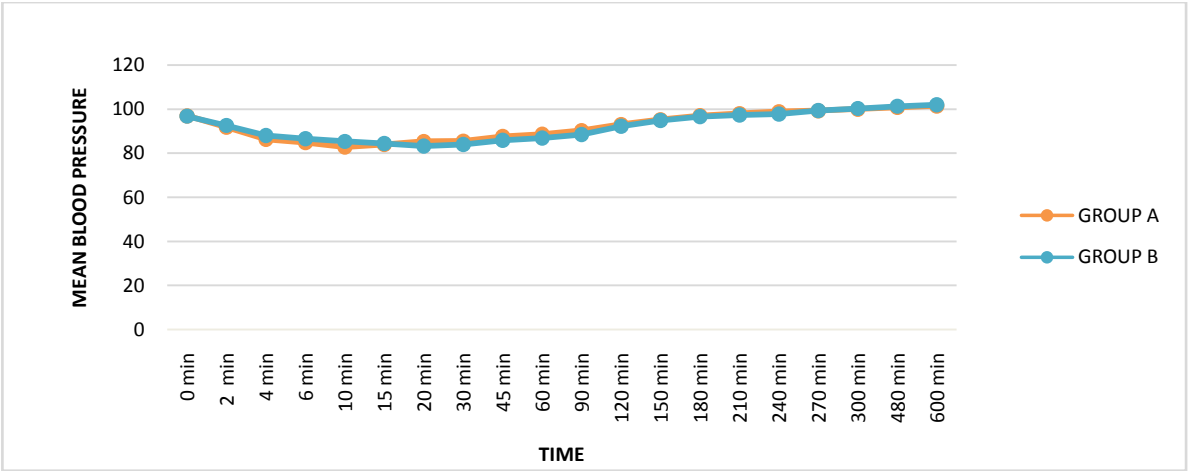


COMPARISON OF PERI-OPERATIVE HEART RATE Vs TIME

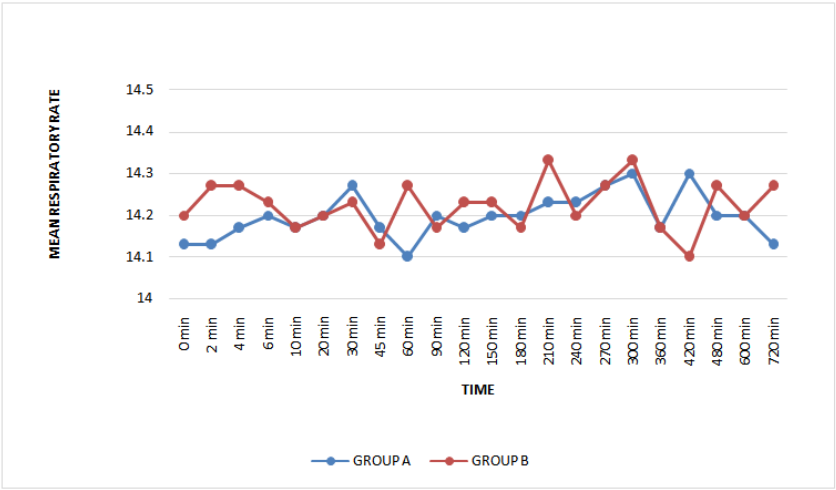


There was no statistically significant difference in perioperative heart rate betweentwo groups.(p>0.05).

COMPARISON OF PERI-OPERATIVE MEAN BLOOD PRESSURE VERSUS TIME



There was no statistically significant difference in perioperative mean blood pressure between two groups.(p>0.05).



There was no statistically significant difference in perioperative O2 Saturation between two groups. (p>0.05).

TABLE 6 : PERI-OPERATIVE COMPLICATIONS

COMPLICATION	GROUP A		GROUP B	
	INTRAOP	POSTOP	INTRAOP	POSTOP
NAUSEA/VOMITING	1(3.3%)	0	0	0
HYPOTENSION	2(6.6%)	0	1(3.3%)	0
BRADYCARDIA	0	0	0	0
RESPIRATORY DEPRESSION	0	0	0	0
PRURITUS	1(3.3%)	0	0	0
URINARY RETENTION	0	0	0	0
SHIVERING	0	0	0	0

Hypotension was noted in 2 patients of Group A and in 1 patient of Group B. Nausea-vomiting and pruritus was noted in 1 patient of Group A.

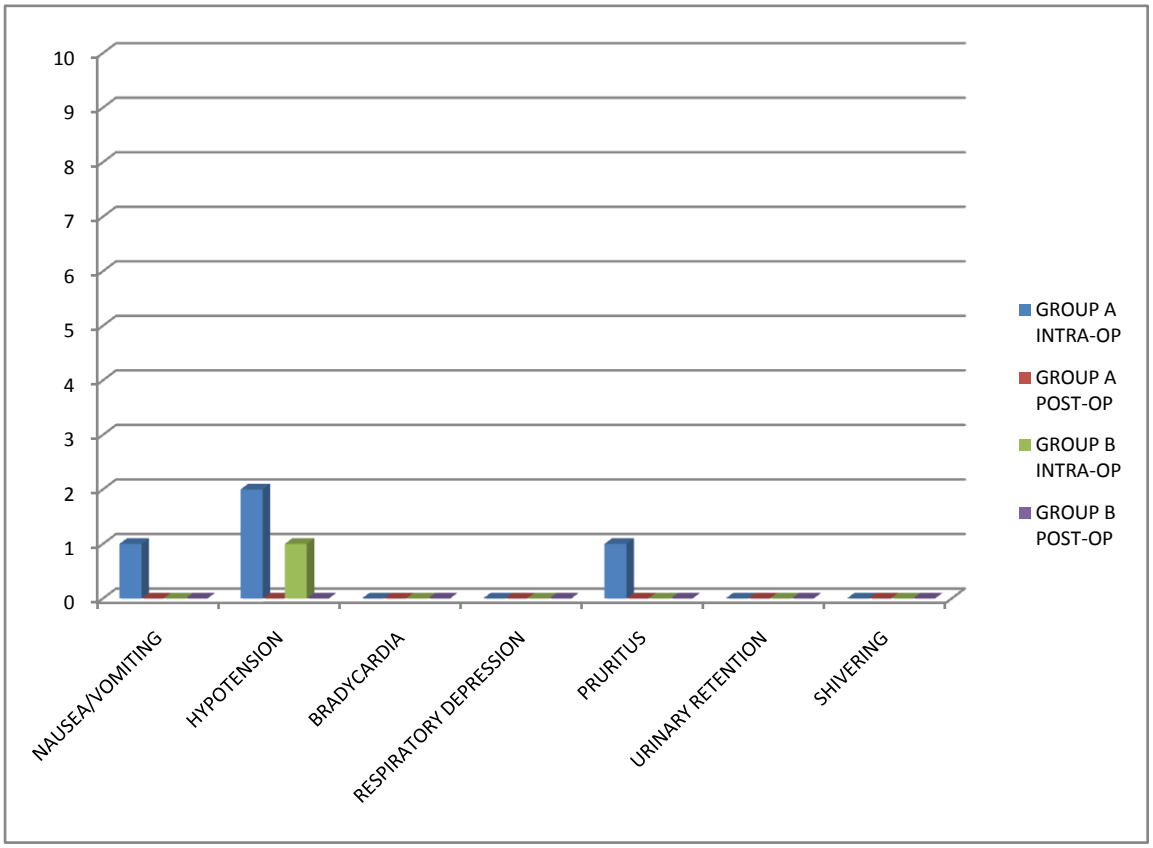


TABLE 7: SEDATION

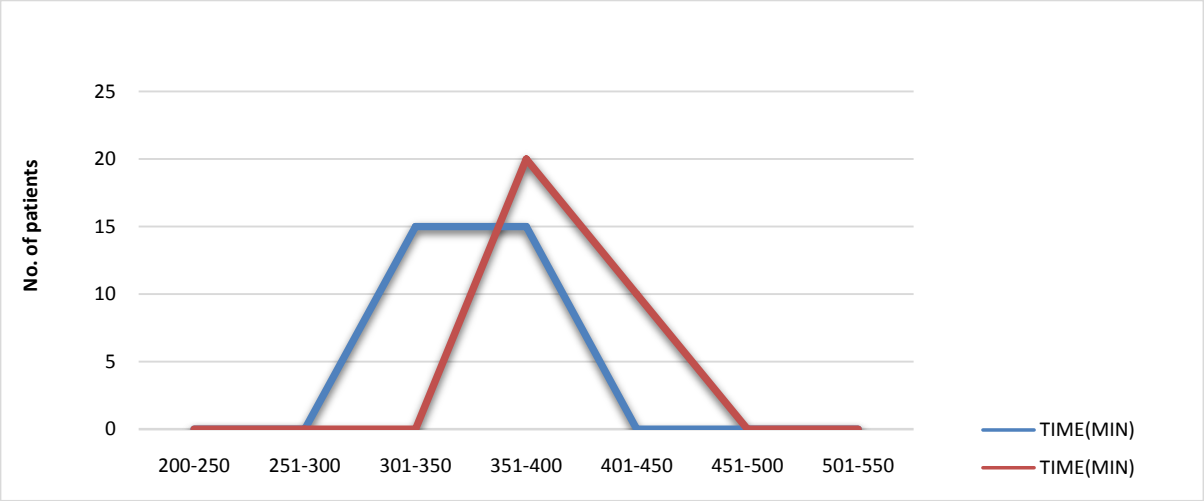
SCORE	GROUP A	GROUP B
1	4(13.3%)	2(6.6%)
2	24(80%)	25(83.33%)
3	2(6.6%)	3(10%)
4	0	0
5	0	0
6	0	0
TOTAL	30	30

TABLE 8: TOTAL DURATION OF ANALGESIA (min)

TIME(MIN)	GROUP A	GROUP B
200-250	0	0
251-300	0	0
301-350	15	0
351-400	15	20
401-450	0	10
451-500	0	7
501-550	0	0
MINIMUM TIME	320	360

MAXIMUM TIME	380	420
MEAN	350.3	393.66
SD	19.99853	17.11

Duration of analgesia was prolonged in GROUP B as compared to GROUP A.
(P<0.05)



V. Discussion

Neuraxialanesthesia greatly expands the anesthesiologist' armamentarium, providing alternative to general anesthesia when appropriate.In recent years, the use of intrathecal adjuvants has gained popularity, with the intention of reducing the dose of local anesthetics and improving analgesia during the postoperative period, and thus reducing the demand for postoperative rescue analgesics.

Fentanyl is commonly added to intrathecal bupivacaine.

Intrathecal (IT) nalbuphine produces a dose dependent anti-nociception when used alone or in combination with local anesthetics without the undesirable side-effects of a μ agonist like Fentanyl.

The aim of this study was to compare the effects of Fentanyl andNalbuphine added to hyperbaric bupivacaine for spinal anaesthesia. Our study consisted of 60 patients aged between 20-60 years, ASA physical status I, II undergoing lower limb surgeries. They were randomly divided into two groups after obtaining informed consent.

We selected 60 patients of ASA Grade 1 & 2 of 20-60 years of age and allocated in two groups:
GROUP A:received 3 mL of 0.5% heavy bupivacaine (15 mg) + 0.5ml ofFentanyl(25 μg) to a total volume of 3.5mL.
GROUP B :received 3 mL of 0.5% heavy bupivacaine (15 mg)+ 0.5 mL Nalbuphine(0.8 mg) with 0.9% normal saline to a total volume of 3.5mL.

DEMOGRAPHIC VARIABLES:
In our study Age,Sex,ASA Grading and Duration of surgery were comparable between two groups.(p>0.05).

PRE-OPERATIVE HEMODYNAMIC PARAMETERS:
There was no statistically significant difference found between two groups regarding pre-operative heart rate,blood pressure, spo_2 and respiratory rate.(p>0.05).

CHARACTERISTICS OF SENSORY BLOCKADE:
1. Onset of sensory blockade:
H Gomma et al[8] (2014) study found that there was no statistically significant difference between onset of sensory block between fentanyl(25 μg) and nalbuphine(0.8 mg) group.
RajeshMahajan et al[12],concluded that intrathecal fentanyl did not alter onset of bupivacaine sensory block.
In our study (Table 5) there was no statistically significant difference was present regarding the onset of sensory blockade as it was 1.57±0.08 min in Group A and 1.53±0.12 min in Group B (P>0.05).

2. Time to achieve sensory level at T10 dermatome:

Neelam et al[10](2017) study also found that all three groups fentanyl(30 µg)+bupivacaine, nalbuphine(0.6 mg)+bupivacaine, and bupivacaine were comparable with regards to time to achieve highest sensory level.

In our study (Table 5) there was no statistically significant difference was present regarding time to achieve sensory level at T10 dermatome as it was 4.36±0.41 min in Group A and 4.55±0.46 min in Group B (P>0.05).

3. Duration of regression of sensory block to S2 dermatome:

S. Naaz et al[13] (2017) study found that time to sensory regression to S1 dermatome was more in Nalbuphine (0.8 mg) group as compare to Fentanyl(25µg) group.

In our study (Table 6) there was statistically significant difference was present regarding duration of regression of sensory blockade to S_2 dermatome and it was 195.16± 7.82 min in Group A and 201.16 ± 11.42 min in Group B (P <0.05).

CHARACTERISTICS OF MOTOR BLOCKADE:

1. Onset of grade 4 motor block:

S.Naazet al[13](2017) study showed that time to reach complete motor block was more in nalbuphine(0.8 mg) group than fentanyl (25µg) group.

In our study (Table 5), there was statistically significant difference was present regarding time to achieve complete motor block as it was 6.13 ± 0.58 min in Group A and 7.83± 0.53 min in Group B (P <0.05).

2. Regression of motor block to grade 1:

S. Naaz et al[13](2017) study concluded that duration of motor block was comparable in Fentanyl, Nalbuphine(0.8 mg) and Nalbuphine(1.6 mg) group.

Neelam et al[10] (2017)found that there was no statistically significant difference regarding duration of motor block between three groups.

In our study (Table 5) there was no statistically significant difference found between duration of motor block (time to get regression of motor block to grade 1 from grade 4) as it was 184.3±19.7 min in group A and 185±15.86 in group B.(p>0.05).

COMPLICATIONS:

In S. Naaz et al[13](2017) study incidence of hypotension, pruritus, nausea vomiting, shivering, respiratory depression and urinary retention were more in Fentanyl (25µg) group as compare to Nalbuphine(0.8 mg) group.

In our study, hypotension was developed in 2 patients (6.6%) of group A and in 1 patient (3.3%) of group B. Incidence of nausea-vomiting noted in 1 patient (3.3%) of group A and not in Group B. Incidence of pruritus noted in 1 patient (3.3%) of group A and not in Group B.

There was no any incidence of bradycardia, respiratory depression, urinary retention and shivering noted in both the groups.

SEDATION:

In K Gupta et al[9] (2017) study concluded that there was negligible sedation by fentanyl (25 µg) and nalbuphine (2mg)which were beneficial for the patient to remain calm

In our study (Table 7), in group A, 4 patients (13.3%) show grade 1, 24 patients (80%) show grade 2 and 2 patients (6.6%) show grade 3 sedation score.In group B, 2patients (6.6%) show grade 1, 25 patients (83.33%) show grade 2 and 3 patients (10%) show grade 3 sedation score.

DURATION OF ANALGESIA:

In S. Naaz et al[13](2017) study, the duration of analgesia was more in NL group(nalbuphine 0.8 mg) 450± 109.38 min than F group(fentanyl 25µg) 300±88.53 min.

In our study (Table 8), there was statistically significant difference found regarding duration of analgesia as indicated by demand for first rescue analgesia in post-operative period between two groups, which was prolonged in GROUP B (393.66±17.11 min) as compared to GROUP A(350.3±19.99 min). (P<0.05).

VI. Conclusion

Addition of Nalbuphine to intrathecal hyperbaric bupivacaine is more efficient in prolonging the duration of sensory block and post operative analgesia as compared to fentanyl without any significant side-effects.

CONFLICTS OF INTEREST: NIL

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