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Comparative evaluation of epidural 0.75% ropivacaine and 0.75% ropivacaine with dexmedetomidine in lower abdominal surgeries, Govt Medical College

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Abstract---Background: For the lower abdomen, perineum, and lower limb surgery, spinal anesthetic is the most usually used block. Fentanyl, ketamine, tramadol, neostigmine, magnesium sulfate, and other adjuncts have been used to extend the analgesic impact of local anesthetics. Aim and objective: In this study, We looked for research that compared epidural with 0.75% ropivacaine and 0.75% ropivacaine with dexmedetomidine. The length of sensory and motor block, postoperative analgesia, and adverse effects of epidural anesthesia for lower abdominal procedures were all secondary objectives. Materials and Methods: Following the permission of the Institutional Ethical Committee and valid informed consent from all patients. This research looked at 100 ASA Grade I and II patients who had lower abdomen operations and were between the ages of 20 and 55. The patients were divided into two groups at random. Patients in Group A (n=50) received 20 mL of 0.75 percent Ropivacaine 150 mg epidurally. Patients in Group B (n=50) were given 20ml of 0.75 percent Ropivacaine with dexmedetomidine (1 g/kg body weight). The Student's t-test was used to compare categorical variables between groups. The P-value was determined to finally evaluate the levels of significance. $P < 0.05$ was considered as significant at 5% significance level; $P < 0.01$ was considered to be significant at 1% significance level and a $P < 0.001$ was considered highly significant. Results: Group A had an average age of 39.1 ± 8.72 years, whereas Group B had an average age of 41.28 ± 8.55 years. There was no discernible age

difference between the two groups. Both groups had similar average surgery times (Group A: 104.80 ± 9.56 min and Group B: 111.42 ± 9.88 min). Table 2 shows the motor and sensory features of both groups. After giving the study medication in the epidural space, the time needed for the start of sensory block to the T10 dermatome in Group A was 12.22 ± 1.59 min minutes and in Group B was 10.02 ± 1.39 minutes, with a statistically significant difference between the two groups ($P = 0.001$). Conclusion: The anesthetic in both groups was found to be effective, and the patients' hemodynamics were stable. In terms of longer sensory block, postoperative analgesia with lower rescue analgesic doses, and patient satisfaction, the 0.75 percent ropivacaine with dexmedetomidine group did better.

Keywords---dexmedetomidine, ropivacaine, epidural anesthesia, lower abdominal surgeries.

Introduction

For the lower abdomen, perineum, and lower limb surgery, spinal anesthetic is the most usually used block. Many adjuncts have been used to prolong the analgesic effect of local anesthetics, including fentanyl, ketamine, tramadol, neostigmine, magnesium sulfate, and others [1, 2]. When compared to bupivacaine, ropivacaine, a novel amide local anesthetic, has less cardiovascular and central nervous system toxicity and a lower risk of the motor block during postoperative epidural analgesia [3]. The use of opioids as an adjuvant reduces the amount of local anesthetic used and produces improved analgesia [3, 4]. Dexmedetomidine, a novel 2 agonist, has emerged as a panacea for a variety of perioperative and critical care applications and procedures [6]. It inhibits sympathetic outflow and norepinephrine release by acting on both pre-and post-synaptic sympathetic nerve endings. Sedative, anxiolytic, analgesic, sympatholytic, and hemodynamic effects are all caused by this action [7]. Dexmedetomidine causes tolerable hypotension and bradycardia, but the drug's most notable characteristic is the absence of opioid-related adverse effects such as respiratory depression, itching, nausea, and vomiting. Dexmedetomidine has been tested epidurally in humans without causing any neurological deficits [8, 9]. When dexmedetomidine is used with ropivacaine in epidural and caudal anesthesia, it gives extended postoperative analgesia with few adverse effects [10]. In this study, we looked for research that compared epidural ropivacaine to ropivacaine with dexmedetomidine. Secondary goals included determining the features of sensory and motor block duration, postoperative analgesia, and epidural anesthetic side effects for lower abdominal procedures.

Materials and Methods

Source of data

After receiving consent from the institutional ethics committee, the study was carried out at the Govt medical college in Suryapet. Each patient signed a written informed consent form. The study comprised 100 patients (ASA I, II) of either sex

who were undergoing lower abdominal operations between the ages of 18 and 55.

Study design

This was a Prospective, randomized, study.

Sample size

100 patients were studied.

Inclusion criteria

ASA I/II patients between 18 and 55 years of age undergoing lower abdominal surgeries were included.

Exclusion criteria

Patients with known allergy to the study drugs, any contraindications to epidural anesthesia like hypotension, uncooperative patients, previous laminectomy, spine abnormality, and Neurologic, cardiopulmonary or psychiatric disease, active liver, and kidney disease.

Intervention

100 patients were randomly allocated into two groups, each group with 50 patients.

- Group A: patients receiving 20 ml of 0.75% Ropivacaine 150mg epidurally (n=50).
- Group B: patients receiving 20ml of 0.75% Ropivacaine with dexmedetomidine (1 µg/kg bodyweight) (n=50).

A complete pre-anesthetic check-up was performed the day before surgery. Patients were instructed to limit their intake of liquids and solids by mouth for at least 6 hours before the procedure. The use of the visual linear analog scale (VAS) to measure the amount of analgesia in the postoperative phase was discussed. This was done with a 10-centimeter line. The first end mark of '0' denotes 'no pain,' whereas the second end mark of '10' denotes severe suffering.' The night before surgery, all patients were given a pill of alprazolam 0.25 mg. On the day of surgery, a 45-minute intramuscular injection of glycopyrrolate 0.2 mg was administered, followed by an intravenous infusion of midazolam 0.04 mg/kg body weight soon before the procedure.

Pulse rate, non-invasive systolic and diastolic blood pressure (DBP), and respiration rate were all measured before surgery. Good intravenous access was established in the operating theatre, and patients were preloaded with 10 ml/kg body weight of Ringer Lactate solution over 15-20 minutes. The multipara monitor was connected, and baseline pulse rate, noninvasive systolic and diastolic blood pressure (SBP and DBP), oxygen saturation, and electrocardiogram (ECG) measurements were taken before the monitoring began. An anesthesiologist

manufactured the study medicine, which was subsequently administered to another anesthesiologist who was unaware of the nature of the drug. The patients were placed on their sides in the lateral decubitus posture. The epidural block was administered using a midline route in the L3-L4 intervertebral space (in case of difficulties, the L2-L3) intervertebral space) under aseptic conditions. The skin wheal was raised with 2% lignocaine, and the lumbar epidural space was discovered using an 18G Tuohy needle utilizing the loss of resistance to saline technique. To rule out an intravascular or intrathecal injection, a test dose of 2-3 ml of lignocaine with epinephrine 1:200,000 was given after negative aspiration for blood and CSF. The experimental medicine was slowly administered into the epidural area. Group A got 20 ml of 0.75 percent ropivacaine hydrochloride, while Group B received 20 ml of 0.75 percent ropivacaine hydrochloride + dexmedetomidine (1 g/kg body weight).

To eliminate bias during drug administration, the volume of the medication was kept constant at 22 ml in both groups by adding normal saline. After an epidural block, patients were immediately turned supine. All of the patients were given oxygen at a rate of 6 L/min. Pulse rate, respiration rate, non-invasive SBP and DBP, SpO₂, and ECG were all continuously monitored. Preoperatively, every 5 minutes for the first 30 minutes, and then every 15 minutes until the completion of the operation, readings were taken. Atropine 0.6 mg was given intravenously to patients with bradycardia, defined as a heart rate of fewer than 60 beats per minute. Hypotension was defined as a drop in blood pressure of 20% or less than 90 mm Hg, which was treated with intravenous Ringer's lactate solution or, if needed, a 5 mg injection of ephedrine hydrochloride titrated according to blood pressure. At the start, the pulse rate, systolic blood pressure, and diastolic blood pressure were all measured. Time to the beginning of T10 sensory analgesia, motor blockage, a maximum degree of sensory analgesia, the maximum duration of sensory analgesia, the maximum duration of motor blockade, and side effects and complications for the first 30 minutes, parameters were recorded every 5 minutes, then every 15 minutes.

Statistical analysis

Data were analyzed using SPSS version 13.0 computer software. Numerical variables were presented as mean and standard deviation (SD) and categorical variables were presented as frequency (%). The student's *t*-test was used for between-group comparisons between categorical variables. The 'P'-value was determined to finally evaluate the levels of significance. $P < 0.05$ was considered as significant at 5% significance level; $P < 0.01$ was considered to be significant at 1% significance level and a $P < 0.001$ was considered highly significant.

Results

A 100 patients aged 18 to 55 years old who were scheduled for lower abdominal procedures, a prospective, randomized, comparative research was done in the Department of Anesthesiology & Critical Care Govt Medical College, Suryapet. In the present study, both groups were comparable concerning demographic characteristics and did not show any statistically significant difference ($P > 0.05$) [Table 1]. The average age in years was 39.1 ± 8.720 in Group A, and 41.28 ± 8.559

in Group B. There was no significant difference in age between the groups. The average weight in kgs in Group A was 57.16 ± 9.6856 and in Group B was 58.56 ± 6.960 , there was no significant difference in weight between the groups and the two groups were comparable. The average height in cms in Group-A was 156.2 ± 4.844 and in Group B was 154.48 ± 5.139 , there was no significant difference in height between the groups. two groups were comparable. The sex distribution between the two groups is predominantly female population.

Table 1
Demographic profile of group A and group B

Demographic profile	Group A (n = 50)	Group A (n = 50)	P-value
Age(Yrs)	39.1 ± 8.720	41.28 ± 8.559	0.210
Weight(Kgs)	57.16 ± 9.685	58.56 ± 6.960	0.408
Height(Cms)	156.2 ± 4.844	154.48 ± 5.139	0.088
Sex			
Males	17	10	0.176
Females	33	40	

P > 0.05 non-significant

The number of patients undergoing each type of lower abdominal surgery was comparable in both groups, allowing for a fair comparison. Furthermore, the average operation time was similar in both groups (Group A: 104.80 ± 9.56 min and Group B: 111.42 ± 9.88 min). Table 2 shows the motor and sensory features of both groups. After giving the study medication in the epidural space, the time needed for the start of sensory block to the T10 dermatome in Group A was 12.22 ± 1.59 minutes and in Group B was 10.02 ± 1.392 minutes, with a statistically significant difference between the two groups ($P = 0.001$). The difference in the maximum sensory level achieved in the two groups was highly significant ($P < 0.001$). However, the median maximum sensory level reached in Group A was T5 (23 patients (43%)) dermatome and in Group B was T4 (28 patients (56%)) dermatome. Although the mean time taken to reach the maximum sensory level (Group A: 21.94 ± 2.359971 min vs. Group B: 13.7 ± 1.054 min) was again comparable in both groups ($P = 0.001$). The difference in the onset of complete motor blockade (min) in the two groups was highly significant ($P < 0.001$). The mean time to a total duration of a motor blockade in Group A was 142.28 ± 9.041 minutes and in Group B was 217.42 ± 9.448 minutes. The mean time to the total duration of a motor blockade is statistically significant (P value <0.001). The mean time to a maximum duration of sensory analgesia in Group A was 219.78 ± 10.288 minutes and in Group B was 318.22 ± 12.485 minutes. The mean time to a maximum duration of sensory analgesia is statistically significant (P value <0.001). The results were shown in table-2.

Table 2
Sensory and motor block characteristics in group A and group B

Values in minutes	Group A (n = 50)	Group B (n = 50)	P value
onset of sensory analgesia to T10 Level(min)	12.22 ± 1.594	10.02 ± 1.392	0.001

maximum level of sensory analgesia(min)	21.94 ± 2.359	13.7 ± 1.054	0.001
Maximum sensory level achieved	T5 dermatome	T4 dermatome	0.001
The onset of complete motor blockade(min)	21.86 ± 2.595	16.00 ± 1.277	0.001
Total duration of motor blockade(min)	142.28 ± 9.041	217.42 ± 9.448	0.001
Maximum duration of Sensory analgesia(min)	219.98 ± 10.288	318.22 ± 12.485	0.001

P > 0.05 non-significant, P < 0.05 significant, P < 0.001 highly significant.

Hemodynamic Parameters

The mean pulse rate was compared between the two groups Group A and Group B at 0 to 180 minutes. There was no significant difference between the two groups concerning pulse rate when recorded at these time intervals (figure-1).

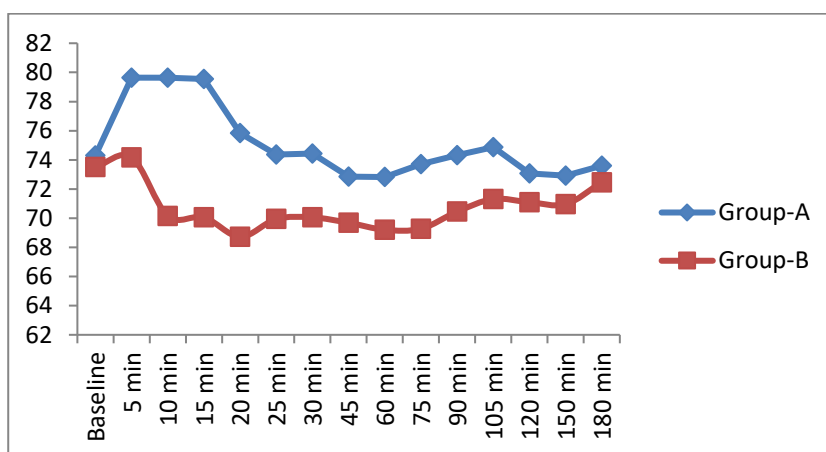


Figure 1. Hemodynamic parameters of Pulse rate changes intra-operatively

The mean systolic blood pressure changes over the time intervals were compared between the two groups Group A and Group B. It was found that systolic blood pressure did not differ between the groups (figure-2).

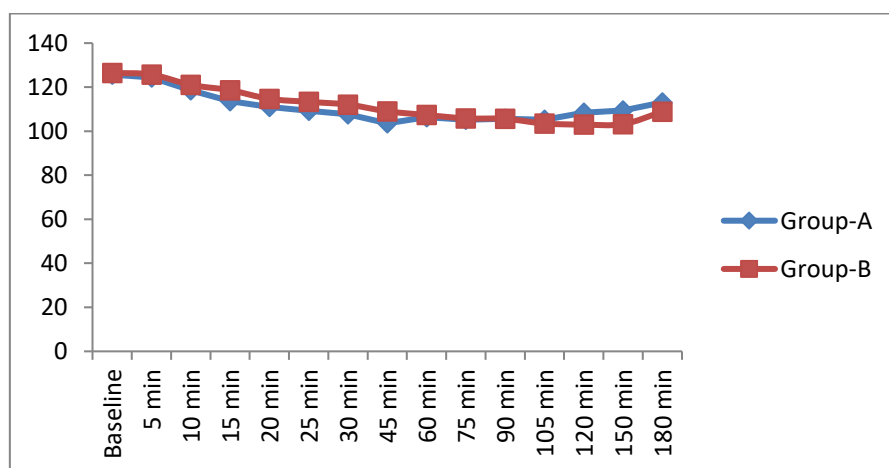


Figure 2. Hemodynamic parameters of Systolic blood pressure changes intra-operatively

The mean diastolic blood pressure changes over the time intervals were compared between the two groups Group A and Group B. It was found that diastolic blood pressure did not differ between the groups, Shows in figure-3.

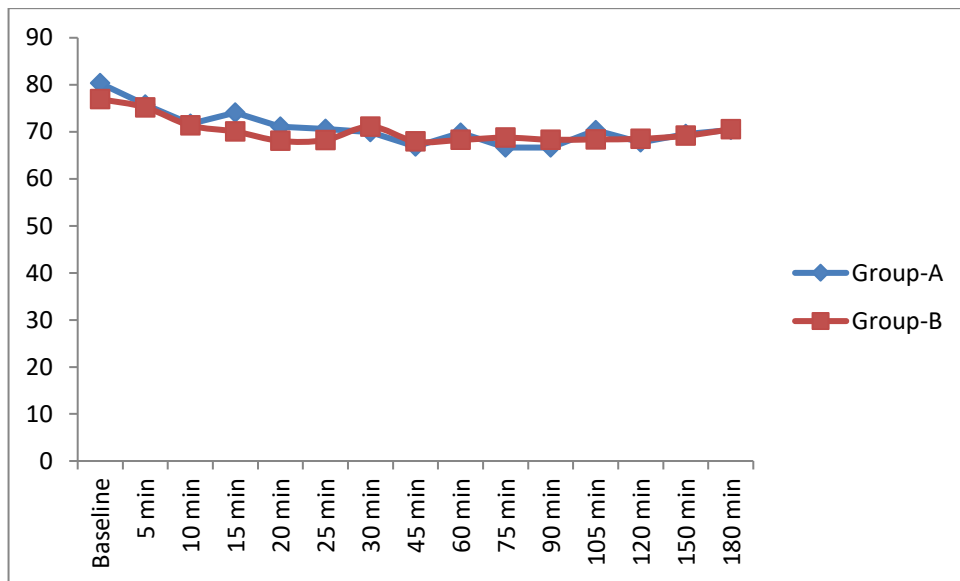


Figure 3. Hemodynamic parameters of diastolic blood pressure changes intra-operatively

Adverse effects of group-A 4 patients had nausea, and 3 patients had hypotension, in Group-B 4 patients had nausea, 4 patients had hypotension, 2 patients had bradycardia during the intraoperative period. There was no difference in the incidence of nausea and hypotension in both groups. However not statistically significant (p value <0.435) as calculated by the chi-square test.

Discussion

In comparison to Ropivacaine alone, the results of this study suggest that supplementing epidural Ropivacaine with Dexmedetomidine considerably extends the duration of sensory and motor block and improves the quality of postoperative analgesia. Secondary to the diverse methods of action of local anesthetics, the mechanism by which 2 adrenergic agonists extend the motor and sensory block of local anesthetics might be an additive or synergistic impact. Presynaptic C-fibers and postsynaptic dorsal horn neurons bind to dexmedetomidine. They cause analgesia by inhibiting C fiber transmitter release and hyperpolarizing postsynaptic dorsal horn neurons [11, 12]. The strong analgesic characteristics of local anesthetics and 2 adrenergic agonists are due to their complementary action. The binding of 2 adrenergic agonists to motor neurons in the dorsal horn may cause the motor block to the last longer [13]. Various authors have investigated the use of Dexmedetomidine as an epidural adjuvant and found that it synergizes with local anesthetics without causing any extra morbidity [14, 15]. When epidural or caudal dexmedetomidine is administered in combination with general anesthesia, clinical investigations show that it potentiates neuraxial local

anesthetics, reduces intraoperative awareness and anesthetic needs, and improves postoperative analgesia [16].

The demographic profile in the present study was comparable and shows any significant difference. the onset of sensory block to T10 dermatome in Group A was 12.22 ± 1.594 min and in Group B was 10.02 ± 1.392 min and this difference between the two groups was statistically significant ($P = 0.001$). These findings were in line with those of Salgado et al.[14], who found that the beginning of the sensory block to the T10 dermatome took 13.8 minutes with 20 ml of 0.75 percent ropivacaine hydrochloride and 1 g/kg dexmedetomidine, and 11.5 minutes with 0.75 percent ropivacaine and 1 g/kg dexmedetomidine. Using 1.5 g/kg dexmedetomidine, Bajwa et al.[15] found that onset at the T10 dermatome was 8.52 ± 2.36 minutes. This discrepancy might be related to the administration of a greater dose of dexmedetomidine. In Group B, the highest sensory level obtained was greater than in Group A. These findings were comparable to those of Shaikh and Rohin[17], who used plain Ropivacaine and obtained a maximum sensory level of T6 dermatome, and Bajwa et al., who used Dexmedetomidine as an adjuvant to Ropivacaine and achieved a maximum sensory level of T5-6 dermatome.

The difference between the two groups' maximal sensory levels was extremely significant ($P 0.001$). However, in Group A, the median highest sensory level obtained was T5 (23 patients (43%) dermatome, whereas in Group B, it was T4 (28 patients (56%) dermatome. When Dexmedetomidine was given as an adjuvant to Ropivacaine, Bajwa, et al.[15] found that the duration to attain maximal sensory level was 13.14 ± 3.96 min. This occurred a bit sooner because of Bajwa et al.[15] employed a greater dosage of dexmedetomidine (1.5/kg). Brown et al. used 20 mL of 0.5 percent Ropivacaine in their study. We found that the meantime to a total duration of a motor blockade is statistically significant ($P \text{ value} < 0.001$). The mean time to the maximum duration of sensory analgesia in Group A was 219.78 ± 10.288 minutes and in Group B was 318.22 ± 12.485 minutes. Brown *et al.*[18] observed that the total duration of sensory block was 333 ± 54 min, using 20 ml of 0.5% Ropivacaine which is nearly consistent with the present study.

Salgado *et al.* [14] saw a considerable improvement in analgesic effectiveness. In our investigation, which was comparable to others [19], no adverse effects such as respiratory depression, pruritis, headache, backache, or vomiting were seen. Dexmedetomidine had a moderate side effect profile, which was consistent with other investigations [20, 21]. Because the majority of the patients in our research were catheterized, the incidence of urine retention could not be determined. Patients in both groups were sedated for the first 30 minutes of the operation due to premedication with injectable midazolam. Patients in the Dexmedetomidine group were more sedated after 30 minutes than those in the ordinary Ropivacaine group, and the difference in sedation score was statistically significant. This was in line with the findings of Bajwa et al. [15],

We discovered that mixing dexmedetomidine with ropivacaine resulted in a significant amount of sedation. Patients in both groups were hemodynamically stable in the current investigation, and the incidence of Bradycardia and hypotension were comparable at all assessed intervals, reaffirming the previously

reported benefits of α -2 agonists in providing a hemodynamically stable perioperative time [22-24]. There was no significant difference in the doses of Atropine and Ephedrine given to the patients in both groups, for treating Bradycardia and hypotension respectively.

Conclusion

The anesthetic in both groups was found to be effective, and the patients were hemodynamically stable. However, the 0.75 percent ropivacaine with dexmedetomidine group performed better in terms of extended sensory block, postoperative analgesia with lower rescue analgesic dosages, and patient satisfaction. However, for brief surgical operations or ambulatory surgery, the longer duration of motor block and sedation generated by 0.75 percent ropivacaine with dexmedetomidine may be undesired.

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