

A Comparative study of hemodynamic alterations with nalbuphine and dexmedetomidine as an adjuvant to bupivacaine in epidural anaesthesia

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Abstract

Background: Epidural anaesthesia is the most sophisticated and effective mode of perioperative anesthesia and analgesia. It not only gives effective postoperative pain relief with multiple advantages but also gives hemodynamic stability. This study evaluates the hemodynamic effects of epidural administration of Nalbuphine and Dexmedetomidine as an adjuvant to Bupivacaine.

Material And Methods: 70 adult patients with age in the range of 18-50 years, posted for infra-umbilical and lower limb surgeries under epidural anaesthesia. Patients were divided into two groups of 35 each.

Group N: 15ml 0.5% Bupivacaine with Nalbuphine 250 mcg/kg epidurally (total volume 17ml).

Group D: 15ml 0.5% Bupivacaine with Dexmedetomidine 1 mcg/kg epidurally (total volume 17ml).

Results: The pulse rate was significantly lower in Dexmedetomidine group than Nalbuphine group at 120 min and 180 min ($p < 0.05$). The systolic blood pressure was significantly lower in Dexmedetomidine group than

Nalbuphine group from 10 min to 60 min ($p < 0.05$). The diastolic blood pressure and mean arterial blood pressure was significantly lower in Dexmedetomidine group than Nalbuphine group from 10 min to 120 min ($p < 0.05$).

Conclusion: We conclude that, Nalbuphine and Dexmedetomidine can be safely administered as an adjuvant to Bupivacaine in epidural anaesthesia for lower limb surgeries as the patients remained hemodynamically stable throughout the study period.

Keywords: Dexmedetomidine, Nalbuphine, Bupivacaine, Hemodynamics, Epidural Anesthesia.

Introduction

Epidural techniques are widely used for surgical anesthesia, obstetric analgesia, post-operative pain control and chronic pain management. Epidurals can be used as a single shot technique or with a catheter that allows intermittent boluses and / or continuous infusion⁽¹⁾. Epidural anesthesia is an excellent measure to provide anesthesia and post-operative pain relief. It causes intra-operative hemodynamic stability with less stress response causing reduced complications and better patient outcome⁽²⁾. Bupivacaine is the most common

local anesthetic used in neuroaxial blocks. Bupivacaine is a long acting local anesthetic, commonly used in the epidural route for surgical anesthetic and post-operative pain control. But, it is associated with cardio-toxicity and neuro-toxicity. Addition of additives along with local anesthetic agent is commonly used to prolong the duration and improve quality of blockade. Commonly used additives are opioids (Nalbuphine⁽³⁾, Fentanyl⁽⁴⁾, Buprenorphine⁽⁵⁾), Ketamine⁽⁶⁾, Midazolam⁽⁷⁾, alpha 2-adrenergic agonists like Clonidine⁽⁸⁾ and Dexmedetomidine⁽⁸⁾ have been used with Bupivacaine. Nalbuphine is an opioid with mixed kappa agonist and mu antagonist properties. Its action on kappa receptors causes good sedation and partial agonism on mu receptors induces a ceiling effect on respiratory depression.⁽³⁾ Dexmedetomidine is selective alpha 2 adrenergic agonist eight times more selective towards alpha-2 adrenoreceptor. It has analgesic, sedative, anxiolytic, neuroprotective and anesthetic sparing effects with better hemodynamic stability. It causes conscious sedation. ⁽⁹⁾ There is limited literature regarding hemodynamic alteration following epidural administration of Nalbuphine and Dexmedetomidine along with Bupivacaine. Hence, this study was planned for hemodynamic assessment following epidural administration of Nalbuphine and Dexmedetomidine.

Material and Methods

The present prospective, observational study was conducted in the Department of Anaesthesiology at a tertiary care center to assess and compare hemodynamic alterations with the use of Nalbuphine and Dexmedetomidine as an adjuvant to Bupivacaine in epidural anaesthesia.

70 adult patients with age in the range of 18-50 years, posted for infra-umbilical and lower limb surgeries under epidural anaesthesia were included in the study only after

obtaining a written informed consent and approval from Institutional Ethics Committee.

Inclusion criteria's were patient belonging to American Society of Anesthesiologist (ASA) Grade I & II, age 18-50 years, Height 150-170 cm, Weight 40-80 kg and willing to undergo surgery under regional anaesthesia.

Exclusion criteria were Patients refusal, ASA Grade III & IV, Contraindications to epidural anaesthesia, History of seizure disorder and neurological disease, History of cardiovascular diseases, Liver, Respiratory, Kidney and Endocrine diseases.

After detailed pre-anaesthetic evaluation, 70 patients satisfying the inclusion and exclusion criteria were included in the study. Preliminary Investigations in the form of Complete blood count, RBS, BTCT, CP, LFT, KFT, ECG, Chest x ray postero-anterior (PA) view were noted. All patients were kept nil by mouth for 8 hrs.

Before surgery, written informed consent was taken from the patient after explaining about the procedure, technique, pain score and was assured that any pain, anxiety or discomfort, during surgery would be treated effectively. All patients were given overnight sedation in the form of Tab. Diazepam 5 mg orally a day prior to surgery.

In operation theatre, multipara monitoring device with ECG, pulse rate, noninvasive blood pressure, SPO2 was attached to the patient and baseline parameters were noted. Co-loading with 10 ml/kg body weight of intravenous Ringer lactate was done after establishing intravenous line with 18 G cannula, 10 to 15 minutes before the block. Thereafter, intravenous fluids were calculated and given as per body weight and operative loss. Patients were premedicated with Inj. Pantoprazole 40 mg and Inj. Ondansetron 4 mg IV slowly.

Under all aseptic precautions, with patient sitting skin over the desired site was infiltrated with 2 ml of 2%

Lignocaine. Epidural space at L2-L3 or L3-L4 interspaces was located using loss of resistance technique using 18G Tuohy needle with midline approach. Epidural catheter, 18 gauge, placed at about 3 cm in epidural space and catheter fixed. Patient was then made supine.

The test dose of 3ml inj. Lignocaine with adrenaline (1:2,00,000) was administered after exclusion of blood in the epidural catheter with negative aspiration. After 5 minutes of administering test dose, patients were given drug epidurally.

Group N: 15 ml Bupivacaine (0.5%) with Nalbuphine 250 mcg/kg epidurally (total volume 17 ml).

Group D: 15 ml Bupivacaine (0.5%) with Dexmedetomidine 1mcg/kg epidurally (total volume 17 ml).

Intra operatively all patients were monitored for: Heart rate (HR), Blood pressure (systolic, diastolic and mean), Respiratory rate, SPO₂.

The pulse rate, RR, NIBP, SPO₂ were monitored continuously. Recordings were done every 5 minute until 30 min, every 10 min until 2 hours and every 30 minute thereafter till the completion of surgery.

Intra-operatively and postoperatively, bradycardia with heart rate <60 beats per minute if occurred, was to be treated with 0.3mg Inj. atropine and hypotension (systolic blood pressure falling more than 20% basal value or less than 80mm Hg) with 3-6mg injection mephenteramine as a bolus. Respiratory depression (SpO₂ < 90% or Respiratory rate < 8 breaths/minute) if any was to be treated by administration of 100% O₂ with face mask or ventilation with IPPV accordingly.

During surgical procedure & postoperatively adverse

effects like hypotension, bradycardia and fall in SPO₂ were monitored and treated accordingly. Monitoring was continued in the postoperative period every 6 hourly for 24 hours in recovery room.

Statistical Analysis

Data were collected, tabulated and analyzed using SPSS ® computer software version 20.0. Numerical variables were presented as mean & standard deviation (SD). As regard numerical variables; unpaired student – t test was done. p value

>0.05	Non-Significant
<0.05	Significant
<0.001	Highly Significant

Results

70 adult patients included in the study were compared with respect to age, weight, height and duration of surgery. The mean (SD) age of patients in Nalbuphine group was 30.57(±8.23) years and in Dexmedetomidine group was 30.77(±8.09) years. The mean (SD) weight of patients in Nalbuphine group was 55.63(± 7.63) and in Dexmedetomidine group was 55.23(±6.40) Kg. The mean height (SD) of patients in Nalbuphine group was 167.69(± 4.48) and in Dexmedetomidine group was 167.03(±4.33). In Nalbuphine group 31(88.6%) patients were males and 4(11.4%) patients were females. In group Dexmedetomidine 32 (91.4%) patients were males and 3 (8.6%) patients were females. Majority of the patients in both groups were male. The mean (SD) duration of surgery in Nalbuphine group was 123.43 (±33.95) min and in Dexmedetomidine group was 116.57 (±33.95). The two groups were comparable with respect to age, height, weight, ASA and duration of surgery(P>0.05).

TABLE 2: MEAN (±SD) PULSE RATE ALTERATIONS IN NALBUPHINE GROUP:

Groups	Basal	10 min	20 min	30 min	40 min	60 min	120 min	180 min	6 hrs	12 hr	18 hr	24 hr
Group N	80.06 ± 9.25	81.77 ± 8.68	79.06 ± 10.97	79.06 ± 9.44	77.68 ± 10.52	77.714 ± 11.72	82.31 ± 12.57	82. 80± 6.98	81.26 ± 3.74	80.31 ± 2.74	80.57 ± 3.09	80.37 ± 2.72
P value		0.119 (NS)	0.454 (NS)	0.423 (NS)	0.080 (NS)	0.148 (NS)	0.500 (NS)	0.935 (NS)	0.383 (NS)	0.872 (NS)	0.739 (NS)	0.850 (NS)

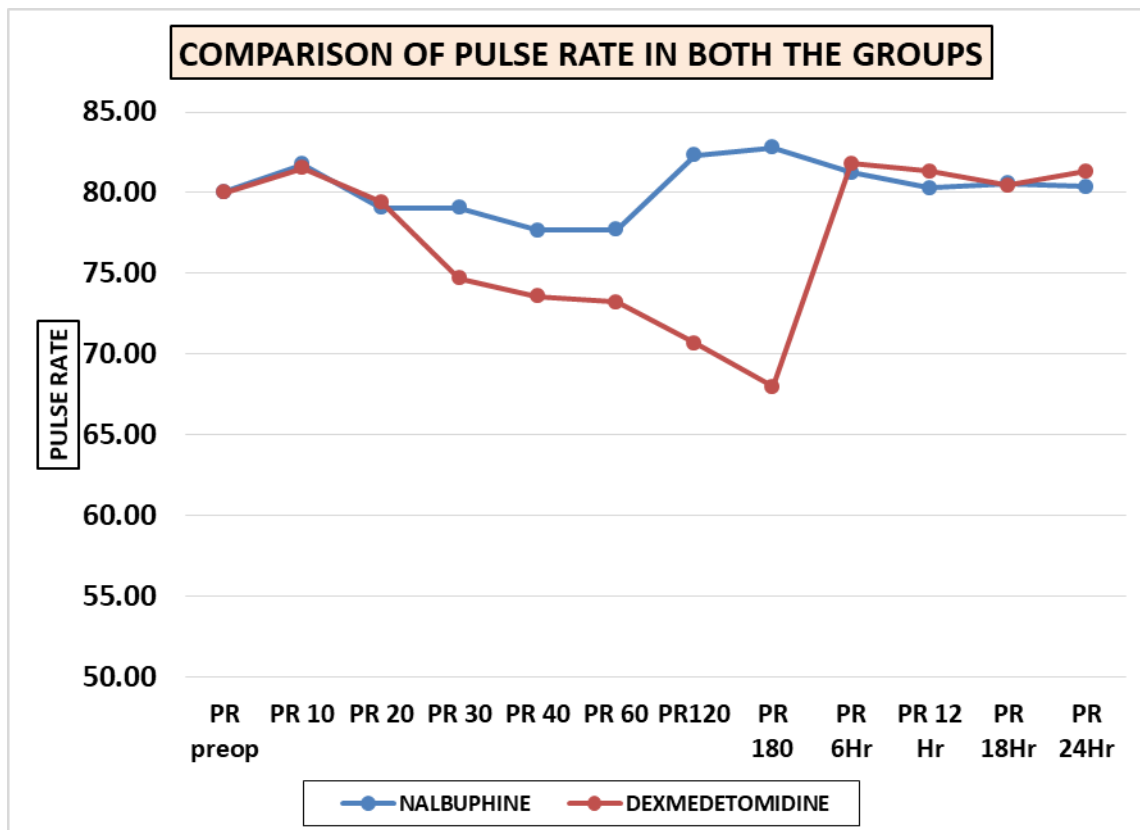
There was no significant change in pulse rate in Nalbuphine group in the study period.

TABLE NO.3- MEAN (±SD) PULSE RATE ALTERATIONS IN DEXMEDETOMIDINE GROUP:

Group	Basal	10 min	20 min	30 min	40 min	60 min	120 min	180 min	6 hrs	12 hr	18 hr	24 hr
Group D	80.00 ± 8.97	81.54 ± 8.82	79.43 ± 10.34	74.68 ± 10.97	73.57 ± 9.86	73.23 ± 10.75	70.67 ± 7.35	68.00 ± 5.66	81.80 ± 4.50	81.34 ± 3.89	80.46 ± 3.69	81.34 ± 3.14
P value		0.161 (NS)	0.638 (NS)	0.001 (HS)	0.000 (HS)	0.000 (HS)	0.000 (HS)	0.795 (NS)	0.146 (NS)	0.364 (NS)	0.756 (NS)	0.441 (NS)

There was significant fall in the pulse rate from 30 minutes to 120 minutes in Dexmedetomidine group.

LINE DIAGRAM 1: MEAN PULSE RATE CHANGES BETWEEN THE GROUPS:



On intergroup comparison, the pulse rate was significantly lower in Dexmedetomidine group than Nalbuphine group at 120 min and 180 min(p<0.05). Fall in the heart rate was never < 60 beats per minute.

TABLE 4: MEAN (±SD) SYSTOLIC BLOOD PRESSURE (SBP) ALTERATIONS IN NALBUPHINE GROUP:

Groups	Basal	10 min	20 min	30 min	40 min	60 min	120 min	180 min	6 hrs	12 hr	18 hr	24 hr
group N	25.46 ± 1.86	22.48 ± 1.78	21.94 ± 2.45	17.83 ± 1.14	18.88 ± 1.19	15.20 ± 1.22	16.53 ± 1.77	33.00 ± 1.24	25.46 ± 1.76	25.34 ± 1.52	26.37 ± 1.92	24.31 ± 1.55
P value		0.224 (NS)	0.254 (NS)	0.004	0.011	0.002	0.000	0.161 (NS)	1.00 (NS)	0.944 (NS)	0.663 (NS)	0.625 (NS)

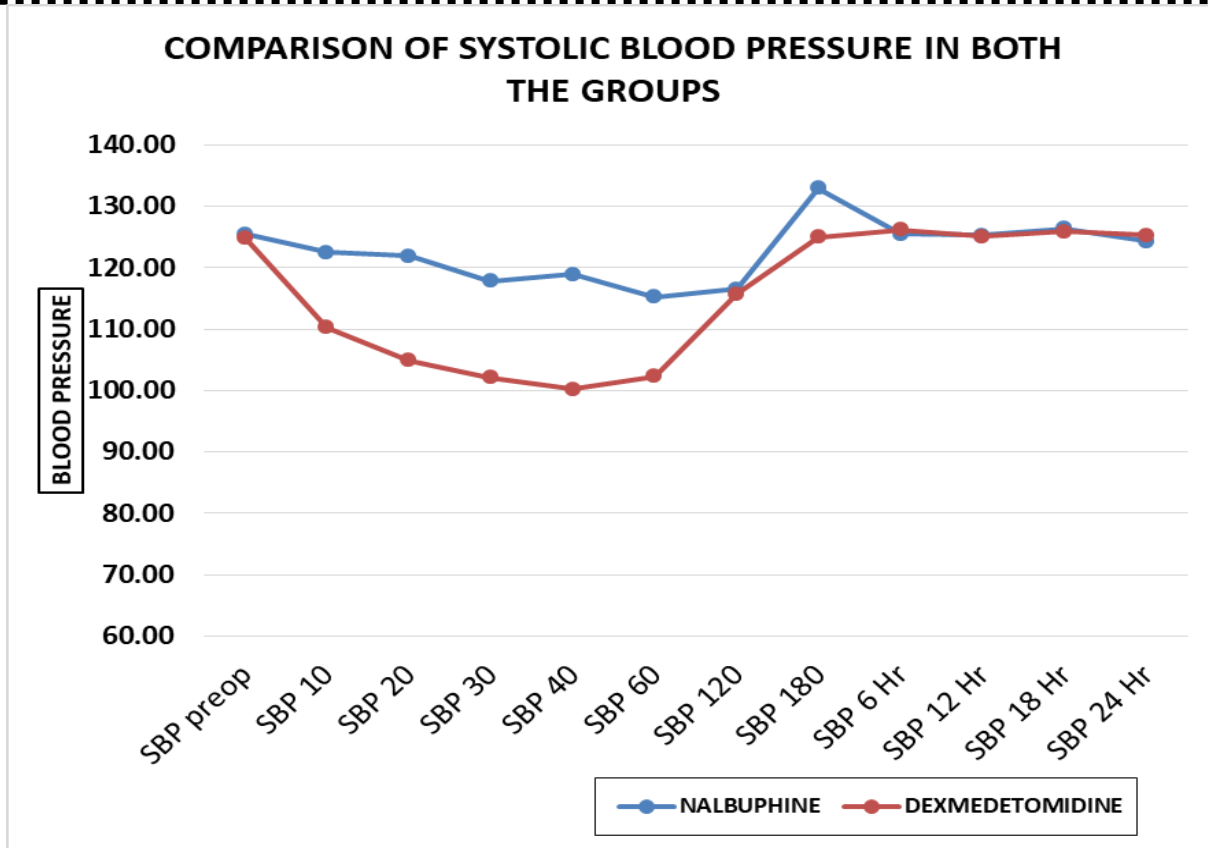
There was significant fall in the systolic blood pressure from 30 minutes to 120 minutes in Nalbuphine group(p<0.05).

TABLE 5: MEAN (±SD) SYSTOLIC BLOOD PRESSURE (SBP) ALTERATIONS IN DEXMEDETOMIDINE GROUP:

Group	Basal	10 min	20 min	30 min	40 min	60 min	120 min	180 min	6 hrs	12 hr	18 hr	24 hr
Group D	124.91±1 2.33	110.23± 13.97	104.94±1 1.55	102.08±9. 13	100.26±8. 71	102.26±8. 51	115.72±4. 67	125.00±7. 07	126.23±5. 87	125.08±5. 65	125.88±6. 75	125.26±5. 15
P value		0.000	0.000	0.000	0.000	0.000	0.007	0.242 (NS)	0.422 (NS)	0.919 (NS)	0.662 (NS)	0.87 7 (NS)

There was significant fall in the systolic blood pressure from 10 minutes to 120 minutes in Dexmedetomidine group.

LINE DIAGRAM 2: SHOWING COMPARISON OF MEAN (±SD) SYSTOLIC BLOOD PRESSURE (SBP) CHANGES BETWEEN THE GROUP



On intergroup comparison, the systolic blood pressure was significantly lower in Dexmedetomidine group than Nalbuphine group from 10 min to 60 min ($p < 0.05$).

TABLE 6: MEAN (\pm SD) DIASTOLIC BLOOD PRESSURE (DBP) ALTERATION IN NALBUPHINE GROUP:

Group	Basal	10 min	20 min	30 min	40 min	60 min	120 min	180 min	6 hrs	12 hr	18 hr	24 hr
Group N	78.57 \pm 9.09	73.91 \pm 10.65	73.31 \pm 10.83	73.43 \pm 10.69	72.08 \pm 10.23	72.51 \pm 10.12	72.47 \pm 8.59	79.50 \pm 4.95	78.77 \pm 4.95	78.31 \pm 4.35	78.86 \pm 4.22	78.34 \pm 4.41
P value		0.002	0.001	0.001	0.000	0.001	0.000	0.141 (NS)	0.885 (NS)	0.884 (NS)	0.856 (NS)	0.876 (NS)

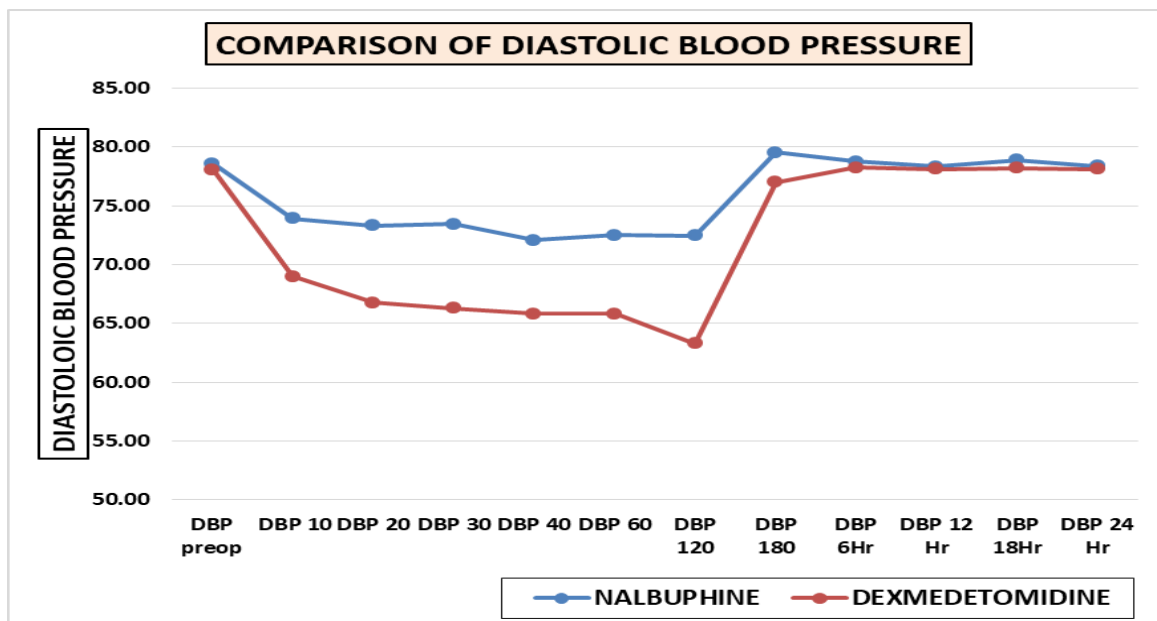
There was significant fall in the diastolic blood pressure from 10 minutes to 120 minutes in Nalbuphine group.

TABLE 7: MEAN (±SD) DIASTOLIC BLOOD PRESSURE (DBP) ALTERATION IN DEXMEDETOMIDINE GROUP

group	Basal	10 min	20 min	30 min	40 min	60 min	120 min	180 min	6 hrs	12 hr	18 hr	24 hr
Group D	78.06±6.5 5	68.97±8.6 6	66.74±7.3 3	66.28±5.6 3	65.80±5.2 5	65.83±4.9 4	63.29±1.9 6	77.00±1.4 1	78.23±3.8 5	78.08±4.4 7	78.20±3.9 8	78.11±4.8 7
P value		0.000	0.000	0.000	0.000	0.000	0.000	0.205 (NS)	0.853 (NS)	0.978 (NS)	0.887 (NS)	0.955 (NS)

There is significant fall in the diastolic blood pressure from 10 minutes to 120 minutes in Dexmedetomidine group.

LINE DIAGRAM 3: MEAN (±SD) DIASTOLIC BLOOD PRESSURE (DBP) CHANGES BETWEEN THE GROUPS:



On intergroup comparison, the diastolic blood pressure was significantly lower in Dexmedetomidine group than Nalbuphine group from 10 min to 120 min ($p < 0.05$).

TABLE 8: MEAN ARTERIAL PRESSURE (MAP) ALTERATION IN NALBUPHINE GROUP :

group	Basal	10 min	20 min	30 min	40 min	60 min	120 min	180 min	6 hrs	12 hr	18 hr	24 hr
group N	94.20±9 .71	90.10±1 2.24	89.52±1 3.35	88.22±1 2.55	87.68±1 2.29	86.74±1 1.78	87.17±9 .16	97.33±4 .71	94.33±4 .75	93.99±2 .92	94.69±2 .89	93.67±4 .00
P value		0.009	0.015	0.001	0.000	0.001	0.000	0.050 (NS)	0.915 (NS)	0.895 (NS)	0.755 (NS)	0.738 (NS)

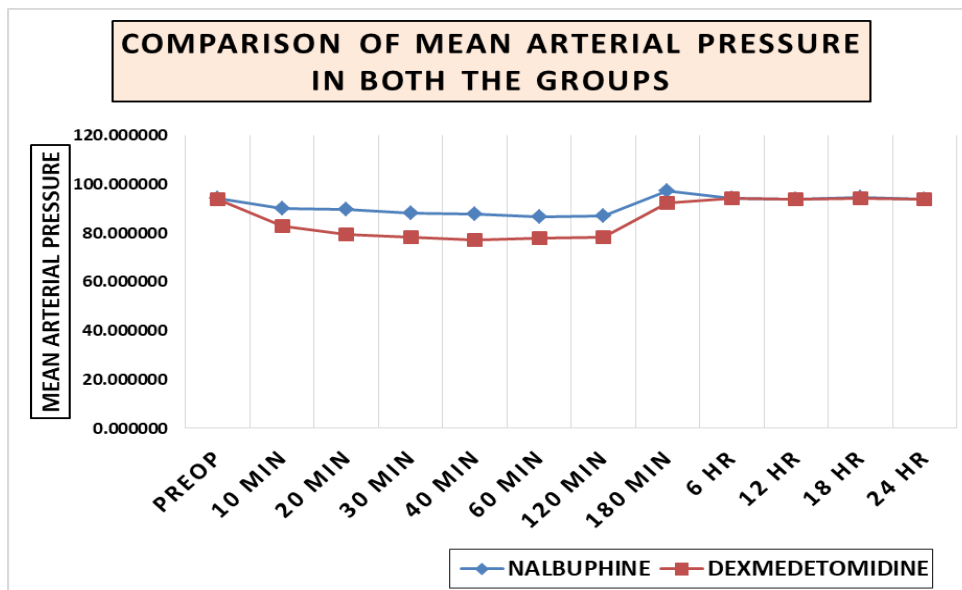
There is significant fall in the mean arterial blood pressure from 10 minutes to 120 minutes in Nalbuphine group ($p < 0.05$).

TABLE 9: MEAN ARTERIAL PRESSURE (MAP) ALTERATIONS IN DEXMEDETOMIDINE GROUP:

group	Basal	10 min	20 min	30 min	40 min	60 min	120 min	180 min	6 hrs	12 hr	18 hr	24 hr
group D	93.68±7.6 9	82.72±9.9 0	79.48±8.1 2	78.21±6.2 8	77.28±5.5 2	77.97±5.3 7	78.42±9.8 2	92.17±4.4 8	94.23±3.5 4	93.75±4.0 2	94.09±4.0 0	93.82±3.4 2
P value		0.000	0.000	0.000	0.000	0.000	0.000	0.358(NS)	0.592(NS)	0.943(NS)	0.716(NS)	0.897 (NS)

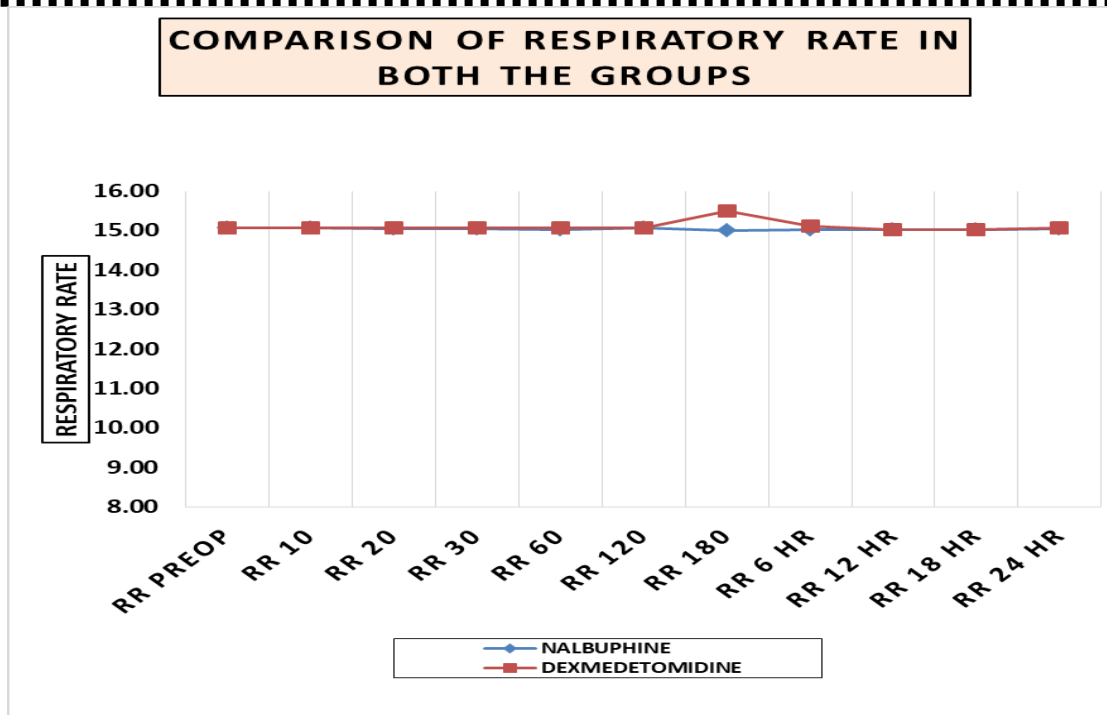
There is significant fall in the mean arterial blood pressure from 10 minutes to 120 minutes in Dexmedetomidine group ($p < 0.05$).

LINE DIAGRAM NO.4- MEAN (\pm SD) MEAN ARTERIAL PRESSURE (MAP) CHANGES BETWEEN THE GROUPS:



On intergroup comparison, the mean arterial blood pressure was significantly lower in Dexmedetomidine group than Nalbuphine group from 10 min to 120 min ($p < 0.05$).

LINE DIAGRAM 5: COMPARISION OF MEAN (\pm SD) RESPIRATORY RATE CHANGES BETWEEN THE GROUPS:



There was no significant change in Respiratory rate in Nalbuphine and Dexmedetomidine group in the study period.

On intergroup comparison, the Respiratory rate alterations were comparable in Dexmedetomidine group than Nalbuphine group during the study period ($p > 0.05$).

TABLE NO.10: PERIOPERATIVE COMPLICATIONS:

Side effects	Group (n=35)	Group D (n=35)
Hypotension	0	0
Bradycardia	0	0

The hypotension and bradycardia was not observed in any patients of either group.

Discussion

Regional anaesthesia has various advantages over general anaesthesia such as reduced incidence of deep vein thrombosis, pulmonary embolism, reduced cardiac complications in high risk patients, reduced bleeding & transfusion requirement. Regional anaesthesia allow earlier return of gastrointestinal function, decreased stress response may result in less perioperative ischemia and reduced morbidity and mortality in patient with coronary artery disease. Regional anaesthesia may also preserve immunity peri-operatively and allow earlier wound healing⁽¹⁾. In recent times, the role of epidural and subarachnoid opioids for the relief of post-operative pain

promotes a new platform in this field. This is because of the direct action of the opioids on specific opioid receptors that are richly distributed in the posterior horn of the spinal cord. The epidural opioids have a wider margin of safety as against systemic opioids. Though the opioids reduce the toxicity and cardiovascular effects of local anesthetics this type of combinations may bring about additional undesirable problems like itching, nausea and vomiting and / or respiratory depression⁽¹⁰⁾. Nalbuphine is a drug with mixed μ antagonist and κ agonist properties. Nalbuphine has the potential to maintain or even enhance μ -opioid based analgesia while simultaneously mitigating the μ -opioid related side

effects. Nalbuphine was considered as an adjuvant drug in terms of its ability to produce an antagonism of the side effects attendant to spinal opiates, e.g. respiratory depression, pruritus and urinary retention⁽¹⁰⁾.

Alpha-2(2) adrenergic receptor (AR) agonists have been the focus of interest due to sedative, analgesic, perioperative sympatholytic and hemodynamic stabilizing properties. Dexmedetomidine is a new alpha2-agonist approved for use. It has sedative, analgesic, sympatholytic and anxiolytic effect that blunts many cardiovascular responses in the perioperative period. It causes sedation without causing respiratory depression. It is suggested that intrathecal Dexmedetomidine produces its analgesic effect by inhibiting the release of C fibers transmission and by hyperpolarization of post-synaptic dorsal horn neurons⁽¹⁰⁾. Epidural anaesthesia produces less hemodynamic fluctuations. Hence, Hemodynamic alterations caused by epidural administration of Nalbuphine and Dexmedetomidine must be studied. The two groups were comparable with respect to age, weight, height and duration of surgery.

Hemodynamic parameters

A) Pulse Rate

In our study, there was no significant change in the Pulse Rate in Nalbuphine group at various time intervals in the present study. There was significant decrease in the Pulse Rate in Dexmedetomidine group from baseline after 30 minutes upto 120 minutes ($p < 0.05$) and thereafter, Pulse Rate remained near basal values upto 24 hr. On intergroup comparison, the Pulse Rate was less in Dexmedetomidine group than in Nalbuphine group at 120 & 180 minutes. The pulse rate was never < 60 beats per minute in any patient. No patient required inj. Atropine for the treatment.

Kaur S, Attr JP et al (2014)⁽¹¹⁾ in their study found that, there was decrease in PR in Dexmedetomidine group.

Karhade SS et al (2015)⁽¹²⁾ studied the effects of Dexmedetomidine in epidural anaesthesia. There was decrease in Pulse Rate in Dexmedetomidine group in which it remained in the range of 56-70 per minutes. No intervention in the form of inj. Atropine was needed in any patient.

Bajwa SJS et al (2011)⁽⁸⁾ also noted the decrease in Pulse Rate in Dexmedetomidine group than Clonidine group.

Soliman R et al (2016)⁽¹³⁾ noted the decrease in Pulse Rate in Dexmedetomidine group as compared to Fentanyl group. The Pulse Rate never decreased below 20% from baseline.

Gupta K et al (2016)⁽¹⁴⁾ when compared intrathecal Fentanyl with Nalbuphine, they found no statistically significant difference in the Pulse Rate after administering the study drugs.

Hence, the results of our study were in accordance with the studies mentioned above.

B) SBP, DBP and MAP:

It was observed that there was fall in SBP, DBP and MAP from baseline in both the groups. The mean systolic blood pressure never falls below 100 mmHg and the mean diastolic blood pressure never fall below 63 mmHg. The mean arterial blood pressure never falls below 60 mmHg. No intervention was needed in any patient of either group as clinically these parameters were within normal limits.

Karhade SS et al (2015)⁽¹²⁾ noted the fall in MAP in both the group B and group BD but MAP remained above 70 mmHg throughout the surgery. No treatment was required.

Kaur S, Attr JP et al (2014)⁽¹¹⁾ noted fall in SBP < 90 mmHg in first 40 minutes in Dexmedetomidine group.

Soliman R et al(2016)⁽¹³⁾ in their study noted the fall in MAP in group D than group F. The fall was <15% of baseline value and no treatment was required.

Gupta K, Rastogi B et al(2014)⁽¹⁴⁾ noted fall in MAP from baseline in both the groups LD and LF but it never fall <65 mmHg and no treatment was required.

Bajwa SJS et al(2011)⁽⁸⁾ when compared epidural Dexmedetomidine and Clonidine found that MAP fall in both the groups but it never fall >15% of basal value and no intervention was required.

The results of above studies were in accordance with our study.

C) Respiratory Rate

In our study, there was no significant change in Respiratory Rate from baseline in Nalbuphine group and Dexmedetomidine group during the study period. No respiratory depression was observed in any patient of either group. SPO2 was maintained within normal limits in all the patients.

Kamal MM et al (2013)⁽¹⁵⁾ did not found statistically significant difference as regards to respiratory rate in group LM & LD.

Bajwa SJS, Parmar SS et al (2011)⁽¹⁶⁾ observed that none of the patient in either group of Dexmedetomidine and Fentanyl experienced respiratory depression.

Gupta K, Gupta PK et al(2016)⁽¹⁷⁾ found no respiratory depression in any patient of Dexmedetomidine and Fentanyl.

Gupta R, Bogra J(2011)⁽¹⁸⁾ when studied intrathecal Dexmedetomidine did not notice respiratory depression in any patient.

Mukherjee A, Pal A (2011)⁽¹⁹⁾ studied effect of intrathecal Nalbuphine and did not observed significant difference in RR.

The finding from our study was consistent with the findings from above studies.

D) Complications

In our study, bradycardia, hypotension and respiratory depression was not seen in any patient of either Group.

Mittal A A, Agarwal A et al (2016)⁽²⁰⁾ noted that Hypotension was seen in 28 patients in group RD ,12 patients in group RF and 5 patient in group R.

Gupta R, Bogra J (2011)⁽¹⁸⁾ noted Bradycardia in 2 patients in group D while no patient in group B had bradycardia. Hypotension was seen in 1(3.3%) patient in group R and 2(6.6%) patients in group D. Respiratory depression was not observed in any patients in either group.

In our study, all the patients in both the groups were hemodynamically stable.

Conclusion

We conclude that, Nalbuphine and Dexmedetomidine can be safely administered as an adjuvant to Bupivacaine in epidural anaesthesia for lower limb surgeries as the patients remained hemodynamically stable throughout the study period.

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