International Journal of Life Sciences, Biotechnology and Pharma Research Vol. 14, No. 2, February 2025 Online ISSN: 2250-3137
Print ISSN: 2977-0122

DOI: 10.69605/ijlbpr_14.2.2025.140

ORIGINAL RESEARCH

Comparative randomised double blind study to evaluate the efficacy of dexmedotomidine and nalbuphine used as an adjuvant with 0.5% ropivacaine under epidural anaesthesia in patients of various infraumbilical surgeries

[1]Dr. Rajni Dhaka, [2]Dr. S.P. Chittora, [3]Dr. Gohar Hayat

[1,3]3rd year resident, [2]Senior Professor, Department of Anesthesiology, Jhalawar Medical College, Jhalawar, India

Corresponding Author
Dr. Gohar Hayat
3rd year resident, Department of Anesthesiology, Jhalawar Medical College, Jhalawar, India

Received: 25 January, 2025 Accepted: 17 February, 2025 Published: 26 February, 2025

ABSTRACT

Background: Epidural anesthesia is a widely used technique for providing anesthesia and postoperative analgesia in various lower abdomen and lower limb surgeries. **Objectives:** The current study was aimed to evaluate the efficacy of dexmedetomidine and Nalbuphine as adjuvants with 0.5% ropivacaine in epidural anesthesia. The study was focused on various parameters, including the onset and duration of sensory and motor block, sedation score, and duration of postoperative analgesia. **Materials and Methods**: 150 eligible patients were randomly allocated in 3 groups using computerized random number table. **Group C (n=50) -** Ropivacaine 0.5% (18ml) + Normal saline (2ml) (Total volume-20ml), **Group N (n=50) -** Ropivacaine 0.5% (18ml) + Nalbuphine 200µg/kg (Total volume – 20ml), **Group D (n=50) -** Ropivacaine 0.5% (18ml) + Dexmedetomidine 0.75 µg/kg (Total volume 20ml). **Results:** Group Dpatients shows early onset of sensory block, motor block, time taken to achieve maximum sensory and motor block, along with longer duration of analgesia, compared to Group N and Group C, with statistically significant differences observed at all time points as indicated by the low p-values ($p<0.001$). **Conclusion:** dexmedetomidine is superior to Nalbuphine as an adjuvant to ropivacaine in epidural anaesthesia for better sensory and motor block characteristics and post operative pain management.

Keywords: Epidural block, Dexmedetomidine, Nalbuphine.

INTRODUCTION

Epidural anesthesia is a widely used technique for providing anesthesia and postoperative analgesia in various lower abdomen and lower limb surgeries. It offers several advantages, including intraoperative hemodynamic stability, reduced stress response, improved patient outcomes, and early mobilization by effectively relieving postoperative pain, which decreases the incidence of thromboembolic events. However, the use of epidural local anesthetics alone has limitations, such as regression of sensory block, motor blockade, and hypotension. To enhance analgesia while minimizing side effects, adjuvants are oftenadded to Epidural infusion.[1]

Ropivacaine is widely used due to its longer duration of action and reduced cardiotoxic effects compared to other amide local anesthetics. However, it exhibits limitations such as delayed onset and poor motor blockade. To overcome these drawbacks, various drugs, including morphine, Neostigmine, Fentanyl, hyaluronidase, Midazolam, dexmedetomidine, clonidine, and dexamethasone, have been added to local anesthetics to improve the quality of blockade, duration of action, and postoperative analgesia.[2]

Nalbuphine, a drug with mixed mu antagonist and kappa agonist properties, has gained attention as an adjuvant in epidural anesthesia.[3]Another adjuvant that has shown promising results in epidural anesthesia is dexmedetomidine. It belongs to the class of alpha-2

DOI: 10.69605/ijlbpr_14.2.2025.140

adrenergic agonists and has a highly selective action on alpha-2 receptors.[4]The currentstudy was aimed to evaluate the efficacy of dexmedetomidine and Nalbuphine as adjuvants with 0.5% ropivacaine in epidural anesthesia. The study was focused on various parameters, including the onset and duration of sensory and motor block, sedation score, and duration of postoperative analgesia.

MATERIALS AND METHODS

Study source

This hospital based prospective randomized double blind comparative study was conducted on the patients undergoing various infra umbilical surgery under epidural anesthesia after obtaining approval from the local ethical committee at Jhalawar Medical College & Associated Group of Hospitals, Jhalawar. Written and informed consent of patient was taken.

Inclusion criteria: Patient age between 18 – 65 years, Patients with written and informed consent, PatientsbelongingtoASAgrade-I andgrade-II, Infra-umbilical surgeries (general surgeries, genitourinary surgeries, gynecologic surgeries, orthopedic surgeries)

Exclusion Criteria: ASA grade III or more, Patient refusal, Patient sensitive / allergic to local anesthetic agents, Infection at the site of lumbar puncture, Spinaldeformities, previousspinalsurgeries, Severe systemic disease andneurologicaldisorders, Historyof coagulopathy, Surgery duration > 120 minutes.

Sample size and randomisation: The sample size was calculated to be 150 patients with a power 95 percent and confidence interval 95 percent and type – 1error of 0.05 but for compensating the loss to drop outs and attrition sample size was kept 150.150 eligible patients were randomly allocated in 3 groups using computerized random number table.**Group C (n=50) -** Ropivacaine 0.5% (18ml) + Normal saline (2ml) (Total volume-20ml),**Group N (n=50) -** Ropivacaine 0.5% (18ml) + Nalbuphine 200µg/kg (Total volume – 20ml),**Group D (n=50) -** Ropivacaine 0.5% (18ml) + Dexmedetomidine 0.75 µg/kg (Total volume 20ml).

Anaesthetic technique: Pre-anesthetic evaluation was done on the day before surgery according to standard protocol and relevant demographic data was collected from all the patients before surgery.

The patient was placed in sitting position. Under all aseptic precautions, The epidural space was identified by loss of resistance(LOR)technique using midline approach. 20G epidural catheter was placed at about 5 cm in epidural space and fixed aseptically. Patient was then made supine. After negative aspiration of blood, test dose of 3 ml of inj. Lignocaine with adrenaline (1:200000) was given to exclude intravascular or intrathecal placement of catheter. According to their randomization, the prefilled study drug was injected with negative aspiration into epidural space by a blinded anesthesiologist. Surgery was started when T10 level of sensory block and modified Bromage score 1 or 2 achieved.

The independent blinded observer had evaluated the sensory and motor blocks every two minutes for 10 min., then every five minutes for 20 min. and then every ten minutes for next 30 min., and finally every 15 min. until the sensory block had regressed to the S1 dermatome. During surgery, the patient's heart rate, blood pressure, SpO_2 and respiratory rate was recorded at 0,1,3, 5, 10,15, 20, 25, 30, min and every 15 minutes thereafter.

Statistical calculations were carried out using Microsoft Office Excel 2010 and Graph Pad Prism 6.05 (quickcale) Software (Graph pad software Inc. La Jalla CA USA). Chi square test and student t-test were used appropriately to test the statistical significance of the parameters. A P-value < 0.05 was considered statistically significant. P value < 0.001 was considered highly significant. P value > 0.05 was considered not-significant. The trend of hemodynamic parameters and postop visual analogue scale in the post operative period were compared by plotting trend diagrams.

RESULTS

The demographic profile of the patients comparing age, sex, weight, height and also type of surgeries show no statistically significant difference and were comparable in 3 groups of our study. All base line vital parameters were similar in both groups.

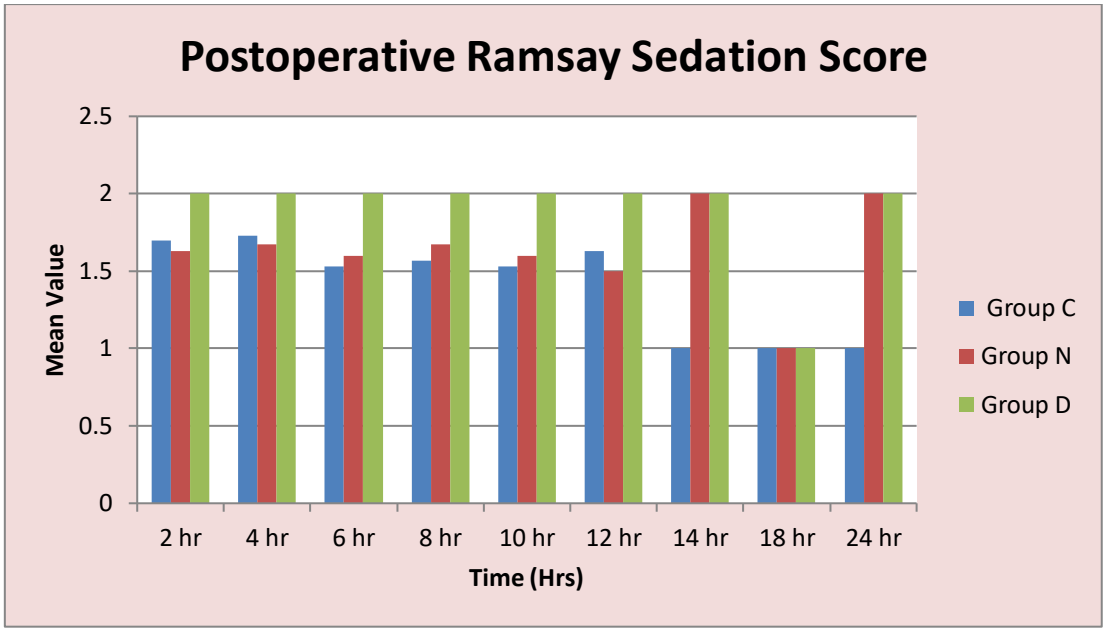
Table 1: Comparison of Epidural block Parameters

Epidural block characteristics	Group C		Group N		Group D		P value		
	Mean	SD	Mean	SD	Mean	SD	C&N	C&D	N&D
Onset of sensory block (min)	14.36	2.48	11.16	2.13	9.48	1.80	<0.001	<0.001	<0.001
Time to Max Sensory Level (min)	25.43	2.54	20.33	2.14	15.35	1.99	<0.001	<0.001	<0.001
Onset of Motor block (min)	20.05	2.75	15.15	1.50	13.04	1.12	<0.001	<0.001	<0.05
Time to achieve maximum Motor block (min)	29.69	1.79	26.56	2.48	24.87	2.78	<0.001	<0.001	<0.05

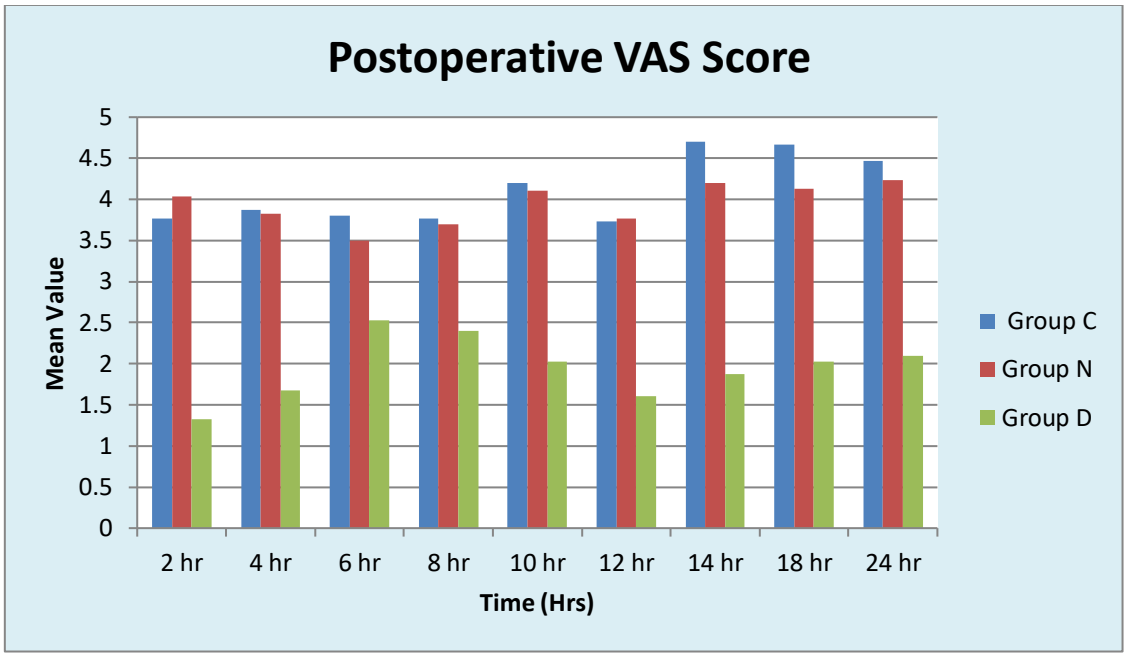
DOI: 10.69605/ijlbpr_14.2.2025.140

Duration of sensory block (min)	399.66	49.54	434.28	60.47	478.46	92.86	<0.001	<0.001	<0.001
Duration of Motor block (min)	341.79	44.35	351.49	51.53	393.33	85.69	0.315	<0.004	<0.05
Duration of Analgesia (min)	424.61	48.06	478.41	58.16	520.82	93.13	<0.001	<0.001	<0.001

Group Dpatients shows early onset of sensory block, motor block, time taken to achieve maximum sensory and motor block, along with longer duration of analgesia, compared to Group N and Group C, with statistically significant differences observed at all time points as indicated by the low p-values (p<0.001).
This graphsuggest that group N and Group C experienced lower levels of sedation as measured by the RSS compared to group D over the course of the study.



Group D consistently displayed lower VAS scores compared to Group N and Group C, with statistically significant differences observed at all time points as indicated by the low p-values (p<0.001).



DOI: 10.69605/ijlbpr_14.2.2025.140

DISCUSSION

Perioperative pain management is one of the important tasks to the anesthesiologist. Pain relief is necessary for both humanitarian and therapeutic reasons. Uncontrolled pain in the postoperative period can have detrimental physiological effects. Pain can greatly impede the return of normal pulmonary functions such as inability to cough, bronchospasm which leads to atelectasis and hypoxemia especially in upper abdominal and thoracic surgeries.

ASSESSMENT OF EPIDURAL BLOCK

Onset of Sensory Block

In our study, the mean time for onset of sensory block was 14.36 ± 2.48 min. in Group C, 11.16 ± 2.13 min. in Group N as compared to 9.48 ± 1.80 min. in Group D. The difference in the mean time for onset of sensory block was statistically significant (P<0.001). Thus, we observed that the addition of dexmedetomidine with Ropivacaine in epidural significantly decreases the onset of sensory block as compared to Nalbuphine and Ropivacaine alone.

Our result are comparable with those of **Khobragade S et al(2017)[5]** study in which onset of sensory blockade was achieved early with mean time of 10.06 ± 4.42 minutes in Group D which showed significant difference from Group N, where the mean time for onset of sensory blockade was 13.88 ± 7.83 minutes. (p=0.014).

Time taken to achieve highest level of sensory block

In our study, the meantime taken to achieve maximum level of sensory block was 25.43 ± 2.54 min. in Group C, 20.33 ± 2.14 min. in Group N as compared to 15.35 ± 1.99 min. in Group D and was statistically significant (P<0.001). Our result coincides with a study by **Mittal AA et al (2016)[6]** the time to reach peak sensory level was (15.55 ± 1.43) min. in Group RD, (20.17 ± 2.48) min. in Group RF and (33.25 ± 6.155) min. in Group R.

Onset of Motor Block

In our study, the mean time for onset of motor block (modified Bromage scale grade 1) was 20.05 ± 2.75 min. in Group C, 15.15 ± 1.50 min. in Group N as compared to 13.04 ± 1.12 min. in Group D and was statistically significant (P<0.001). Study done by **Khare A et al (2023)[7]**also found early onset of motor block in dexmedetomidine group (9.65±2.05 min) as compared to Nalbuphine group(10.33±1.84 min).

Time taken to achieve complete motor block (modified Bromage grade 3)

In our study, the mean time taken to achieve complete motor block (modified Bromage grade 3) was 29.69 ± 1.79 min. in Group C, 26.56 ± 2.48 min. in Group N as compared to 24.87 ± 2.78 min. in Group D. Our results were supported by the study done by**Jacob M et al (2017).[8]**Theyobserved that time taken tocomplete motor blockade in dexmedetomidine group (43.2 ± 5.3 min) was less when compared to ropivacaine group (48.8 ± 6.1 min; P < 0.001).

Duration of sensory block (regression up to L5)

In our study, the mean time for complete recovery of sensory block (regression up to L5) was 396.66 ± 49.54 min. in Group C, 434.28 ± 60.47 min. in Group N as compared to 478.46 ± 92.86 min. in Group D(P<0.001). Thus, we observed that the addition of dexmedetomidine with epidural Ropivacaine significantly increases time for duration of sensory block as compared to Nalbuphine and Ropivacaine alone.

Our results were supported by the study conducted by **Khare A et al (2023)[7]** where they found that Mean time for complete recovery of sensory block (regression up to S1) was statistically longer in Group D (194.92 ± 4.72 min.) as compared to in Group N (186.14 ± 5.99 min.) (P < 0.001).

Duration of Motor block (regression up to M1)

In our study, the mean time for complete recovery of motor block (regression up to M1) was 341.79 ± 44.35 min. in Group C, 351.49 ± 51.53 min. in Group N as compared to 393.33 ± 85.69 min. in Group D(P<0.001).

Similar results were also found in study by **Mittal AA et al (2016)[6]** in which the mean time of complete motor recovery was (328.50 ± 31.82) min. in Group RD, (235.0 ± 21.84) min. in Group RF and (174.25 ± 13.18) min. in Group R. This showed that dexmedetomidine Group had prolonged motor recovery.

Mean duration of analgesia: In our study, the mean duration of analgesia 424.61 ± 48.06 min. in Group C, 478.41 ± 58.16 min. in Group N as compared to 520.82 ± 93.13 min. in Group D which was statistically significant **(p<0.001)**. Thus, we observed that epidural dexmedetomidine with ropivacaine led to prolongation of sensory blockade and duration of analgesia as compared to epidural Nalbuphine with ropivacaine. The comparison of VAS scores among three groups revealed significant differences throughout the study period. Group D consistently displayed lower VAS scores compared to Group N and Group C, with statistically significant differences observed at all time points as indicated by the low p-values (p<0.001).

Dalal ST et al (2020)[10] studied analgesic efficacy of epidural Nalbuphine in lower abdominal surgeries and found that the duration of analgesia in Group R was 4.68 ± 0.62 hr (280.8 min) and in Group R+N was 11.56±1.25 hr (693.6 min) which is statistically significant (p<0.001).

Sedation Score (Ramsay sedation score)

The comparison of sedation scores among three groups demonstrated significant differences over the study period. Group C consistently displayed lower

DOI: 10.69605/ijlbpr_14.2.2025.140

sedation scores compared to Group N and Group D, as evidenced by the statistically significant differences ($p<0.001$). Group N and Group D maintained higher sedation scores at these intervals, indicating a greater level of sedation.Mean heart rate, systolic blood pressure, diastolic blood pressure, mean arterial blood pressure and SpO2 in the Group D appeared to be lower than that of Group N and group C at maximum time intervals intraoperatively or postoperatively, but there was no statistically significant difference among the Groups ($P >0.05$).

CONCLUSION

From our study we concluded that epidural dexmedetomidine 0.75 µg/kg with 0.5% ropivacaine (18 ml) used for various lower limb or lower abdominal surgeries, achieved faster onset and higher level of sensory block with prolonged recovery of sensory & motor block, significant postoperative pain relief and a prolonged duration analgesia in comparison to epidural Ropivacaine alone or 200µg/kg Nalbuphine with 0.5% ropivacaine (18 ml) with stable haemodynamics and unremarkable side effects

REFERENCES

1. Macrae WA “Chronic pain after surgery.” Br J Anaesth2011; 87: 88-98.
2. Gupta A, Kaur S, Attri JP & Singh A. “Epidural analgesia: Concepts, safety issues, and techniques.” Indian J Anaesth. 2018; 62(9):690-697.
3. Kaur S, Attri JP, Kaur G, Singh TP. Comparative evaluation of ropivacaine versus dexmedetomidine and ropivacaine in epidural anaesthesia in lower limb orthopedic surgeries. Saudi journal of anaesthesia. 2014 Oct; 8(4):463.
4. Chatrath V, Joginder Pal Attri, Anju Bala, Ranjana Khetarpal, Deepti Ahuja“Epidural Nalbuphine for postoperative analgesia in orthopedicsurgery**.”**Anesthesia: Essays and Researches 2015;9(3); 11-15.
5. Khobragade SM, Jagdish Kalbhor, Ruchi Saran, Sandhya Manjrekar“A comparative study ofdexmedetomidine and Nalbuphine as an adjuvant to bupivacaine in lower limb surgeries done under epidural anaesthesia.*”*MedPulse International Journal of Anesthesiology. 2017; 3(1): 34-42.
6. Mittal A A, Agarwal A, Pilendran S, Chand T, Saxena A. “Role of Fentanyl versus Dexmedetomidine as an Adjuvant to Ropivacaine in Epidural Anaesthesia for Infra-Umbilical Surgeries.” International Journal of Scientific Research.2016; 5(3)305-308.
7. Khare A, Suman Kumari, Beena Thada, Maina Singh, Veena Mathur:A comparative study to evaluate the efficacy of dexmedetomidine and Nalbuphine as an adjuvant with 0.5% ropivacaine under epidural anaesthesiain patients undergoing various infraumblical surgeries. J YSR Univ Health Sci 2023; 12:46-53.
8. Jacob M, Nitesh Agrawal, Debashish Paul:Study of additive effect of Dexmedetomidine added to epidural Ropivacaine for orthopedic lower limb procedures.International Journal of Biomedical Research2017; 8(12): 699-703.
9. Meitei AJ, Ningombam T, Singh TH, Rajkumar G,Devi NA, Singh YA. A comparative study of ropivacaine versus ropivacaineplus dexmedetomidine under epidural anesthesia in lower limb surgeries.J Med Soc 2019; 33:20-7.
10. Dalal ST, SanjotNinave: Postsurgical analgesic efficacy of epidural nalbuphine in lower abdominal surgeries. J. Evolution Med. Dent. Sci. 2020; 9(04):216-222.