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Original Research Article

A Clinical Comparative Study of Ropivacaine with Dexmedetomidine or Fentanyl as an Adjuvant in Thoracic Epidural for Patients Undergoing Abdominal Surgeries

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Conflict of interest: Nil

Abstract:

Background: Thoracic epidural anaesthesia is commonly used for providing adequate perioperative analgesia in patients undergoing abdominal surgeries. Adding adjuvants to local anaesthetics can enhance analgesic efficacy and prolong the duration of sensory and motor blocks. This study compares the effectiveness and safety of Dexmedetomidine and Fentanyl as adjuvants to Ropivacaine in thoracic epidural anaesthesia in abdominal surgeries.

Aim and Objectives: To compare the onset and duration of sensory and motor blocks, analgesic efficacy, hemodynamic stability, and incidence of complications between Dexmedetomidine and Fentanyl as adjuvants to Ropivacaine in patients undergoing elective abdominal surgeries.

Materials and Methods: This study employed a unique prospective, randomized, double-blinded, controlled trial design to compare the effectiveness and safety of Dexmedetomidine and Fentanyl as adjuvants to Ropivacaine in thoracic epidural anaesthesia. The trial was conducted with 80 ASA grade I-II patients aged 25-60 years scheduled for elective abdominal surgeries. Patients were randomly assigned to two groups: Group A received 20 ml of 0.75% Ropivacaine with Dexmedetomidine 1 µg/kg, and Group B received 20 ml of 0.75% Ropivacaine with Fentanyl 1 µg/kg. The onset and duration of sensory and motor blocks, duration of analgesia, hemodynamic parameters, and postoperative complications were assessed and compared between the groups.

Results: Patients in Group A (Ropivacaine with Dexmedetomidine) had a significantly faster onset of sensory block ($p = 0.0001$) and longer duration of sensory ($p = 0.0001$) and motor blocks ($p = 0.0001$) compared to Group B (Ropivacaine with Fentanyl). The total duration of analgesia was also significantly longer in Group A ($p = 0.0001$). Hemodynamic parameters were well-maintained in both groups, though Group B exhibited slightly better hemodynamic stability. Postoperative complications were minimal and comparable between groups, with pruritus occurring only in Group B.

Conclusion: Dexmedetomidine, as an adjuvant to Ropivacaine in thoracic epidural anaesthesia, provides faster onset and longer duration of sensory and motor blocks, as well as superior analgesic efficacy compared to fentanyl. Despite slightly better hemodynamic stability in the Fentanyl group, dexmedetomidine proves to be a more effective adjuvant for enhancing the quality of anaesthesia in elective abdominal surgeries.

Keywords: Thoracic Epidural Anaesthesia, Ropivacaine, Dexmedetomidine, Fentanyl, Sensory Block, Motor Block, Analgesia, Hemodynamic Stability, Elective Abdominal Surgeries.

Introduction

Thoracic epidural anaesthesia (TEA) has become a cornerstone in the management of perioperative pain for patients undergoing abdominal surgeries. [1, 2] Its ability to provide superior analgesia, reduce the stress response to surgery, and enhance recovery has been well documented. [3] Among the local anaesthetics commonly used for TEA, Ropivacaine is favoured for its long duration of action and lower propensity for motor blockade, making it a safer option for postoperative analgesia. [4, 5]

In recent years, there has been growing interest in using adjuvants with local anaesthetics to improve the quality of anaesthesia and prolong the duration of analgesia. Dexmedetomidine, a selective α2-adrenergic agonist, has gained attention for its sedative, anxiolytic, and analgesic properties without significant respiratory depression. [6,7] Its use in TEA has shown promising results in enhancing the analgesic effect of Ropivacaine, providing stable hemodynamics, and reducing opioid consumption postoperatively. [6, 7]

Fentanyl, a potent opioid, is another commonly used adjuvant in epidural anaesthesia. [8] It is known for its ability to provide rapid and effective analgesia. [8, 9] When combined with Ropivacaine, Fentanyl has been shown to enhance the depth of anaesthesia and prolong postoperative pain relief. [9] However, its use is associated with potential adverse effects, including respiratory depression, nausea, and pruritus.

The comparative efficacy of Dexmedetomidine and Fentanyl as adjuvants to Ropivacaine in TEA for abdominal surgeries has not been extensively studied. This randomized controlled trial aims to evaluate the clinical outcomes of these combinations, focusing on intraoperative hemodynamic stability, the duration of postoperative analgesia, and the incidence of adverse effects. By comparing these two adjuvants, the study seeks to provide evidence-based guidance for optimizing pain management in patients undergoing abdominal surgeries.

Materials and Methods

This prospective, randomized, double-blinded, comparative study was conducted at SVBP Hospital, associated with LLRM Medical College, Meerut, affiliated with Chaudhary Charan Singh University, Uttar Pradesh. The study spanned 18 months, from October 2022 to April 2024, and included 80 patients classified as American Society of Anesthesiologists (ASA) grade I-II, aged between 25 and 60, who were scheduled for elective abdominal surgeries.

Ethical Approval and Patient Consent

Before the study commenced, institutional ethics committee approval was obtained on March 14, 2023 (Approval No. SC-1/2023/1382). The study was also registered with the National Clinical Trial Registry of India (CTRI/2024/01/061452). All participants were fully informed about the study's purpose, procedures, and potential risks, and their written consent was obtained.

Randomization and Blinding

Patients were randomly assigned into groups of 40, each using a sealed envelope technique. A qualified anesthesiologist who prepared the relevant drugs accordingly opened a sealed envelope containing instructions. Both the patients and the investigators were blinded to the group assignments.

Study Groups

- **Group A (RD):** Received 20 ml of 0.75% Ropivacaine combined with Dexmedetomidine 1 μg/kg.
- **Group B (RF):** Received 20 ml of 0.75% Ropivacaine combined with Fentanyl 1 μg/kg.

Inclusion Criteria

- ASA physical status I and II patients.
- Age 25-60 years.
- Both male and female patients undergoing elective abdominal surgeries.

Exclusion Criteria

- Age less than 25 years or more than 60 years.
- Patients unwilling to consent.
- Emergency surgeries or surgeries lasting more than 3 hours.
- ASA physical status class III or above.
- Known hypersensitivity to amide local anaesthetics or dexmedetomidine.
- Systemic or local infection, pre-existing major systemic illness, cardiovascular malformations, coagulopathy, or spinal deformities.
- Patients on anticoagulant or antiplatelet therapy.

Pre-Anaesthetic Assessment

A comprehensive pre-anesthetic check-up was conducted, including a detailed systemic examination and airway assessment. Necessary investigations were ordered according to the individual patient's requirements. Patients were pre-medicated with Tablet Pantoprazole 40 mg and Tablet Alprazolam 0.5 mg the night before surgery and 3 hours before surgery.

Anesthetic Technique

In the operating room, standard monitoring was initiated, and baseline vitals were recorded. Patients were preloaded with 10-20 ml/kg Ringer's solution. After positioning the patient in the sitting position, the T10-T12 intervertebral space was identified, and the epidural space was accessed using an 18-gauge Tuohy needle and the loss of resistance technique. An epidural catheter was inserted and fixed with an additional 5 cm into the epidural space, ensuring the standardization of the anesthetic technique across all patients.

Following a test dose of 3 ml of 2% Lignocaine with 1:200,000 Epinephrine to rule out intravascular or intrathecal injection, the study drugs were administered as per group allocation. The epidural solution was administered at a rate of 3 ml/10 sec. The onset of sensory block was assessed using the pinprick method.

Intraoperative Management

Patients received standard premedications, followed by induction with Propofol and intubation facilitated by Succinylcholine. Maintenance anaesthesia included Vecuronium, Nitrous Oxide, and Oxygen. At the end of surgery, patients were reversed with Neostigmine and Glycopyrrolate.

Monitoring and Data Collection

Hemodynamic parameters were recorded at regular intervals, and complications were noted and managed accordingly. Postoperative pain was assessed using the Visual Analogue Scale (VAS), and rescue analgesia was provided with Epidural Tramadol when VAS scores were ≥4.

Outcome Measures

- **Primary Outcomes:** Duration of analgesia
- **Secondary Outcomes:** Hemodynamic parameters, onset of sensory block, duration of sensory and motor block and incidence of complications.

Statistical Analysis

Data were analyzed using SPSS version 20. Quantitative data were described as mean ± standard deviation (SD) and compared using the Student's t-test. Categorical data were expressed as percentages and compared using the chi-square test. A p-value of <0.05 was considered statistically significant.

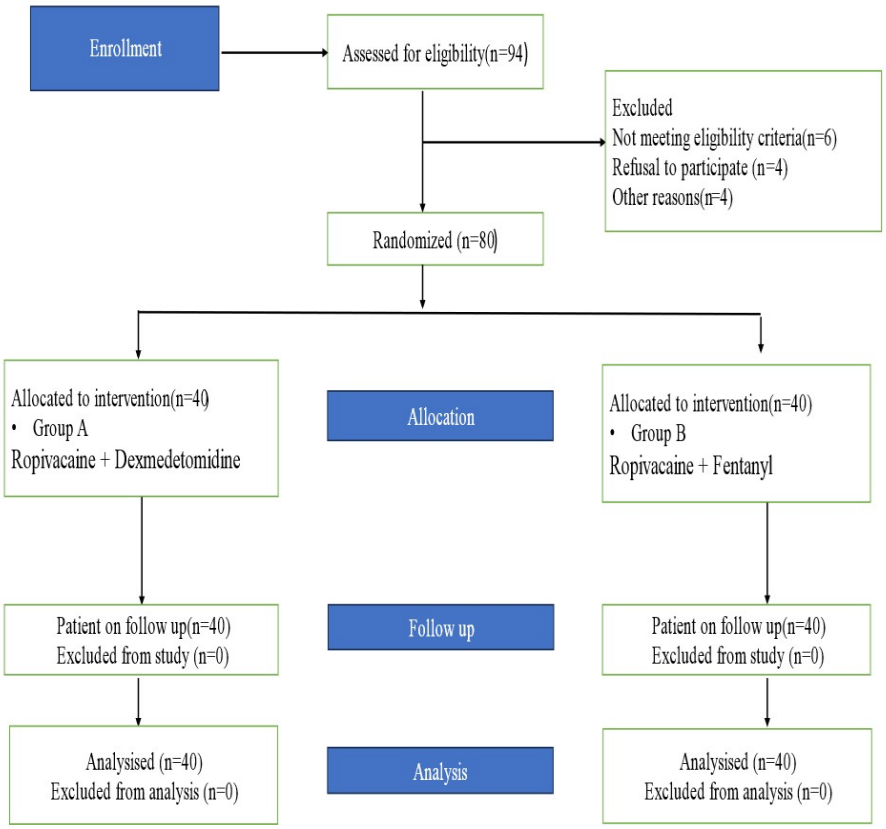

Figure 1: The Consolidated Standard of Reporting Trial (CONSORT) Flow diagram depicting the progress through the phases of the trial.

Results

The study included 80 patients, equally divided into Group A (Ropivacaine + Dexmedetomidine) and Group B (Ropivacaine + fentanyl). The mean age of patients in Group A was 38.73 ± 11.07 years, and in Group B, it was 38.38 ± 10.67 years. There was no statistically significant difference between the groups regarding age distribution (p = 0.886). The gender distribution was identical in both groups, with 27.5% males and 72.5% females, and the difference was not statistically significant (p = 1.00).

Table 1: Baseline Characteristics of Study Participants

Parameter	Group A (R+D)	Group B (R+F)	p-value
Age (years)	38.73 ± 11.07	38.38 ± 10.67	0.886
Gender (M/F)	11/29	11/29	1.00
Weight (kg)	63.55 ± 7.09	63.45 ± 5.42	0.428
Height (meters)	1.67 ± 0.07	1.66 ± 0.06	0.944
BMI (kg/m²)	22.76 ± 2.01	23.08 ± 1.71	0.447
ASA Grade (I/II)	15/25	11/29	0.340

Physical Characteristics

The patients' mean weight in Group A was 63.55 ± 7.09 kg, while in Group B, it was 63.45 ± 5.42 kg (p = 0.428). The mean height in Group A was 1.67 ± 0.07 meters, and in Group B, it was 1.66 ± 0.06 meters (p = 0.944). The Body Mass Index (BMI) was similar between the groups, with Group A having a mean BMI of 22.76 ± 2.01 kg/m² and Group B 23.08 ± 1.71 kg/m² (p = 0.447).

ASA Physical Status

In Group A, 60% of patients were ASA Grade I, and 40% were Grade II. In Group B, 27.5% were ASA Grade I, and 72.5% were Grade II. The difference in ASA grading between the groups was not statistically significant (p = 0.340).

Surgical and Anesthetic Outcomes

The mean duration of surgery was 117.20 ± 23.27 minutes in Group A and 115.85 ± 21.31 minutes in Group B, with no significant difference between the groups (p = 0.787). However, the onset of sensory block was significantly faster in Group A (9.30 ± 1.11 minutes) compared to Group B (12.41 ± 1.03 minutes) with a statistically significant p-value of 0.0001.

Table 2: Surgical and Anesthetic Outcomes

Parameter	Group A (R+D)	Group B (R+F)	p-value
Duration of Surgery (minutes)	117.20 ± 23.27	115.85 ± 21.31	0.787
Onset of Sensory Block (min)	9.30 ± 1.11	12.41 ± 1.03	0.0001
Duration of Motor Block (min)	276.62 ± 11.43	195.05 ± 18.12	0.0001
Duration of Sensory Block (min)	336.11 ± 20.57	243.88 ± 22.35	0.0001
Duration of Analgesia (min)	388.18 ± 14.96	292.02 ± 22.17	0.0001

Hemodynamic Parameters

Heart Rate: Significant differences in heart rate were observed between the two groups at several time points. Group A showed a consistently lower heart rate than Group B, with significant differences at 4 minutes (p = 0.044), 6 minutes (p = 0.004), 8 minutes (p = 0.002), and at multiple points after that.

Blood Pressure: Systolic blood pressure (SBP), diastolic blood pressure (DBP), and mean arterial pressure (MAP) were also significantly lower in Group A compared to Group B at various intervals, particularly beyond the 40-minute mark (e.g., SBP at 60 minutes, p = 0.006; DBP at 60 minutes, p = 0.016; MAP at 60 minutes, p = 0.006).

Sensory and Motor Block

Group A exhibited a longer duration of both sensory and motor block. The mean duration of the motor block was 276.62 ± 11.43 minutes in Group A compared to 195.05 ± 18.12 minutes in Group B (p = 0.0001). Similarly, the duration of the sensory block was significantly longer in Group A (336.11 ± 20.57 minutes) compared to Group B (243.88 ± 22.35 minutes) with a p-value of 0.0001.

Analgesia Duration

The duration of analgesia, defined as the time when VAS Score > 4, was significantly longer in Group A (388.18 ± 14.96 minutes) compared to Group B (292.02 ± 22.17 minutes) with a statistically significant p-value of 0.0001.

Complications

Complications were minimal and comparable between the two groups. The most notable difference was the incidence of pruritus, which was observed in 12.5% of patients in Group B but absent in Group A. Other complications, such as nausea, vomiting, shivering, and dry mouth, were similarly distributed between the two groups, and none were statistically significant (p = 0.17).

Table 3: Complications

Complication	Group A (R+D)	Group B (R+F)	p-value
Nausea	2 (5%)	2 (5%)	1.00
Vomiting	1 (2.5%)	1 (2.5%)	1.00
Shivering	2 (5%)	2 (5%)	1.00
Dry Mouth	1 (2.5%)	1 (2.5%)	1.00
Pruritus	0 (0%)	5 (12.5%)	0.17

Discussion

The primary objective of this study was to compare the efficacy and safety profiles of the selective α2 agonist Dexmedetomidine and the opioid fentanyl when administered epidurally along with Ropivacaine in patients undergoing elective abdominal surgeries. Despite the increasing availability of laparoscopic procedures, open abdominal surgeries remain prevalent in developing regions, primarily due to the lack of equipment and trained personnel. One significant challenge associated with open abdominal surgeries, especially upper abdominal surgeries, is the substantial impairment of pulmonary function postoperatively. This impairment is often due to reflex diaphragmatic changes and incisional pain, leading to marked diaphragmatic dysfunction.

One of epidural analgesia's key benefits is its role in promoting early postoperative mobilization. By effectively managing pain, epidural anaesthesia facilitates quicker recovery and reduces the risk of complications associated with prolonged immobility. This early mobilization accelerates physical recovery and enhances psychological well-being by restoring a sense of autonomy and normalcy. Epidural analgesia can significantly reduce vital and functional residual capacity (FRC) by 30-40% of pre-operative values, with a return to normal typically occurring within 2-3 days post-surgery.

In this study, 80 patients classified as ASA grade I-II, aged 25-60, were randomly assigned to two groups. Group A (R+D) received 0.75% Ropivacaine combined with Dexmedetomidine 1 µg/kg, while Group B (R+F) received 0.75% Ropivacaine combined with Fentanyl 1 µg/kg. The primary endpoint was the total duration of analgesia, with secondary endpoints including intraoperative hemodynamic parameters, the duration of sensory and motor blocks, and the incidence of complications.

The demographic characteristics of the patients, including age, gender, body weight, height, BMI, and ASA physical status, were comparable between the two groups, with no statistically significant differences.

In terms of surgical and anaesthetic outcomes, the mean duration of surgery was similar between the groups ($p = 0.787$). However, the onset of sensory block was significantly faster in Group A compared to Group B ($p = 0.0001$), consistent with previous studies by Vasupalli R et al. [10] and Agrawal S et al. [11].

Hemodynamic parameters revealed that Group A had a consistently lower heart rate than Group B at several time points, with statistically significant differences observed at 4, 6, 8, 30 minutes, and beyond. Similarly, systolic, diastolic, and mean arterial blood pressures were lower in Group A, with significant differences noted, particularly beyond the 40-minute mark. These findings align with Rastogi B et al. [12] studies and Singh RB et al. [13].

Oxygen saturation (SpO2) levels remained above 95% in all patients throughout the study, with no significant differences between the groups.

The study also found that the duration of sensory and motor blocks was significantly longer in Group A compared to Group B ($p = 0.0001$). This aligns with the results of studies by Bajwa SJ et al. [14]and Singh R et al. [15], which also reported prolonged motor block duration in the group receiving dexmedetomidine.

The duration of analgesia was notably longer in Group A, with a mean duration of 388.18 ± 14.96 minutes compared to 292.02 ± 22.17 minutes in Group B ($p = 0.0001$). Similar results were observed in the study by Mittal AA et al. [15], which reported prolonged analgesia in the Dexmedetomidine group.

Regarding postoperative complications, the incidence of nausea, vomiting, shivering, and dry mouth was comparable between the groups. However, only Group B has observed pruritus, affecting 12.5% of the patients.

Conclusion

The present study concludes that the use of dexmedetomidine as an adjuvant to Ropivacaine in thoracic epidural anaesthesia results in a faster onset of sensory block, prolonged duration of both sensory and motor block, and superior analgesic efficacy compared to fentanyl. The total duration of analgesia was significantly longer in the Dexmedetomidine group, indicating its better overall analgesic profile. While both groups maintained hemodynamic stability, patients receiving Ropivacaine with Fentanyl were slightly more stable, though without clinical significance. Overall, dexmedetomidine proved to be a more effective adjuvant than fentanyl, enhancing the quality of anaesthesia and reduc-

ing the total analgesic requirement, making it a valuable option for patients undergoing elective abdominal surgeries.

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