e-ISSN: 0975-1556, p-ISSN:2820-2643

Available online on www.ijpcr.com

International Journal of Pharmaceutical and Clinical Research 2023; 15(5); 1919-1925

Original Research Article

A Comparative Study of Ropivacaine versus Ropivacaine Plus Dexmedetomidine under Epidural Anaesthesia in Lower Limb Surgeries

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Received: 26-02-2023 / Revised: 24-03-2023 / Accepted: 20-04-2023
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Conflict of interest: Nil

Abstract

Background: We designed a prospective study to examine the effectiveness of ropivacaine versus ropivacaine plus dexmedetomidine under epidural anaesthesia in lower limb surgeries because there are few studies that have examined the efficacy of dexmedetomidine as an adjuvant to ropivacaine in epidural anaesthesia.

Methods: A prospective, randomised, double-blind, hospital-based study titled "A Comparative Study Of Ropivacaine Versus Ropivacaine Plus Dexmedetomidine Under Epidural Anaesthesia In Lower Limb Surgeries: Study at SMS Medical College Jaipur During 2021–23" was conducted on patients having lower limb surgery under epidural anaesthesia at the department of anaesthesia attached to S.M.S. Medical College, Jaipur with the goal of comparing ropivacaine versus ropivacaine plus dexmedetomidine under epidural anesthesia in lower limb surgeries.

Results: The mean Sensory onset (min) in Group R was significantly higher (9.63±1.938 min) as compared to that in Group RD, 4.97±1.426 min. Time to achieve the highest level of sensory block and motor onset (in minutes) for groups R and RD was 16.53 ±1.196 and 11.80± 1.157, and also 14.77± 2.897 and 10.57± 2.932, respectively. A significant difference was observed in relation to the time to achieve the highest level of sensory block and motor onset (min). The mean SD of the sedation score was 1.80±0.407 and 2.90±0.607 in Groups R and RD. Respectively, this observation was statistically significant. (P= <0.001S). The mean duration of sensory and motor block in Group R and Group RD was 393.53±23.47 and 528.83±53.50 minutes, respectively, as well as 263.13±29.218 and 394.67±46.85 min, respectively.(P=<0.001S).i.e., groups were comparable according to the duration of the motor block. The mean value for the total number of rescue doses in Group R was 2.77 ± 0.43 more than in Group RD (1.97 ± 0.83), which was statistically highly significant.

Conclusion: It was determined that the dexmedetomidine group performed better in terms of longer sensory block duration, postoperative analgesia with lower doses of rescue analgesic needed, and improved patient satisfaction. Dexmedetomidine produces a motor block and drowsiness that can last for a long time, which may not be ideal for ambulatory surgery or quick surgical operations.

Keywords: Sensory, Motor, Lower Limb, Dexmedetomidine, Ropivacaine.

Introduction

With rising demand for post-operative pain treatment and a desire to reduce the need for intravenous anaesthetic medications during the post-operative period, the use of neuraxial blocks for orthopaedic surgery has rapidly expanded during the last few decades. To extend the duration of intraoperative and postoperative analgesia and to reduce the negative effects of large dosages of local anaesthetics, various adjuvants are used with local anaesthetics.[1]

With rising demand for post-operative pain treatment and a desire to reduce the need for intravenous anaesthetic medications during the post-operative period, the use of neuraxial blocks for orthopaedic surgery has rapidly expanded during the last few decades. To extend the duration of intraoperative and postoperative analgesia and to reduce the negative effects of large dosages of local anaesthetics α_2, various adjuvants are used with local anaesthetics.[1]On the basis of past research, it was shown that when Dexmedetomidine is combined with Ropivacaine during epidural and caudal anaesthesia, the result is sustained postoperative analgesia with few adverse effects.[3-5]

We designed a prospective study to examine the effectiveness of ropivacaine versus ropivacaine plus dexmedetomidine under epidural anaesthesia in lower limb surgeries because there are few studies that have examined the efficacy of dexmedetomidine as an adjuvant to ropivacaine in epidural anaesthesia.

Material and Methods

Study Area: The study was conducted in Department of Anaesthesia attached to S.M.S. Medical College, Jaipur.

Study Design: Hospital based, prospective, randomized, double blinded, interventional study.

Study Period: After the approval of plan by research review board and institutional ethics committee for 1 year

Study Universe: patients undergoing lower limbs surgery under Epidural anaesthesia.

Eligibility Criteria

Inclusion Criteria:

1. Patients giving consent to participate in study.
2. Patient posted for lower limb surgeries belonging to ASA Grade I and II
3. Age group 20 - 65 yrs
4. Weight 40 to 70 kg
5. Height > 140 cm

Exclusion Criteria:

1. Patient not willing to give consent.
2. Patients with history of bleeding & coagulation disorders or patients on anticoagulants.
3. Chronic history of headache and backache
4. Patients with uncontrollable hypertensive, uncontrollable diabetes mellitus, severe cvs malformation, psychiatric illness, neurological disorder, morbid obesity, compromised renal cardiac or respiratory status.
5. H/o spinal surgery, spinal deformity or infection at local site.
6. Pregnancy.
7. Allergic to any of concerned drugs.

Sample Size: A sample size of (n=30) cases in each group is required at 95% confidence interval with 80% power to verify the expected difference of 4.20 in mean and SD 2.5 for time to onset of sansory block to T10 dermatome in both groups as per seed article. This sample size is adequate to cover all other study variables too. (As per Seed Article Journal of Medical Society.January-April 2019;33

Study Groups: The study was conducted in following two groups of patients. Each group was consist of 30 patients.

Group A:(n=30):-patients were receive 20 ml (150 mg) of 0.75% Ropivacaine diluted to 22ml Normal Saline

Group B:(n=30):-patients were receive 20ml (150mg) of 0.75% Ropivacaine plus Dexmedetomidine 1μg/kg diluted to 22ml of Normal Saline.

Sampling Technique: Simple random technique through sealed envelope method.

Randomization: It was a statistical procedure by which the participants are allocated into 2 different groups. In this study randomization was done by sealed envelope method. A total of 60 envelopes (30 per group) were made, each envelope mentioning a particular study group.

Blinding: This trial is so planned that neither the investigator nor the patient is aware of the group allocation and the drugs used.

Statistical Analysis

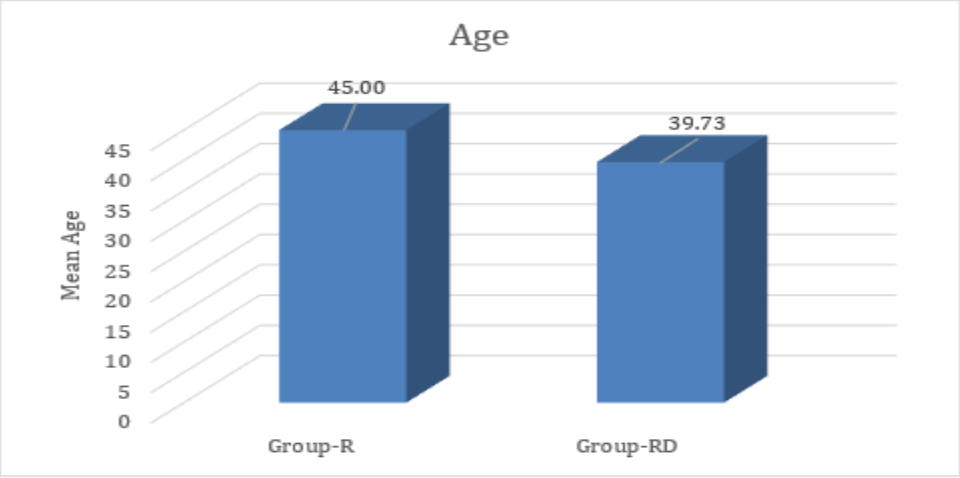
- For significance in difference in mean time duration for need of first rescue analgesia in both groups) → STUDENT'S T test was applied.
- For significance in difference in median VAS Score, at 0-6 hours, 6 – 12 hours, 12-24 hours post operative period in both group

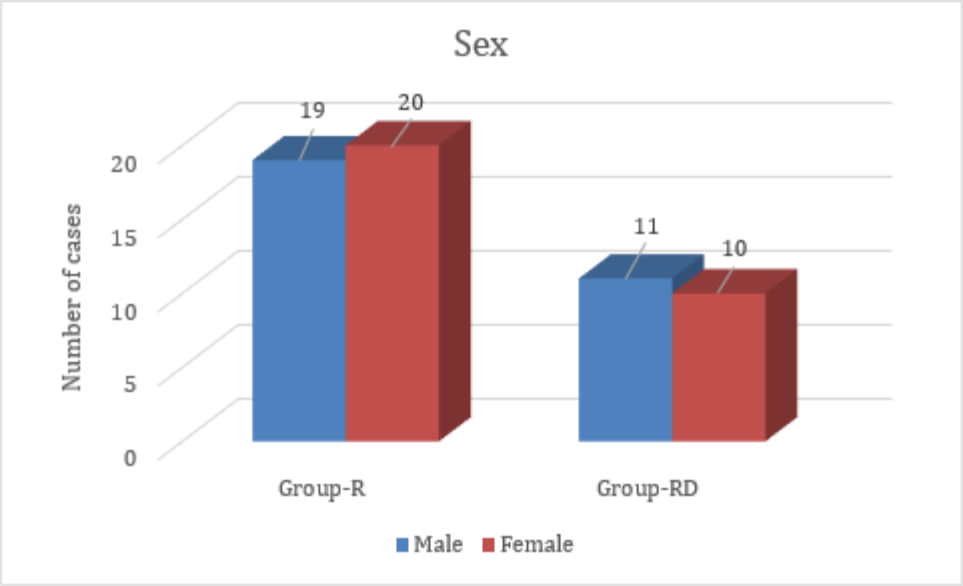
Results

Table 1: Socio-demographic profile

Variable	Group-R	Group-RD	p-value
Mean age in yrs	45.00±12.281	39.73±13.751	0.295
Male : Female	19:11	20:10	0.99
ASA (I:II)	24:6	27:3	0.47

Both groups were comparable





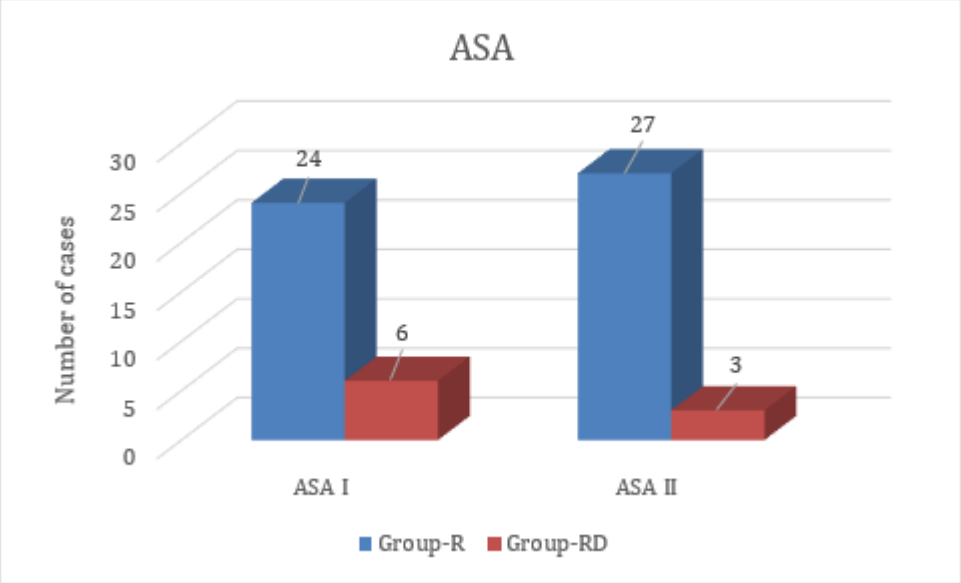


Table 2: Outcome profile

Variable	Group-A	Group-B	p-value
Sensory onset (min)	9.63±1.938	4.97±1.426	<0.001
Time to achieve the highest level of sensory block(min)	16.53 ±1.196	11.80± 1.157	<0.001
Motor onset(min)	14.77± 2.897	10.57± 2.932	<0.001
Intensity of motor block	2.63±0.490	3.30±0.466	<0.001
Sedation score	1.80±0.407	2.900.607	<0.001
Duration of sensory block (mint)	393.53±23.475	528.83±53.509	<0.001
Duration of motor block (mint)	263.13±29.218	394.67±46.855	<0.001
No. of rescue analgesia given in 24 hr	2.77 .± 430	1.97 ± 0.83	<0.01

The mean Sensory onset (min) in Group R was significantly higher (9.63±1.938 min) as compared to that in Group RD, 4.97±1.426 min. Time to achieve the highest level of sensory block and motor onset (in minutes) for groups R and RD was 16.53 ±1.196 and 11.80± 1.157, and also 14.77± 2.897 and 10.57± 2.932, respectively. A significant difference was observed in relation to the time to achieve the highest level of sensory block and motor onset (min). The mean SD of the sedation score was 1.80±0.407 and 2.90±0.607 in Groups R and RD. Respectively, this observation was statistically significant. (P= <0.001S). The mean duration of sensory and motor block in Group R and Group RD was 393.53±23.475 and 528.83±53.509 minutes, respectively, as well as 263.13±29.218 and 394.67±46.855 min, respectively. (P =<0.001S).i.e., groups were comparable according to the duration of the motor block. The mean value for the total number of rescue doses in Group R was 22.77± 0.430 more than in Group RD (1.97 ± 0.83), which was statistically highly significant.

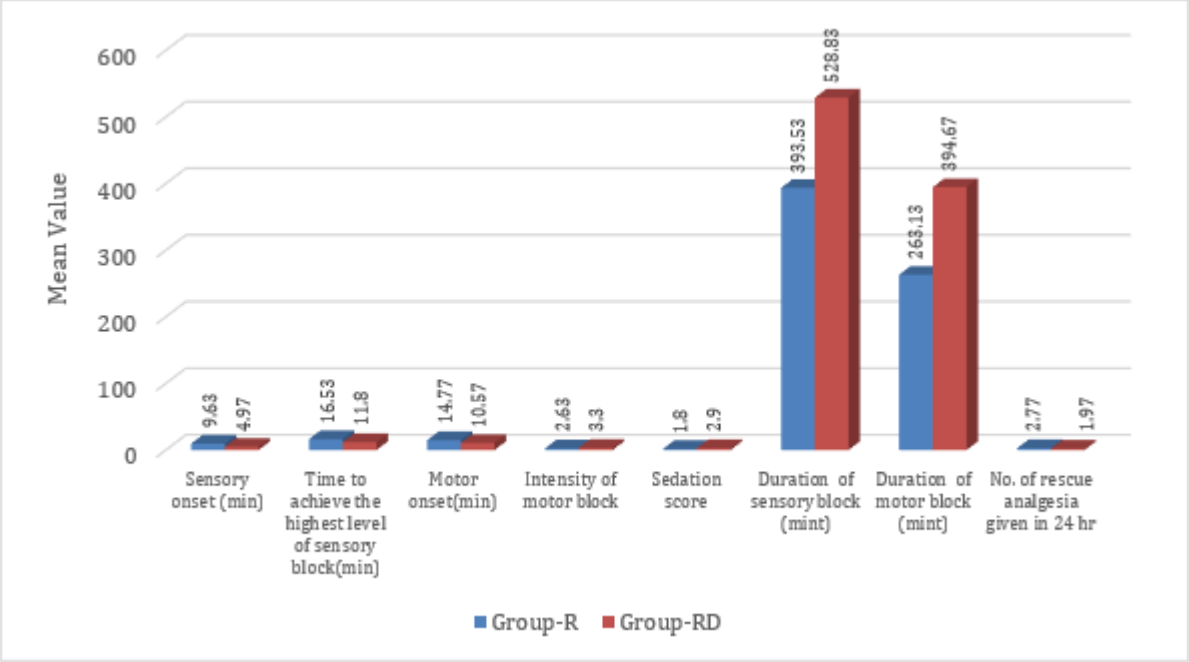
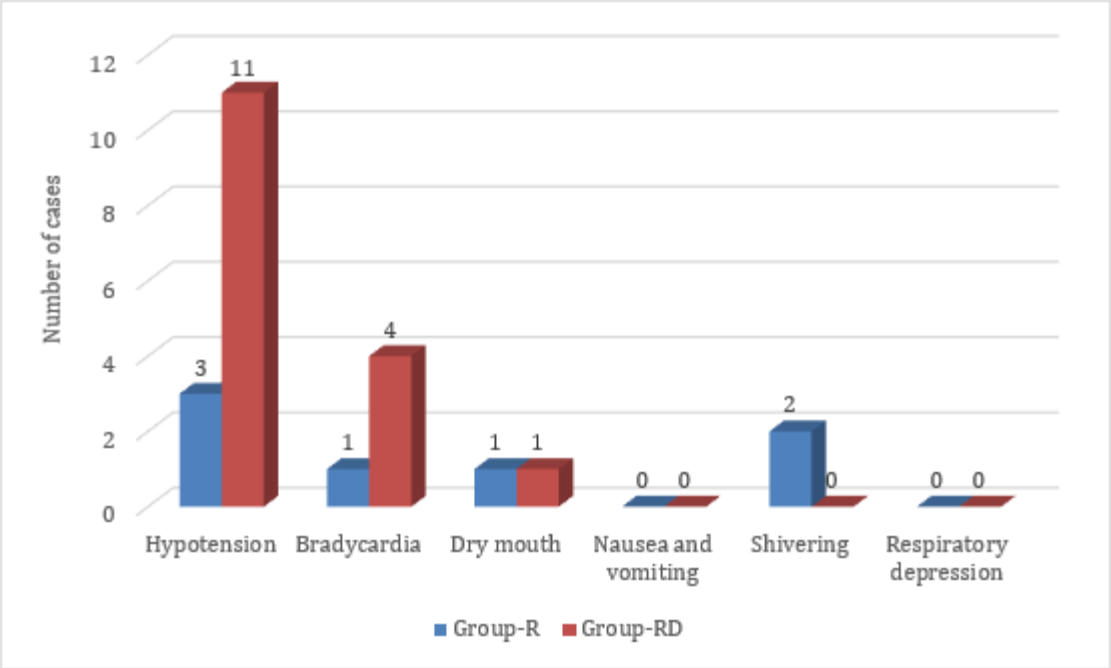


Table 3: Distribution of the cases according to adverse effect

	Group R(N=30)		Group RD(N=30)		
	No	%	No	%	p-values
Hypotension	3	10	11	36.67	0.03S
Bradycardia	1	3.33	4	13.33	0.350NS
Dry mouth	1	3.33	1	3.33	0.472NS
Nausea and vomiting	0	0	0	0	N/A
Shivering	2	6.67	0	0	1.000NS
Respiratory depression	0	0	0	0	N/A



The relative frequency of various side effects during and following surgery in both groups is shown in the table below. In contrast, the incidence of hypotension was greater in the RD group (36.67% vs. 10%) (P=0.03S). Hypotension was treated with mephentermine.

There was statistically no difference between the groups for other negative symptoms as bradycardia, dry mouth, and shivering (3.33% vs 13.33%), (3.33% vs 3.33%), and (6.67% vs 0), respectively. The drug atropine was applied to bradycardia. No patient from either group experienced respiratory depression, nausea, or vomiting.

Discussion

The demographic profile used in this study was similar and did not reveal any appreciable differences. These outcomes were consistent with the findings of Salgado et al.[6], who noted that the mean time for the beginning of sensory block to the T10 dermatome was 13.8 min with 20 ml of 0.75% ropivacaine hydrochloride and the onset to the T10 dermatome was 11.5 min with 0.75% ropivacaine and 1 g/kg dexmedetomidine.

When Bajwa et al.[7] used 1.5 g/kg of dexmedetomidine, the onset time at the T10 dermatome was 8.52±2.36 minutes. The increased dexmedetomidine concentration utilised may be the cause of this variation. In comparison to Group R, Group RD had a greater mean maximum sensory level attained. These findings were consistent with those of studies by Shaikh and Rohin[8] using Ropivacaine alone, in which T6 dermatome was the highest sensory level attained, and by Bajwa et al.[7] using Dexmedetomidine as an adjuvant to Ropivacaine, in which T5-6 dermatome was the highest sensory level attained.

In comparison to Group RD, which was nearly equivalent, Group R took longer on average to attain the highest sensory level. When Dexmedetomidine was given as an adjuvant to Ropivacaine, Bajwa et al.[7] found that the duration to attain maximum sensory level was 13.14 3.96 min. This occurred a little early because Bajwa et al.[7]

employed a greater dose of dexmedetomidine (1.5 /kg).

In comparison to Group R, Group RD dramatically extended the overall time of sensory block. Using 20 ml of 0.5% ropivacaine, Brown et al.'s observation that the total time of the sensory block was 333 54 min is almost identical to the findings of the current investigation.

The greatest motor block's onset and duration were comparable with the epidural Dexmedetomidine that was employed in our investigation. Salgado et al.[6] and Bajwa et al.[7] noted similar outcomes.

The analgesic efficacy of Dexmedetomidine as an epidural adjuvant is supported by the greatly postponed need for rescue analgesia in the current trial when 1 /kg Dexmedetomidine was added to Ropivacaine. Salgado et al. also observed noticeably enhanced analgesic effectiveness.[6] Similar to other studies, none of the adverse effects such as respiratory depression, pruritis, headache, backache, and vomiting were observed in our investigation.[7-9]

Conclusion

The dexmedetomidine group, it was determined, performed better in terms of prolonged sensory block duration, postoperative analgesia with lower doses of rescue analgesic needed, and patient satisfaction scores. For quick surgical operations or ambulatory surgery, however, a lengthy duration of the motor block and sedation caused by dexmedetomidine may not be desirable.

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