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A Comparative Study of Epidural Ropivacaine with Dexmedetomidine 1 µg/Kg and Ropivacaine with Clonidine 1µg/Kg by Epidural Route in Patients Undergoing Lower Abdominal and Lower Limb Surgery

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Abstract

The aim of the current study was to evaluate the efficacy of dexmedetomidine and clonidine as adjuvants to Ropivacaine in the context of epidural anesthesia for procedures involving the lower abdomen and lower limbs. A total of Sixty patients with ASA I and II who were scheduled for lower limb and abdominal procedures under epidural anesthesia was included in the study. A pre-anesthetic checkup is performed one day before the procedure. Patients were screened for systemic illnesses, and laboratory tests were performed. The process for epidural anesthesia was described to the patients, and a signed agreement was acquired. Patients were randomized into two groups using computer-generated numbers: ropivacaine along with clonidine (RC) and ropivacaine along with dexmedetomidine (RD). Both the Ropivacaine and Clonidine and Ropivacaine and Dexmedetomidine groups differed significantly in the time it took for sensory and motor blockade to take effect. It follows that a synergistic effect of deep and persistent motor blockade, prolonged duration of sensory blockade, and effective sedation may be achieved when Ropivacaine and Dexmedetomidine are administered epidurally together. The dexmedetomidine group did have more severe but manageable side effects. As a result, ropivacaine mixed with dexmedetomidine has the potential to be an effective and safe epidural blocking agent for procedures involving the lower abdomen and leg surgeries.

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Introduction

Epidural anesthesia is a flexible treatment used for both anesthesia and postoperative pain relief. Epidural anesthesia has several benefits, including the ability to provide anesthesia for an extended period of time with regular top-ups. It is also the recommended technique for giving postoperative analgesia. In addition to promoting intraoperative hemodynamic stability, it has been shown to lessen the perioperative stress response, which lowers complications and improves patient outcomes. By reducing postoperative

pain, it facilitates early mobility and lowers the risk of thromboembolic events. Even though all regional anesthetic techniques offer excellent muscle relaxation and ideal operating conditions for surgeons, patients still experience a great deal of anxiety and fear due to their apprehension about

surgery, the unfamiliarity of the operating room, and the noise produced by sophisticated equipment. The quest has long been on for medications having sedative qualities that may be administered to local anesthetics as adjuvants to overcome this restriction.

Adjuvants such as fentanyl, morphine, ketamine, and α-2 agonists like clonidine and dexmedetomidine have been investigated for their potential to enhance local anesthetic efficacy in various regional anesthetic procedures. Each adjuvant has its own unique pharmacological profile and potential adverse effects. All of these medications gave the patient great sedation, forgetfulness, reduced anxiety, and a longer period of anesthesia and analgesia along with excellent hemodynamic stability. As an adjuvant in regional anesthesia, α-2 adrenergic agonists have both sedative and analgesic effects. A α-2 adrenergic agonist that is eight times more selective than clonidine is dexmedetomidine. These adjuvants lessen the need for anesthetic drugs due to their analgesic qualities and enhancement of local anesthetic effects. Their stable hemodynamics and heightened sympathoadrenal stability result in a reduced oxygen demand, making them very valuable pharmacological agents. After receiving ethical approval, a prospective clinical study was designed at Sri Venkateswaraa Medical College Hospital to compare the clinical profile and efficacy of two α-2 adrenergic agonists, dexmedetomidine and clonidine, when used as adjuvants in epidural anesthesia for patients undergoing lower limb and abdominal surgeries. Particular emphasis was placed on the sedative qualities of the drugs and their capacity to provide pain relief both during and after surgery. Few studies have been conducted in the Indian population to show the effects of epidurally administered dexmedetomidine in combination with local anesthetics. Our study's objective was to evaluate the effects of ropivacaine and dexmedetomidine administered as adjuvants for epidural anesthesia.

Aim

The aim of the research was to evaluate the efficacy of dexmedetomidine and clonidine when combined with Ropivacaine for the purpose of providing epidural anesthesia during operations that include the lower abdomen and lower limbs.

Objectives

The objectives of the study were to compare

1. When the sensory blockade begins and lasts
2. Motor blockade onset and duration
3. Analgesic duration
4. Modifications in intraoperative hemodynamics

Materials And Methods

Following approval from the college's ethical committee, sixty patients with ASA-I and II were scheduled for lower abdominal and lower limb surgeries under epidural anesthesia. A pre-anesthetic checkup is performed one day before the procedure. Patients were screened for systemic illnesses, and laboratory tests were performed. The process for epidural anesthesia was described to the patients, and signed agreement was acquired. Patient preparation involves an 8-hour fast. Patients were given Rantidine 150 mg and Alprazolam 0.5 mg the night before surgery. Patients were randomized into two groups using computer-generated numbers: ropivacaine with clonidine (RC) and ropivacaine with dexmedetomidine (RD). Blinding was accomplished by ensuring that the resident doctors preparing the study medication was not participating in the study.

Boyles anesthesia apparatus was examined. Before the operation, a functional suction device, a stylet, and appropriate-size endotracheal tubes with medium and large blades were kept available. Atropine, adrenaline, mephentermine, ephedrine, dopamine, noradrenaline, dobutamine, nitro-glycerine, and amiodarone were kept on hand in an emergency medication tray. Once the usual monitoring was connected in the operating room, loss of resistance to air was used to identify and confirm the epidural space. A test injection of 3 millilitres of a 2% lignocaine hydrochloride solution containing 1:2,000,000 adrenaline was performed. Afterwards, the thesis medication is taken as follows: 15ml of 0.75 percent ropivacaine with 1 mcg/kg clonidine is given to Group RC, and 15ml of 0.75 percent ropivacaine with 1 mcg/kg dexmedetomidine is given to Group RD. The bilateral pin-prick approach for motor block assessment and verification of the sensory level and modified Bromage scale.

Inclusion criteria:

- ASA physical status classes I and II.
- Individuals between the ages of 18 and 60.

Exclusion criteria:

- Psychiatric diseases.
- History of drug addiction and allergy to amide-based local anaesthetics.
- ASA III & IV
- Contraindications to epidural anesthesia
- Spinal anomalies.
- Hematologic disorders.
- Abnormal bleeding or coagulation test results.
- An infection of the skin on the local level.
- Patients with hemodynamic instability, including bradycardia, orthostatic hypotension, and atrioventricular block.

Statistical analysis

The descriptive statistical analysis was used in the present study. Number (%) is used to describe categorical data, whereas Mean ± SD (Min-Max) is used to display continuous values. To find out whether study parameters comparing two or more groups on a categorical scale were significant, the Chi-square/Fisher Exact test was used. We used the students' t-test, Anova, and Chi-square to examine the data statistically, and we found the p-value. We used Excel and Word to create charts, tables, and other documents. The significance levels are $P > 0.05$, $P < 0.05$, and $P < 0.001$.

Results

The two groups were similar since there was no discernible variation in the distribution of ages and sexes, as well as in terms of height and weight. It was also discovered that the distribution of surgical length and type was similar. Patients receiving lower limb procedures, vaginal hysterectomies, and hernioplasty were seen in both groups.

Discussion

Epidural anesthesia is often regarded as the most efficient treatment option due to the fact that it offers a comprehensive and versatile administration of anesthesia. The benefits include the regulation of the stress response via the use of sympatholysis, constant hemodynamics that led to a less cardiac morbidity, decreased pulmonary difficulties as a consequence of intense physiotherapy and early mobility, less blood loss, and a decreased possibility of complications of clotting after surgery.

There is a dearth of data that compares the dosages of clonidine and dexmedetomidine that are administered via the epidural route. The administration of epidural clonidine at dosages ranging from 1 to 4 μg/kg has been the subject of several investigations. These studies have brought to light the fact that a dosage of 1 μg/kg has been shown to lengthen the duration of pain relief without causing any unintended side effects. In several studies, the use of epidural dexmedetomidine at dosages ranging from 1 to 2 μg/kg has been investigated. It is not possible to extend the action of ropivacaine by administering dosages of 1 μg/kg ropivacaine. Within the context of epidural anesthesia, we administered clonidine and dexmedetomidine at dosages of 1 μg/kg along with ropivacaine. These doses were equal and low.

According to Bajwa et al. individuals receiving dexmedetomidine (8.52 ± 2.36 min) experienced the beginning of sensory analgesia at T10 sooner than those getting clonidine (9.72 ± 3.44 min), and this was also linked to a greater and faster degree of sensory blockage. When dexmedetomidine is given epidurally, it has been shown to reach a maximum concentration in the cerebrospinal fluid in 5 minutes, with a 0.7-minute distribution half-life. Epidural dexmedetomidine has a dose-dependent antinociception effect that is linked to its affinity for the spinal cord's alpha 2 receptors. Moreover, dexmedetomidine is more lipid soluble than clonidine.

Our study found that individuals receiving dexmedetomidine experienced sensory blockage at a substantially earlier time (6.30 ± 3.67 min) than those getting clonidine (7.63 ± 3.67 min). There was a considerably greater dermatomal spread in group RD.

As part of a research study carried out by Neogi et al., children received clonidine and dexmedetomidine together with 0.25% ropivacaine caudally in order to decrease the pain that they experienced after surgical procedures. When comparing the groups that were administered clonidine (13.17 ± 0.68 hours) and dexmedetomidine (13.17 ± 0.68 hours), it was observed that there was no significant difference in

the average duration of analgesia between the two groups.

For the purpose of this investigation, caudal analgesia was used as an adjunct to general anesthesia, and a CRIES score of four or above indicated the length of time that the patient was under analgesic treatment.

Anand VG et al., Kannan et al., conducted study on sixty children were divided in to 2 groups of 30 each drugs administered through caudal anaesthesia for lower abdominal surgeries. The mean weight in RC and RD groups are 59.60 ± 8.96 and 59.27 ± 11.01.

In our present study the weights of patients in groups RC and RD are equivalent and not statistically significant. The average weight in group RC is 58.96 ± 8.01 kgs, whereas in group RD it is 58.34 ± 10.97 kgs. According to research by Casati et al., patients who received 0.5% ropivacaine during surgery were more likely than those who received bupivacaine to have an insufficient motor blockade. Instead of using 0.5% ropivacaine, 0.75% was chosen for the current study. The research team of Sruthi Arunkumar et al. found that 0.75% Ropivacaine is just as effective as 0.5% bupivacaine in blocking motor and sensory nerve impulses, and it has less cardiotoxicity and adverse effects than clonidine. The 0.75% Ropivacaine group also had a faster average start time of sensory block compared to the 0.5% Bupivacaine group.

According to research by Bajwa SJ, Bajwa SK, Kaur J, et al., the ropivacaine with dexmedetomidine group exhibited a beginning of sensory analgesia at T10 of 8.52 ± 2.36 minutes, whereas the ropivacaine with clonidine group showed a similar time frame of 9.72 ± 3.44 minutes.

According to the findings of our study, the onset of sensory analgesia had a duration of 6.30 ± 3.67 minutes in the group that received ropivacaine along with dexmedetomidine, whereas the group that received ropivacaine along with clonidine had a duration of 7.63 ± 3.67 minutes.

Bajwa SJ, Arora V, Kaur J et al found that the average duration of motor blockage was 246.72 ± 30.46 minutes in the ropivacaine with dexmedetomidine group and 228.44 ± 27.18 mins in the ropivacaine with clonidine group, which was not statistically significant.

In the study conducted by Bajwa SJ, Bajwa SK, Kaur J, and others, it was shown that the group administered ropivacaine along with dexmedetomidine experienced the onset of sensory analgesia at T10, which was 8.52 ± 2.36 minutes. On the other hand, the group administered ropivacaine along with clonidine demonstrated a comparable time frame of 9.72 ± 3.44 minutes respectively.

Both Bajwa et al. and Swami et al. found that there were no differences in hypotension or bradycardia that were statistically significant between persons who were taking either clonidine or dexmedetomidine.

In our research, three patients in group RD reported dry mouth, and the patient receiving dexmedetomidine had a higher risk of hypotension and bradycardia than the one receiving clonidine.

Bajwa et al. found a greater incidence of nausea and dry mouth in the postoperative phase. In our current research the duration of 2 segment regression, Bromage grade 1, sensory regression to S 1, and 1st epidural top up were all similar and statistically significant ($p < 0.001$).

Table 1 Demographic data

PARAMETER, (No of patients-30)	GROUP – (RC)	GROUP – (RD)	P - VALUE
Age	38.67± 19.45	41.56± 13.98	0.937
Weight	58.96± 8.01	58.34± 10.97	0.997

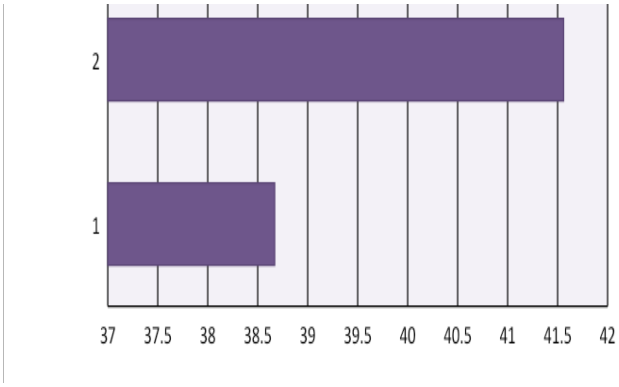

Figure 1 Age distribution in each group

The patients who took part in this project were in the age group of 18 to 60 years. On statistical comparison the two groups were comparable and statistically not significant.

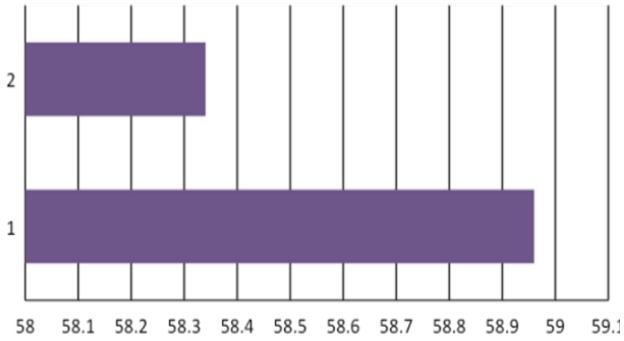

Figure 2 Comparison of weight in (kgs) in both the groups

The weight of the patients in group RC & group RD are comparable and statistically not significant. The mean weight in group RC is 58.96± 8.01 kgs and & group RD is 58.34± 10.97 kgs.

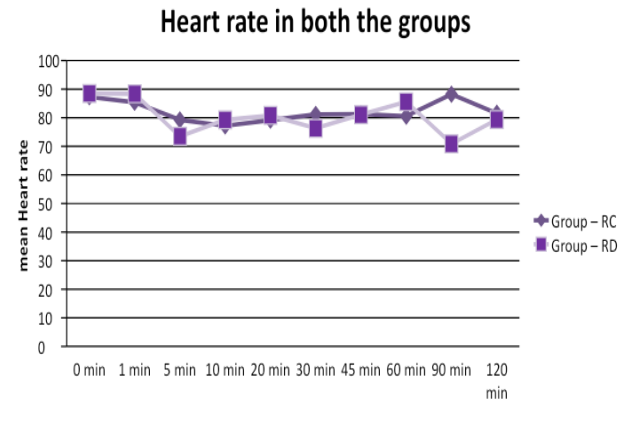

Figure 3 The heart rate is compared between 2 groups at 10, 45, 60 and 90 the study is statistically Significant. (P < 0.05)

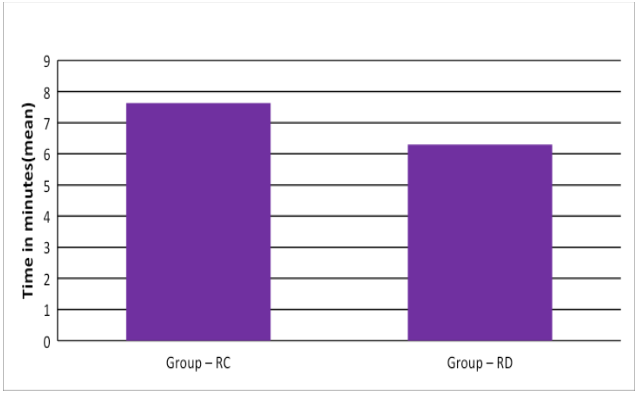

Figure 4 Time from injection to T10 sensory level

Onset of sensory blockade in both groups is comparable and the distribution of patients was statistically significant, onset is delayed in group I.

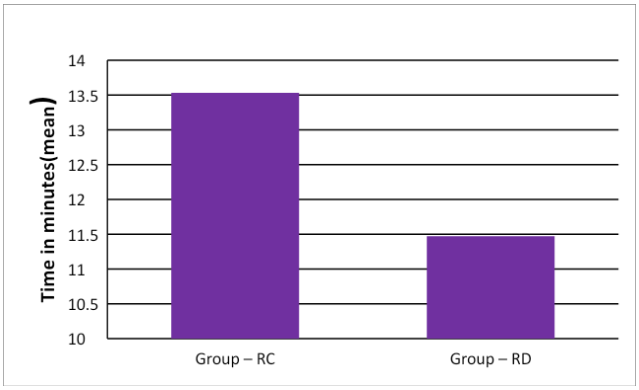

Figure 5 Time from injection to maximum sensory block

Time for maximum sensory blockade is comparable and the distribution of patients was statistically significant. Onset is delayed in Group RC.

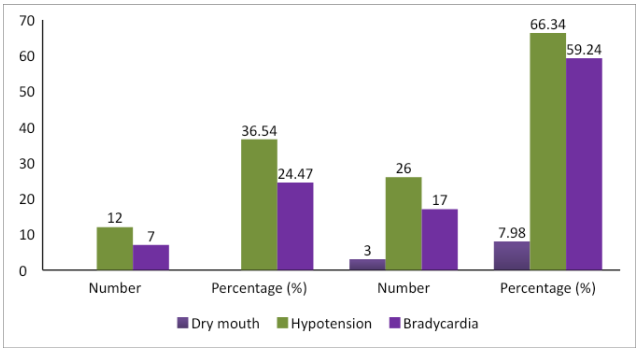

Figure 6 Comparison of side effects in both the groups

In this study side effects of 2 groups were compared, 7.98% patients of RD group had experienced dry mouth, 66.34 % developed hypotension, 59.24% developed bradycardia. In RC group 36.54% developed hypotension and 24.47% developed bradycardia.

Conclusion

There was a significant difference in the start of sensory and motor blockage between the groups that were given ropivacaine with clonidine and those who were given ropivacaine with dexmedetomidine. In the group that received Ropivacaine with Dexmedetomidine, the motor obstruction was much stronger than in the group that received Ropivacaine with Clonidine; nevertheless, the difference between the two groups was not statistically significant. By a wide margin, the duration of the sensory block was much greater in the group that received Ropivacaine with Dexmedetomidine as opposed to the group that received Ropivacaine with Clonidine.

Table 2 Comparison of mean Heart rate in two groups

HR (bpm)	Group – RC	Group – RD	P value
Pre-op	87.29± 12.12	88.47± 13.86	0.543
1 min	85.39 ± 10.46	88.38± 13.43	0.278
5 min	79.26± 9.78	73.48 ± 10.21	0.234
10 min	77.15 ± 8.45	79.27 ± 11.57	0.003
20 min	79.16 ±9.67	80.80 ± 12..38	0.738
30 min	81.17± 12.39	76.30 ± 9.47	0.237
45 min	81.26± 12.18	81.07 ± 10.38	0.008
60 min	80.56 ± 11.39	85.57 ± 9.48	0.678
90 min	88.23± 16.19	70.87 ± 11.49	0.009
120 min	81.56±14.56	79.34 ± 8.58	0.167

Table 3 Comparison of time for onset of sensory and motor block

Variables	Group – RC	Group – RD	P value
Time from injection to sensory level T10 (in min)	7.63 ± 3.67	6.30 ± 3.67	0.039
Time for maximum sensory block (in minutes)	13.53± 4.01	11.47± 3.79	0.028
Onset time for Bromage 3 (in minutes)	20.56 ± 5.89	20.17 ± 7.30	0.020

Table 4 Comparison of side effects in two groups

Side effects	Group – RC		Group – RD	
	Number	Percentage (%)	Number	Percentage (%)
Dry mouth	0	0	3	7.98
Hypotension	12	36.54	26	66.34
Bradycardia	7	24.47	17	59.24

The sedation ratings of the group that received Ropivacaine and Dexmedetomidine were significantly higher than those of the group that received Ropivacaine and Clonidine. The group who received Ropivacaine in conjunction with Dexmedetomidine were more likely to have side symptoms, such as hypotension, bradycardia, and dry mouth, compared to the group that received Ropivacaine in conjunction with Clonidine.

Furthermore, when compared to clonidine at doses of 1 μg/kg, it has been shown that dexmedetomidine is an exceptional adjuvant to ropivacaine for the purpose of epidural anesthesia. This is because it has a more rapid onset, maintains its effects for a longer period of time, and produces a more profound sense of drowsiness. The methodology that was used resulted in the results that were obtained from this research.

Ethical Approval

This research was conducted in line with the principles of the Declaration of Helsinki. All procedures involving study participants were carried out with care and consideration for their welfare, in compliance with ethical standards and regulations.

Author Contribution

Dr. Anand. B, Professor, Department of Anesthesiology, Sri Venkateswaraa Medical College Hospital and Research Institute made substantial contributions to the conception, design, acquisition, analysis, or interpretation of data for the work. Dr. Raghuraman. T.R, Assistant Professor, Department of Anesthesiology, Sri Venkateswaraa Medical College Hospital and Research Institute, was involved in drafting the manuscript. Dr. Prabhuram Niranjan, Assistant Professor, Department of Anesthesiology, Sri Venkateswaraa Medical College Hospital and Research Institute was instrumental in revising it critically for important intellectual content. All authors gave final approval of the version to be published and agreed to be accountable for all aspects of the work, ensuring its accuracy and integrity.

Conflict of Interest

The authors declare no conflict of interest, financial or otherwise.

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