Original Research Article

# A Comparative Study of Epidural 0.5%Bupivacaine with Nalbuphine And 0.5% Bupivacaine with Fentanyl in Lower Abdominal and Lowerlimb Surgeries

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**Received: 06-08-2021 / Revised: 28-08-2021 / Accepted: 14-10-2021**

## Abstract

**Background:** Epidural opioids have unique advantages over conventional, intermittent IV/ IM administration, in that patients given epidural opioids have fewer respiratory complications and can be mobilized sooner in the postoperative period. **Aim:** To compare the effects of epidural 0.5%Bupivacaine with nalbuphine and 0.5%Bupivacaine with fentanyl in lower abdominal and lower limb surgeries. **Methods and materials:** A randomized, single blinded, clinical study was conducted involving 60 patients belonging to ASA Grade I & II posted for elective infra umbilical surgeries. Patients were randomly divided into 2 groups of 30 each. Group A received 15ml of 0.5% bupivacaine + 1 ml of nalbuphine (10 mg); Group b received 15ml of 0.5% bupivacaine + 1 ml of fentanyl (50□g).**Results:** Demographic parameters in both groups were comparable ($p > 0.05$). Nalbuphine and fentanyl when used with Bupivacaine has comparable onset of time for sensory blockade and motor blockade. Total duration of sensory blockade is more with Nalbuphine and bupivacaine and has provided excellent analgesia in the immediate intraoperative and postoperative period. It produced postoperative analgesia for a period of 4-7hours. As reported in several studies Nalbuphine offered good cardiovascular stability without the risk of respiratory depression which was noted with fentanyl. No significant side effects were noted with epidural nalbuphine when compared to fentanyl.**Conclusion:** Epidural Nalbuphine with 0.5%bupivacaine significantly prolongs the total duration of sensory blockade with better postoperative analgesia when compared to Epidural Fentanyl with 0.5%bupivacaine.

**Key words** - Nalbuphine, Bupivacaine, Fentanyl.

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## Introduction

Analgesia, one of the components of triad of anaesthesia, has now extended to relief of postoperative pain, chronic pain and cancer pain. Epidural anesthesia [1]. offers a wide range of applications than the spinal anaesthesia. An epidural block can be performed at the lumbar, thoracic or cervical level. Epidural techniques are widely used for operative anesthesia, obstetric analgesia, postoperative pain control, and chronic pain management. It can be used as a single shot technique or with a catheter that allows intermittent boluses and/or continuous infusion. The knowledge of specific opiate receptors in the substantia gelatinosa of the posterior horn of spinal cord resulted in wide spread use of epidural opiates in the treatment of acute and chronic pain. A local anaesthetic– opioid combination provides superior analgesia during perioperative and postoperative period. Epidural opioids have unique advantages over conventional, intermittent IV/IM administration, in that patients given epidural opioids have fewer respiratory complications and can be mobilized sooner in the postoperative period [2]. Though pure opioid agonists like morphine and fentanyl has already established its role in epidural administration for pain relief, its side effects like respiratory depression, nausea, vomiting, urinary retention etc., has made physician to search for a better drug for epidural employment. The agonist/antagonist opioid agent Nalbuphine can be expected to offer some scope in this respect, since the respiratory depression reaches ceiling level at higher dose of this drug [3]. This study was designed to evaluate the effectiveness of relief of pain, onset of pain relief and side effects due to epidural administration of bupivacaine with nalbuphine mixture and bupivacaine with fentanyl in patients who had undergone lower abdominal and lower limb surgeries.

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## Material and methods

The present study was done at Gandhi medical college, secunderabad during 2015- 2017 on 60 patients in between age group of 20-60 years of ASA grade I & II undergoing elective infra-umbilical surgeries after obtaining approval for the study from Institutional Ethics Committee. Written consent was obtained from all the patients.

**Inclusion Criteria:**

Patients posted for elective infra-umbilical surgeries under ASA Grade I and II including both males and females.

**Exclusion Criteria:**

Obese patients**,** Patients with uncontrollable hypertension**,** uncontrollable diabetes mellitus**,** severe CVS abnormalities, renal or hepatic failure**,** H/O neurological surgeries**,** spine deformities**,** coagulation defects, those on anti-coagulants.

Informed consent was obtained after explaining the procedure. All patients were subjected to pre anaesthetic checkup on the day before surgery to find out systemic illness complicating anaesthesia. On the day of surgery, the patients were shifted to the operation theatre and baseline vital hemodynamic parameters such as heart rate, non-invasive arterial blood pressure, oxygen saturation and ECG were noted. Intravenous line was secured with an 18G intravenous catheter and preloading was done with 500ml of Ringer's Lactate. Premedication was given with I.V. Ondansetron 4mg and I.V. Ranitidine 50mg. The patients were explained about the 10 point visual analogue of pain scale.

The patients were randomly chosen into two groups.

**Group A:** Received 15 ml of 0.5% bupivacaine with 1 ml of nalbuphine (10mg).

**Group B:** Received 15 ml of 0.5% bupivacaine with 1 ml of fentanyl(50□g).

The following equipment's were kept ready before administering epidural anaesthesia.

- Boyles machine with $O_2$ source.
- Working Laryngoscope and appropriate size ET tubes
- Suctioning apparatus,
- Vasopressors.
- All emergency drugs.

**Technique**

After thorough aseptic precautions L1-L2 or L2-L3 Space located and using a16 gauge Huber point Tuohy needle epidural space was identified with loss of resistance technique. Epidural catheter was inserted and aspirated to rule out subarachnoid or intravascular placement of the catheter. The placement was confirmed by 3ml of 2% lidocaine with adrenaline 1: 2 00,000 and fixed. On confirmation, Group A patients were given 15 ml of 0.5% bupivacaine with 1 ml of nalbuphine (10mg) into the epidural catheter as a single bolus dose and Group B patients were given 15 ml of 0.5% bupivacaine with 1 ml of fentanyl (50□g) into the epidural catheter as a single bolus dose and the patients were positioned for the surgery.The following were noted down as Onset of sensory blockade, motor blockade, Time taken for maximum motor blockade according to modified Bromage scale, Total duration of sensory blockade, total duration of motor blockade, Quality and duration of analgesia, Pulse rate, blood pressure, respiratory rate, Spo2. Surgeons were asked to proceed with the surgery only after the maximum level of blockade was established. Intraoperatively, complications like bradycardia were dealt with I.V. atropine (5-10μg/kg). A fall in systolic blood pressure by 20% from the baseline value was considered as hypotension and managed with IV fluids, oxygen and inj. Mephentermine I.V (6mg boluses). Any episodes of desaturation (SpO2<90%) or respiratory depression (< 10 breaths per minute) were noted. At the end of surgery patients were observed in the recovery room for further two hours and sent to postoperative ward. Patients were asked to mark a point scale on the 10 point visual analogue scale of pain according to the intensity of pain. The observation was done every 30minutes. The pain relief is graded according to VAPS as follows. Supplementary analgesia was given when VAPS more than 4. The total number of rescue analgesics (inj. Diclofenac 75 mg IM) in the first 24 hours was noted down to assess the quality of analgesia. The side effects due to opiods like nausea, vomiting, pruritis, urinary retention were noted down. Descriptive statistical analysis had been carried out in the present study. Results on continuous measurements were presented on Mean ± SD and results on categorical measurements were presented in Number (%). Significance was assessed at 5 % level of significance. Student t test (two tailed, independent) had been used to find the significance of study parameters on continuous scale between two groups (Inter group analysis) on metric parameters. Leven's test for homogeneity of variance had been performed to assess the homogeneity of variance. . Chi-square/ Fisher Exact test has been used to find the significance of study parameters on categorical scale between two or more groups.

Significant figures

- Significant (P value:0.01<P< 0.05)
- Highly significant (P value : P<0.01)

**Statistical software**: The Statistical software namely Open Epi, Version 2.3 was used for the analysis of the data and Microsoft word and Excel have been used to generate graphs, tables etc.

**Results**

The present study done at Gandhi medical college, secunderabad, comprised of 60 patients randomly divided into two groups, one receiving 15 ml of 0.5% Bupivacaine Hydrochloride with 1 ml of Nalbuphine 10 mg epidurally (Group A) and the other receiving 15 ml of 0.5% Bupivacaine Hydrochloride ith 1 ml of fentanyl(50□g) epidurally (Group B).

There were statistically no significant difference between mean age, weight, gender and ASA grading in both groups. The duration of surgery was statistically not significant in the two groups (p > 0.05). [Table 1]

There was statistically no significant difference in the types of surgeries between the two groups. [Table 2]

There was statistically no significant difference in the baseline parameters between the two groups. [Table 3]

The time of onset of sensory blockade, motor blockade not statistically significant (p> 0.05). The time taken for peak motor blockade and duration of motor blockade was statistically not significant (p > 0.05). The duration of sensory blockade was highly significant (p < 0.01). In group A the minimum time was 240 minutes and maximum 320 minutes with a meantime of 285.33 minutes. In group B the minimum time was 200 minutes and maximum 280 minutes with a mean time of 247 minutes [Table 4].

**Table 1: Comparison of demographic data in both groups**

| Demographic Parameters Mean± S.D. | | Group A (n=30) | Group B (n=30) | p value |
|---|---|---|---|---|
| Age in years | | 38.43 ± 9.56 | 39.06 ± 9.83 | 0.802 |
| Weight in KGs | | 63.03 ± 9.44 | 62.7 ± 9.59 | 0.894 |
| SEX | Male | 22 ( 73% ) | 23 ( 77% ) | 0.72 |
| | Female | 8 ( 27% ) | 7 ( 23% ) | 0.72 |
| ASA | Grade 1 | 12 ( 40 %) | 12 ( 40 %) | 1.0 |
| | Grade 2 | 18 ( 60 %) | 18 ( 60 %) | 1.0 |

**Table 2: Comparison of types of surgeries performed**

| Study groups | Type of surgery | Freequency | Percent |
|---|---|---|---|
| **Group A** | TVH | 3 | 10 |
| | Herniorrhaphy/ plasty | 15 | 50 |
| | Varicose veins | 4 | 13 |
| | Appendicectomy | 5 | 17 |
| | Below knee Amputation | 3 | 10 |
| | Total | 30 | 100 |
| **Group B** | TVH | 3 | 10 |
| | Herniorraphy/ plasty | 14 | 47 |
| | Varicose veins | 5 | 17 |
| | Appendicectomy | 4 | 13 |
| | Below knee Amputation | 4 | 13 |
| | Total | 30 | 100 |

**Table 3: Comparison of baseline variables**

| Baseline Parameters | Group A (Mean ± S.D.) | Group B (Mean ± S.D.) | p value |
|---|---|---|---|
| HR | 81.73 ± 9.34 | 81.23 ± 8.98 | 0.8333 |
| SBP | 127.6 ± 7.96 | 125.76 ± 7.49 | 0.3603 |
| DBP | 83.23 ± 5.36 | 80.1 ± 7.78 | 0.07475 |
| MAP | 98.1 ± 5.1 | 95.13 ± 6.92 | 0.06344 |
| RR | 15.8 ± 0.80 | 15.9 ± 1.047 | 0.7446 |

**Table 4: Variable in motor and sensory blockade**

| | | N | Mean | S.D | p value |
|---|---|---|---|---|---|
| Onset of sensory block in mins | | | | | |
| | Group A | 30 | 5.76 | 1.61 | 0.92 |
| | Group B | 30 | 5.8 | 1.47 | |
| Onset of motor blockade in mins | | | | | |
| | Group A | 30 | 12.6 | 1.49 | |
| | Group B | 30 | 13.3 | 1.41 | |
| Time taken for P.M.B. in mins | | | | | |
| | Group A | 30 | 21.86 | 2.37 | 0.118 |
| | Group B | 30 | 22.93 | 2.88 | |
| Duration of sensory blockade | | | | | < 0.01 |
| | Group A | 30 | 285.33 | 27.76 | |
| | Group B | 30 | 247 | 19.68 | |
| Duration of motor blockade | | | | | 0.0616 |
| | Group A | 30 | 170.4 | 13.23 | |
| | Group B | 30 | 163 | 16.64 | |

**Table 5: Comparison of VAS scores between the two groups**

| Time | | VAS score | |
|---|---|---|---|
| | | 0-4 | 5-10 |
| 0 – 6 Hours | Group A | 30(100%) | 0 |
| | Group B | 24(80%) | 6 (20 %) |
| 6 – 12 hours | Group A | 21 (70%) | 9 (30%) |
| | Group B | 6 (20 %) | 24 (80%) |
| 12 – 24 hours | Group A | 2 (7%) | 28 (93%) |
| | Group B | 0 | 30(100%) |

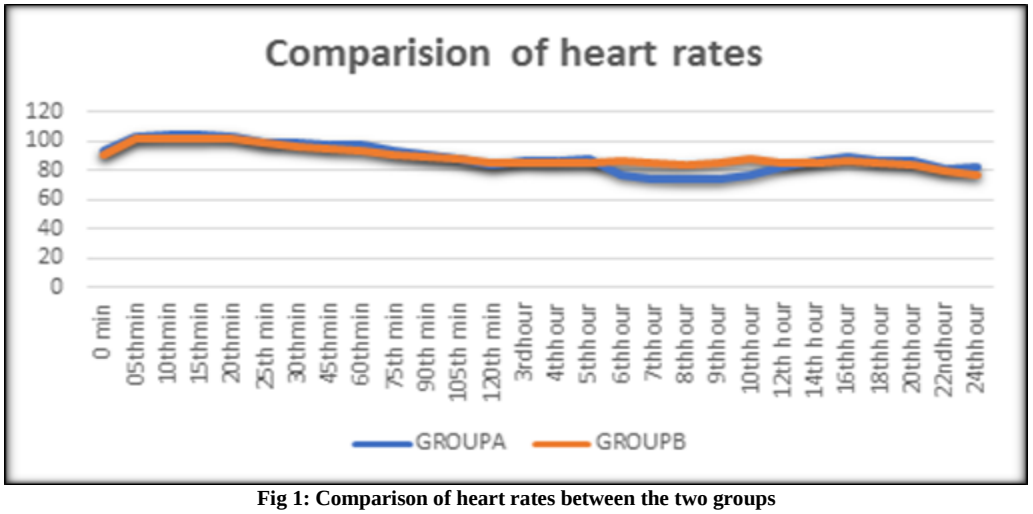


**Fig 1: Comparison of heart rates between the two groups**

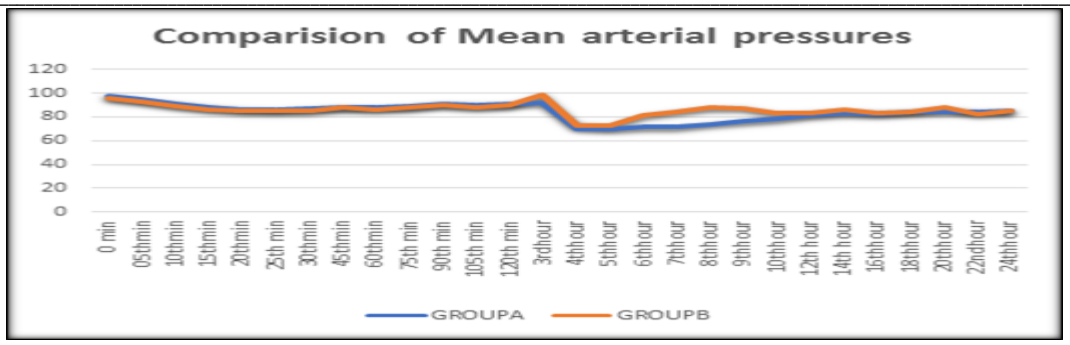


**Fig 2: Comparison of mean arterial pressures between the two groups**

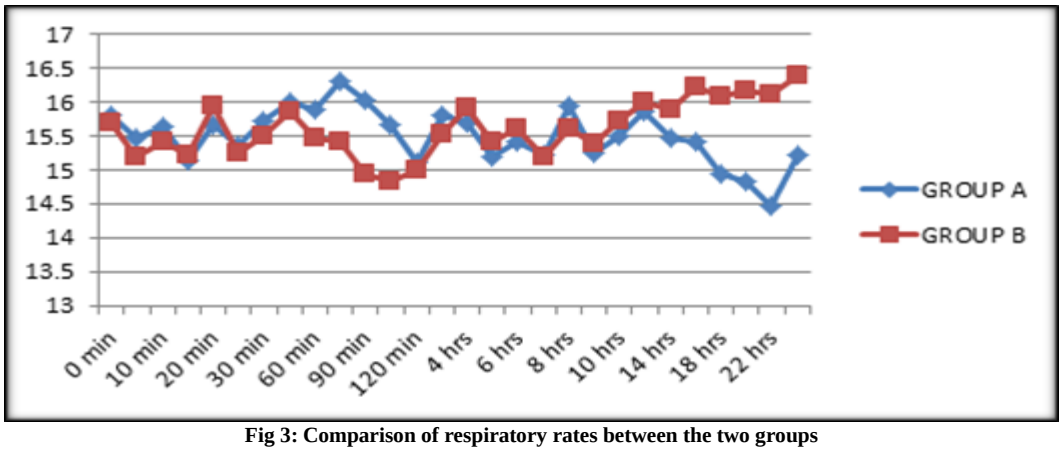


**Fig 3: Comparison of respiratory rates between the two groups**

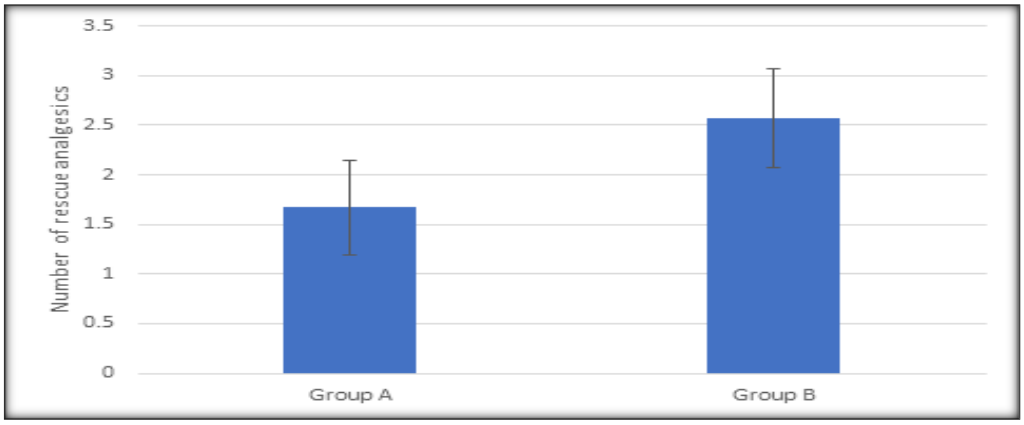


**Fig 4: Number of rescue analgesics required in both groups**

**Table 6: Side effects in both groups**

| Side Effects | Group- A | | Group- B | | p value |
|---|---|---|---|---|---|
| | N | % | n | % | |
| Nausea and vomiting | 1 | 3.3 % | 3 | 10 % | 0.3 |
| Respiratory depression | - | | 4 | 13.3% | 0.04 (p<0.05) |
| Urinary retention | - | | - | | |
| Pruritus | - | | 3 | 10% | 0.07 |
| Hypotension | 2 | 6.6 % | 3 | 10 % | 0.63 |
| Bradycardia | 1 | 3.3 % | 2 | 6.6% | 0.5 |
| Shivering | 1 | 3.3 % | 2 | 6.6% | 0.5 |

Comparision of heart rates between the two groups Mean heart rates in both the groups were compared and it was observed that p-value was significant only at 6th, 7th, 8th, 9th and 10th hours and at rest of the times, the p-values were insignificant. [Figure 1]

Mean arterial pressures in both the groups were compared and it was observed that P-value was significant only at 3rd, 6th, 7th, 8th, 9th and 10th hours and at rest of the times, the P-values were insignificant. [Figure 2]

There was statistically no significant difference in respiratory rates between the two groups. [Figure 3]

30% of patients in group A had a pain score more than 4 during 6- 12 hours of postoperative period as compared to 80 % in group B. The pain scores were similar in both the groups in the first six hours of postoperative period. [Table 5]

Rescue analgesic (inj. Diclofenac) was given when VAS score was more than 4. The number of rescue analgesics required in the first 24 hrs of post-operative period in group B were significantly higher ($p < 0.01$) when compared with group A. [Figure 4]

1 patient in Group A (3.33%) and 3 patients (10%) in Group B experienced nausea and vomiting which were not significant statistically. 4 patients (13.2%) in Group B experienced respiratory depression which is significant statistically. 3 patients (10%) in Group B experienced pruritis which was not significant statistically. 2 patients in Group A (6.67%) and 3 patients in Group B (10%) had hypotension which was not significant statistically. 1 patient in Group A (3.33%) and 2 patients in Group B (6.67%) experienced bradycardia which were not significant statistically. 1 patient in Group A (3.33%) and 2 patients in Group B (6.67%) had shivering which were not significant statistically. All the side effects were treated immediate. [Table 6]

**Discussion**

Traditionally epidural bupivacaine was used for post-operative analgesia. The epidural bupivacaine 0.5% causes motor, sensory and autonimic blockade, 0.25%- 0.125% cause's sensory and autonomic blockade. Epidural and intrathecal opioids are today being used for intra operative and post-operative analgesia. Epidural administration of narcotics for postsurgical analgesia gained increasing popularity following the discovery of opioid receptors in the spinal cord capable of producing potent analgesia as reported by Yaksh and Rudy in 1976.[4] It is now clear that epidural administration of opioids is superior to traditional intravenous and intramuscular injections of opioids because this modality of analgesia has unique advantages over conventional, intermittent IV/IM administration of narcotics. Patients given epidural narcotics have fewer respiratory complications and can be mobilized sooner in the postoperative period.

In our study demographic data comparing age, sex, weight shows no statistically significant difference among both the groups. Onset of sensory blockade is taken as the time from the completion of the injection of the study drug till the patient does not feel the pin prick at T12 level on the dependent side. Mean time of sensory blockade in our study was Group- A - 5.76min, Group- B - 5.80min. The time of onset of sensory blockade was not significant ($p > 0.05$). In group a minimum time was 3 minutes and maximum 8 minutes. In group B the minimum time was 4 minutes and maximum 9 minutes. Kamel HS et al compared the effects of epidural nalbuphine and clonidine added as adjuvants to bupivacaine for full term primigravida in labor. The shortest onset time of analgesia was recorded in the bupivacaine and nalbuphine group. H.M. Gomaa et al [5] compared the intra-operative and post-operative analgesic effect of intrathecal nalbuphine and intrathecal fentanyl as an adjuvant to bupivacaine during cesarean delivery. The onset of sensory blockade was similar in both fentanyl and nalbuphine groups. Santosh Kumar et al,[6] compared the effects of epidural bupivacaine with buprenorphine over epidural bupivacaine with fentanyl for lower limb surgeries. onset of analgesia in bupivacaine with fentanyl group was 6.6 min, which is comparable to our study. Suraj Dhale and Vaishali Shelgaonkar,[8] in 2000, studied different doses of epidural fentanyl (25µg, 50µg,75µg) with 0.5% bupivacaine for perioperative analgesia found that 50µg had a quicker onset of analgesia within which is close to our observation. In this study also, rapid onset in group A and group B patients is due to synergistic effect of nalbuphine and fentanyl with bupivacaine. High lipid solubility and high potency may explain the faster onset of pain relief. High lipid solubility results in fast distribution to opioid receptors present in spinal cord and CNS and increases its final concentration there. R. Fournier, et al,[9] studied and reported the administration of intrathecal nalbuphine resulting in a significantly faster onset of sensory blockade. Manisha Sapate et al,[10] compared the effects of addition of nalbuphine to intrathecal bupivacaine. The time of onset of sensory blockade was similar in both nalbuphine group and bupivacaine group. This in contradiction with our findings. The time of onset of motor blockade was statistically not significant ($p > 0.05$). In group The minimum time was 10 minutes and maximum 15 minutes with a meantime of 12.6 minutes. In group B the minimum time was 10 minutes and maximum 15 minutes with a meantime of 13.3 minutes. This is in agreement with other studies. Tiwari Ak, Tomar GS,[11] evaluated the effects of addition of 2 different doses of intrathecal nalbuphine to intrathecal hyperbaric 0.5% bupivacaine in infra umbilical surgeries. The onset of motor blockade was similar in all groups. The time taken for peak motor blockade was statistically not significant ($p > 0.05$). In group a minimum time was 18 minutes and maximum 26 minutes with a meantime of 21.86 minutes. In group B the minimum time was 18 minutes and maximum 30 minutes with a mean time of 22.93 minutes. Santosh Kumar et al,[7] compared the effects of epidural bupivacaine with buprenorphine over epidural bupivacaine with fentanyl for lower limb surgeries. The mean time to achieve complete motor blockade was 18.9 min in bupivacaine with buprenorphine group and 18.63 in bupivacaine with fentanyl group which was statistically insignificant in both the groups which is comparable to our study. The duration of sensory blockade was statistically highly significant ($p < 0.01$). In group a minimum time was 240 minutes and maximum 320 minutes with a meantime of 285.33 minutes. In group B the minimum time was 200 minutes and maximum 280 minutes with a mean time of 247 minutes. The findings in the present study were consistent with those of other studies. Manisha Sapate et al,[10] compared the effects of addition of nalbuphine to intrathecal bupivacaine. The duration of sensory blockade was significantly prolonged in nalbuphine group compared to bupivacaine group.

Tiwari AK, Tomar GS,[11] evaluated the effects of addition of 2 different doses of intrathecal nalbuphine to intrathecal hyperbaric 0.5% bupivacaine in infra umbilical surgeries. The duration of sensory blockade were significantly prolonged in nalbuphine groups when compared with bupivacaine group. Arghya Mukherjee et al,[12] compared intrathecal bupivacaine alone with three different doses of nalbuphine added to bupivacaine. The duration of sensory blockade was significantly and progressively prolonged in all the three groups of nalbuphine when compared with bupivacaine group.The duration of motor blockade was not significant ($p > 0.05$). In group a minimum time was 150 minutes and maximum 200 minutes with a meantime of 170.4 minutes. In group B the minimum time was 140 minutes and maximum 200 minutes with a mean time of 163 minutes. This is in comparison with other studies. Kamel HS et al,[13] compared the effects of epidural nalbuphine and clonidine added as adjuvants to bupivacaine for full term primigravida in labor. The duration of motor blockade was similar in both groups. Manisha Sapate et al,[10] compared the effects of addition of nalbuphine to intrathecal bupivacaine. Mean duration of motor blockade was similar in both groups. Tiwari AK, Tomar GS,[11] evaluated the effects of addition of 2 different doses of intrathecal nalbuphine to intrathecal hyperbaric 0.5% bupivacaine in infra umbilical surgeries. The duration of motor blockade was comparable in both groups. It was one of the explicit aims in the present study to measure the quality of analgesia. The duration of analgesia was taken as the time from the administration of epidural anaesthesia till the requirement of first rescue analgesic. It was measured using VAS at every 5mins in first half an hour then at 15 min up to two hours and there afterwards every 1 hour for 24 hours. Rescue analgesics were given when the VAS score was 5 or more. Quality of analgesia is taken as number of rescue doses in first 24 hours. In the present study, VAS scores in the first 6 hours were less than 5 in all patients in group A (100%) whereas only 24 (80%) of patients had scores less than 5 in group B. During 6 to 12 hrs in the post-operative period, 9 patients in group a (30 %) had VAS scores 5

or more whereas 24 patients in group B (30%) had VAS scores more than 5. After 12 hours up to 24 hours in the post-operative period, 28 patients in group a (93 %) had VAS scores 5 or more whereas all patients in group B (100%) had VAS scores more than 5.

The total number of rescue analgesics required in the first 24 hours in the post-operative period was statistically significant. ($P < 0.01$). In group A, the minimum number of rescue analgesics required was 1 and maximum were 2 with a mean of 1.67. In group B, the minimum number of rescue analgesics required was 2 and maximum were 3 with a mean of 2.57. These findings were in agreement with other studies. Manisha Sapate et al,[10] compared the effects of addition of nalbuphine to intrathecal bupivacaine. Duration of postoperative analgesia was 8 to 9 hours (566 ± 15.5 min) in bupivacaine and nalbuphine group compared to 2 to 3 hours (159.5 ± 18.42 min) in bupivacaine group. Tiwari AK, Tomar GS,[11] evaluated the effects of addition of 2 different doses of intrathecal nalbuphine to hyperbaric 0.5% bupivacaine in infra umbilical surgeries. They concluded that nalbuphine hydrochloride (400 μg) significantly prolongs the duration of sensory blockade and postoperative analgesia. H.M. Gomaa et al,[5] Compared intrathecal nalbuphine with intrathecal fentanyl as an adjuvant to hyperbaric bupivacaine in cesarean section. They concluded that the duration of post-operative analgesia was more prolonged in nalbuphine group. Arghya Mukherjee et al,[12] compared intrathecal bupivacaine alone with three different doses of nalbuphine added to bupivacaine, the duration of analgesia was significantly and progressively prolonged in nalbuphine groups when compared with control group. In the present study, mean heart rates in both the groups were compared and it was observed that P-value was significant only at 6$^{th}$, 7th, 8th, 9th and 10$^{th}$ hours and at rest of the times, the P-values were insignificant. Mean arterial pressures in both the groups were compared and it was observed that P-value was significant only at 3$^{rd}$, 6$^{th}$, 7th, 8th, 9th and 10$^{th}$ hours and at rest of the times, the P-values were insignificant. The mean arterial pressures were more in group B when compared with group A. More stable hemodynamic pattern was seen in group A. This difference in hemodynamics could be due to poor post-operative analgesia in group B when compared with group A. The findings are in agreement with other studies. Santosh Kumar et al[7] compared the effects of epidural bupivacaine with buprenorphine over epidural bupivacaine with fentanyl for lower limb surgeries. In bupivacaine with fentanyl group, MAP from baseline 98.97 mmHg fell to 87.90 mmHg at 45 min then picking up slowly to 93.7 mmHg at 120 min thereafter remained significantly high throughout the study which is comparable to our study. Manisha Sapate et al,[10] compared the effects of addition of nalbuphine to intrathecal bupivacaine. There was statistically significant difference in hemodynamic parameters like heart rate, mean, systolic and diastolic BP, but clinically these parameters were within normal limits and did not require any intervention. Tiwari AK, Tomar GS [11] evaluated the effects of addition of 2 different doses of intrathecal nalbuphine to hyperbaric 0.5% bupivacaine in infra umbilical surgeries. There were statistically no significant differences hemodynamically. H.M. Gomaa et al,[5] Compared intrathecal nalbuphine with intrathecal fentanyl as an adjuvant to hyperbaric bupivacaine in cesarean section. Both groups were comparable in providing hemodynamic stability. Kamel HS et al,[13] compared the effects of epidural nalbuphine and clonidine added as adjuvants to bupivacaine for labor analgesia. Only nalbuphine group showed stable hemodynamics throughout the whole study. F N Minai et al,[14] compared equianalgesic doses of morphine and nalbuphine in patients undergoing total abdominal hysterectomy under general anaesthesia. They found that patients in the morphine group showed a rise of mean blood pressure and heart rate to 20% above the baseline in whereas in the nalbuphine group it remained within 20% of baseline. Van Den Berg et al,[15] Compared equipotent doses of nalbuphine, tramadol, pethidine and placebo in reducing the hemodynamic stress response to laryngoscopy and tracheal intubation. Only nalbuphine group showed decreased hemodynamic stress response when compared with other three groups. The respiratory depression was monitored by observing the respiratory rate and Oxygen saturation (SpO2). A fall in respiratory rate below 10 breaths per min or fall in SpO2 less than 95 % were considered suggestive of respiratory depression.

There was statistically significant difference in respiratory depression between the two groups. There was no decrease in respiratory rate or SpO2 in nalbuphine group as seen with fentanyl which is pure opioid agonists. The findings in this study were in correlation with many other studies. Kamel HS et al,[13] compared the effects of epidural nalbuphine and clonidine added as adjuvants to bupivacaine for labor analgesia. There was no significant respiratory depression in the mothers in all groups. There were no significant changes in the fetal arterial blood gas analysis indicating no fetal depression in all groups. Tiwari Ak, Tomar GS,[11] evaluated the effects of addition of 2 different doses of intrathecal nalbuphine to hyperbaric 0.5% bupivacaine in infra umbilical surgeries. There was no significant respiratory depression in both nalbuphine groups and bupivacaine group. Culebras et al,[16] compared the analgesic efficacy and adverse effects of intrathecal nalbuphine, at three different doses, and intrathecal morphine for postoperative pain relief after cesarean deliveries. There was no maternal or newborn respiratory depression in both groups. Neonatal conditions (Apgar scores and umbilical vein and artery blood gas values) were similar for all groups. Arghya Mukherjee et al,[12] compared intrathecal bupivacaine alone with three different doses of nalbuphine added to bupivacaine. There was no statistically significant difference in the intraoperative respiratory rate and SpO2 between the groups. Santosh Kumar et al,[7] compared the effects of epidural bupivacaine with buprenorphine over epidural bupivacaine with fentanyl for lower limb surgeries. In bupivacaine with fentanyl Group, mean basal respiratory rate which was 18.4/ min fell to 16.43 at 30th min, which is comparable to our study.

Shaila S Kamath et al,[17] compared the analgesic effect of intravenous nalbuphine and tramadol in patients with post-operative pain. The mean changes in respiratory rate and oxygen saturation were not statistically significant in both groups. Thomas J Gal et al demonstrated that nalbuphine when compared to morphine exhibits a ceiling effect for respiratory depression for more than 30 mg. Moustafa Abdelaziz Moustafa et al,[18] compared the effects of Nalbuphine added to intrathecal morphine on postoperative analgesic requirements and morphine related side effects in total knee arthroplasty. No evidence of respiratory depression was detected in any patient during the study period. The four classic side effects of neuraxial opioids are Pruritus, Nausea and vomiting, Urinary retention and Depression of ventilation. Side effects are caused by the presence of drug either in CSF or systemic circulation. Most side effects are dose dependent. Opioids produce nausea and vomiting by direct stimulation of CTZ in the area postrema of the medulla. The effect is dose related and tolerance to it develops rapidly. The emetic effect can be treated by anticholinergic and phenothiazines, especially those which are antagonists at dopamine receptors. Pruritus is the most common side effect with neuraxial opioids. It may be generalized but is more likely to be localized to the face, neck, or upper thorax. Incidence varies widely. Severe pruritus is rare and more common in obstetric patients. Although opioids may liberate the release of histamine from mast cells this does not appear to be the mechanism, instead pruritus is likely due to cephalad migration of neuraxial opioids to the medulla where the ''itch center'' is suggested to be located and where they interact with the trigeminal nucleus. It occurs due to activation of mu-opioid and 5-hydroxytryptamine 3 receptors and non-nociceptive neurons in the medulla and dorsal horn of the spinal cord, particularly in trigeminal nerve distribution. Urinary retention is due to interaction of the opioid with opioid receptors located in the sacral spinal cord. This interaction promotes inhibition of sacral parasympathetic nervous system outflow, which causes detrusor muscle relaxation and an increase in maximum bladder capacity, leading to urinary retention.

**Conclusion**

Nalbuphine and fentanyl when used with Bupivacaine has comparable onset of time for sensory blockade and comparable motor blockade properties. Epidural Nalbuphine with 0.5%bupivacaine significantly prolongs the total duration of sensory blockade with better

postoperative analgesia when compared to Epidural Fentanyl with 0.5%bupivacaine, with stable hemodynamics and less side effects.

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**Conflict of Interest: Nil**
**Source of support: Nil**