The Journal of International Medical Sciences Academy
2025; (April - June); Vol 38; No. 2

ORIGINAL

Evaluation of Dexmedetomidine as an Adjuvant to Ropivacaine in Epidural Anaesthesia for Gynaecological Surgery

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Abstract

Background: Epidural anesthesia, particularly when combined with an adjuvant, offers superior pain relief and promotes early mobilization compared to using a local anesthetic alone. This study aimed to evaluate the effectiveness and safety of administering a lower dose of dexmedetomidine as an adjuvant for gynecological surgery. **Methods:** Total of 100 patients were equally randomized to two groups i.e. Group R and Group RD. Group RD was prescribed 20 ml of 0.75% ropivacaine with 0.6 µg/kg of dexmedetomidine, while patients in group R administered 20 ml of 0.75% ropivacaine with 1 ml of 0.9% normal saline. Regular monitoring was conducted for hemodynamic variables such as heart rate, non-invasive blood pressure, oxygen saturation, and respiratory rate. Additionally, parameters include sensory block, analgesia duration, quality of intraoperative analgesia, motor block, and recorded sedation score. **Results:** Group RD experienced a shorter average onset time of analgesia at the T6 level compared to Group R. The time required to reach maximum motor block was significantly shorter in Group RD ($p < 0.001$). Sedation scores of 2, 3, and 4 were observed in 46%, 38%, and 8% of patients in Group RD, respectively, while no patients in Group R achieved these scores ($p<0.001$). Excellent analgesia quality was reported by 94% of patients in Group RD, compared to 16% in Group R ($p< 0.001$). In Group RD, the duration of sensory analgesia was significantly prolonged ($p < 0.001$), whereas in Group R, the duration of motor block was notably shorter ($p < 0.001$). All side effects were statistically non-significant, except for dry mouth, which was highly significant ($p<0.001$). **Conclusion:** A lower dose of dexmedetomidine can be used safely and effectively as an adjunct to ropivacaine in epidural anesthesia for lower abdominal gynecological procedures.

Keywords: Analgesia, Epidural anaesthesia, Gynaecological surgery, Dexmedetomidine, Ropivacaine.

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Received: 02 Jul 2024

Accepted: 05 Sept 2024

How to Cite this Article: Duggal G, Kaur H, Garg Sahil, Sara H, Vincent Lintu, Singh H. Evaluation of Dexmedetomidine as an Adjuvant to Ropivacaine in Epidural Anaesthesia for Gynaecological Surgery. J Int Med Sci Acad. 2025;38(2): 75-81.

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Introduction

Epidural anesthesia is widely utilized for both peri-operative surgical anesthesia and post-operative pain management in lower abdominal and limb surgeries [1]. It is especially effective when a local anesthetic is paired with an adjuvant, as this combination enhances pain relief and promotes early mobilization more effectively than using a local anesthetic by itself [2]. Adjuvant drugs alter the effects of local anesthetics and help mitigate side effects. During surgery, these drugs influence the latency, or the onset time of the local anesthetic block, and the duration of analgesia. Postoperatively, they impact the analgesic gap, which is the interval between subsequent doses, as well as the quality of analgesia, reflected in patient satisfaction and perceived pain relief, while also reducing adverse effects of local anesthetics [3]. Key desirable attributes of an adjuvant in neuraxial anesthesia include the ability to provide smooth and prolonged post-operative analgesia with sedation and stable hemodynamics [4]. Various additives to local anesthetics have been studied to extend the duration of the block and enhance postoperative pain relief. Among these, alpha-2 adrenergic agonists are notable for their analgesic and sedative properties when used as adjuvants in regional anesthesia [5]. Particularly, epidural dexmedetomidine has demonstrated a synergistic effect with local anesthetics, prolonging the duration of both sensory and motor block, enhancing postoperative analgesia, and creating a strong motor block without causing additional morbidity. Studies in both humans and animals have reported no neurological deficits with its epidural use [6].

While many studies have emphasized the analgesic and sedative advantages of using dexmedetomidine as an adjuvant in epidural anesthesia, the ideal dosage is still unclear. Therefore, this study aims to assess the efficacy and safety of a lower dose of dexmedetomidine for gynecological surgery.

Material and Methods

This study was conducted as a randomized controlled trial with 100 female patients undergoing elective gynecological surgeries under epidural anesthesia at MMIMSR, Mullana, after receiving approval from the Hospital Ethics Committee. Female patients aged 35 to 65 years with ASA I or II status were included, while those who refused epidural anesthesia, had known sensitivities to the

study drugs, coagulation abnormalities, or local site infections were excluded.

A pre-anesthetic evaluation was conducted one day before surgery, including a thorough medical history, physical examination, and standard laboratory tests. The epidural analgesia technique and pain assessment using the Visual Analog Scale (VAS) were described to all participants. All participants were randomly assigned to two groups of 50 each using the chit method. Patients on Group RD were administered 20 ml of 0.75% ropivacaine combined with 0.6 µg/kg dexmedetomidine (solution completed to 1 ml with 0.9% normal saline), while Group R received 20 ml of 0.75% ropivacaine with 1 ml of 0.9% normal saline, maintaining a total volume of 21 ml for both groups.

All patients fasted overnight and were given 0.25 mg of alprazolam and 150 mg of ranitidine the night before surgery, with an additional dose taken early in the morning with a sip of water. On the day of surgery, baseline parameters (HR, BP, RR, and SpO2) were recorded, and an 18-gauge IV line was established. Patients were preloaded with Ringer Lactate at a rate of 10 ml/kg/hr and received no premedication before being moved to the operating theater. Routine monitoring was initiated, and after recording baseline vitals, the patient was positioned laterally for epidural catheter insertion at the L3-L4 level using an 18G Tuohy needle by the loss of resistance technique. An 18-gauge epidural catheter (Portex epidural minipack) was introduced and secured. To rule out intravascular or intrathecal placement, a test dose of 3 ml of 2% lidocaine with 1:200,000 epinephrine was administered, and monitor the heart rate response and sensory feedback. Subsequently, patients were positioned supine and received the 21 ml study solution as specified.

Hemodynamic parameters (HR, NIBP, SpO2, RR) were monitored initially every 2 minutes for the first 10 minutes, then every 5 minutes up to 30 minutes, every 10 minutes until 90 minutes, and subsequently every 30 minutes throughout the surgery. Parameters such as sensory block onset, duration of analgesia, intraoperative analgesia quality, motor block degree and duration, and sedation score were recorded. Side effects like bradycardia, hypotension, shivering, dry mouth, respiratory depression, dizziness, headache, nausea, and vomiting were monitored throughout the perioperative period. Postoperative block characteristics were observed for 8 hours, including time to regression to Bromage 0 and time to first rescue analgesia. All data were recorded in a proforma for statistical analysis.

Statistical Analysis

Data analysis was conducted using SPSS® Version 21.0 (Chicago, IL). Continuous data were presented as either mean (SD) or median with inter-quartile range (IQR). The Kolmogorov-Smirnov test was employed to assess the normality of quantitative data. For skewed continuous variables, the Mann-Whitney U-test was applied, while the t-test was used for comparing normally distributed variables between groups. Categorical data were expressed as frequencies or proportions, and comparisons were made using the Chi-square test or Fisher's exact test, as appropriate. Statistical significance was set at a p-value of <0.05 with a 95% confidence interval.

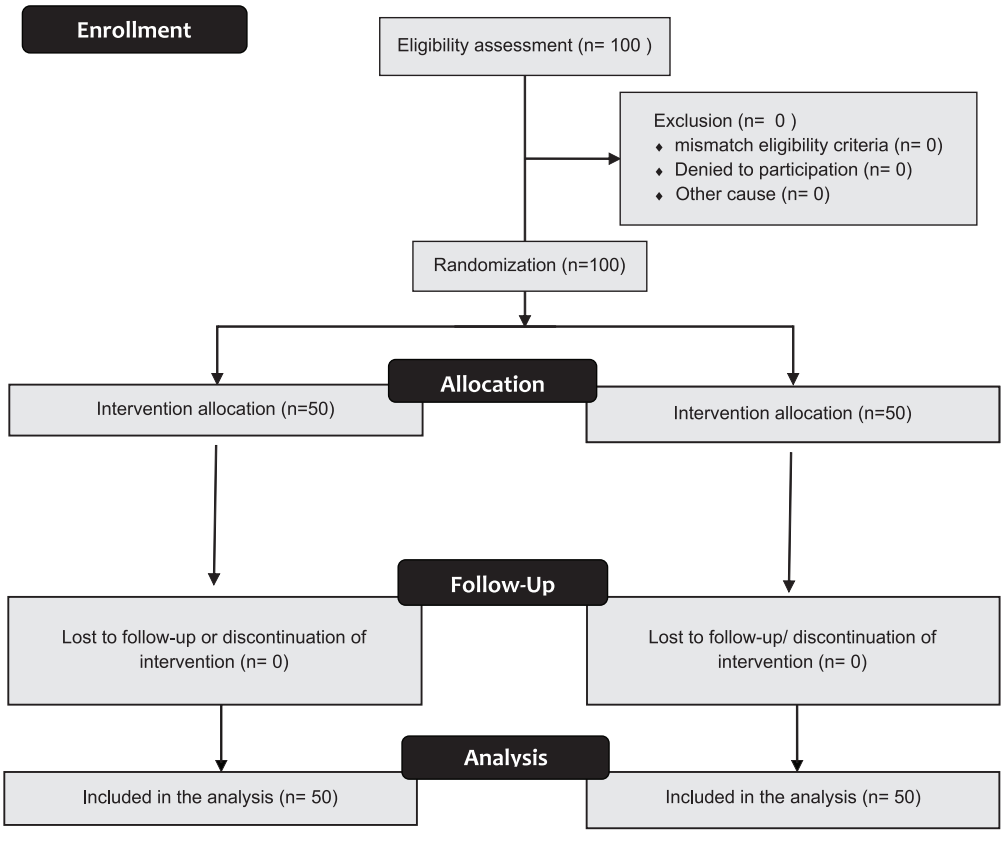

Figure 1. Consort flow diagram showing distribution of patients

Table 2: Demographics characterstics between two groups.

Parameter	Group R Mean ± SD	Group RD Mean ± SD	p value
Age [$](Yrs)	46.62±6.11	47.28±7.69	0.636
Weight[$](Kgs)	66.10±6.10	66.10±7.87	1.00
Height[$](Cms)	157.66±3.00	157.44±2.85	0.71
There was no significant difference in demographic characteristics between both groups (p>0.05).			

[$]Unpaired t-test.

Table 3: Preoperative vitals in both groups.

VITALS	Group R Mean ± SD	Group RD Mean ± SD	t value	p-value
PreOp HR (bpm)	77.40±5.10	77.44±8.06	-.030	.976
PreOpSBP (mmHg)	124.10±6.35	126.64±7.30	-1.857	.066
PreOpDBP (mmHg)	80.84±6.51	79.64±7.13	.878	.382
PreOp SPO2(%)	98.70±.46	98.60±.61	.927	.356
PreOp RR (per min)	14.34±.82	15.82±6.90	-1.506	.135
*Unpaired t-test				

Table 3 shows the comparison of preoperative vitals between the two groups. Both the groups were comparable concerning pre-operative vitals. On statistical analysis the difference was non-significant. (P value>0.05).

Table 4 shows the mean onset time of sensory analgesia up to T6 level in both groups. The time taken was 16.18±3.85minutes with a range of 10 -25 min in group R while 11.16±2.06 min with a range of 8-16 minutes in group RD. On statistical analysis, the difference was highly significant (P value <0.001).

Table 5 shows the distribution of patients according to the maximum sensory level achieved. 8(16%) patients in group R while 19(38%) in group RD achieved T4 level. 42 (84%) patients in group R while 30(60%) patients in group RD achieved sensory level T6. On statistical analysis the difference was significant (P value<0.05).

Table 6 shows the onset time of maximum motor block in both groups.In group R the mean time taken to achieve maximum motor block was 27.70±5.10 minutes with the range of 15-40 while in group RD it was to 22.40±5.17 with range of 15-35 min. On statistical analysis highly significant difference (P value <0.001) was found.

Table 7 shows the distribution of patients according to the grades of motor block. In group R 8(16%) patients achieved grade 1, 15 (30%) patients achieved grade 2 and 27(54%) patients achieved grade 3 motor block. In group RD no patient remained at grade 1, 11(22%) achieved grade 2 and 39(78%) patients achieved grade 3 motor block. Maximum patients in group R (54%) and in group RD (78%) achieved grade 3 motor block. On statistical analysis, the difference was significant (P value <0.05).

Table 8 shows that in group R 18(36%) patients achieved sedation score 0 as compared to only 1(2%) in group RD. In group R score 1 is achieved by 32 (64%) patients as compared to 3(6%)in group RD. In group RD sedation score 2,3 and 4 were achieved by 23(46%),19(38%) and 4(8%) patients respectively while none of the patient achieved these scores in group R. The difference was highly significant on statistical analysis. (P value <0.001).

Table 9 shows that on statistical analysis the decrease in mean heart rate between 6 minutes to 60 minutes from baseline was statistically significant (P value <0.05).

Table 10 shows statistically significant difference in SBP was noted in two groups from 6 – 30 minutes (P value<0.05).

Table 11 shows that during 6 minutes to 50 minutes, difference in DBP found between two groups was statistically highly significant (P<0.001) and during 60 minutes to 80 minutes, Difference found was statistically significant (p<0.05).

Table 4: Onset time of analgesia upto T6 level.

GROUP	RANGE (in min)	Mean (in min)	t VALUE	PVALUE
R	10-25	16.18±3.85	8.130	<.001
RD	8-16	11.16±2.06		
Unpaired t-test				

Table 5: Level of Sensory block achieved in both groups

SENSORY BLOCK LEVEL	GROUP R N (%)	GROUP RD N (%)	*P*
T4	8(16.0%)	20(40%)	.034
T6	42(84.0%)	30(60.0%)	.157

Table 6: Onset time for maximum motor block in both groups.

GROUP	RANGE (In mins)	MEAN (In mins)	t Value	P value
R	15-40	27.70±5.10	-4.210	<.001
RD	15-35	22.40±5.17		

Table 7: Degree of motor block achieved

Motor grade	GROUP R N (%)	GROUP RD N (%)	P value
G1	8(16.0%)	0(0%)	.006
G2	15(30.0%)	11(22.0%)	.433
G3	27(54.0%)	39(78.0%)	.140

Table 8: Sedation scores in both groups

SEDATION SCORE	GROUP R N (%)	GROUP RD N (%)	*P*
0	18(36.0%)	1(2.0%)	<.001
1	32(64.0%)	3(6.0%)	<.001
2	0(.0%)	23(46.0%)	<.001
3	0(.0%)	19(38.0%)	<.001
4	0(0%)	4(8.0%)	.117

Table 9: Mean heart rate at different time intervals between two groups during intraoperative period.

TIME INERVALS	GROUP R MEAN ±SD	GROUP RD MEAN ±SD	t Value	p Value
0 Min	78.84 ± 5.38	80.16 ±10.19	-.810	.420
2 Min	79 ± 6.14	80.62 ± 9.56	-1.009	.316
4 Min	79.26 ± 5.34	77.82 ± 9.76	.916	.362
6 Min	79.84 ± 5.70	75.80 ±10.29	2.428	.017
8 Min	78.88 ± 6.65	73.66 ±10.35	3.000	.003
10 Min	77.66 ± 7.00	72.92 ±10.39	2.675	.009
15 Min	76.68 ±7.37	71.16 ±10.26	3.089	.003
20 Min	75.48 ± 8.10	71.08 ±10.35	2.367	.020
25 Min	73.30 ± 9.53	69.22 ± 8.68	2.238	.028
30 Min	71.80 ± 8.50	68.64 ± 8.70	1.837	.049
40 min	71.18 ± 7.67	67.20 ± 9.23	2.346	.021
50 Min	70.66 ± 7.05	66.84 ± 8.19	2.500	.014
60 Min	69.90 ± 6.95	65.50 ± 7.93	2.951	.004
7o min	69.22 ± 6.45	66.16 ± 8.99	1.956	.053
80min	68.88 ± 6.63	66.24 ± 7.43	1.876	.064
90 Min	68.26 ± 7.23	65.60 ± 8.06	1.738	.085
120 Min	69.88 ± 6.72	65.11 ± 7.13	2.477	.071
150 Min	72.00 ± 4.95	66.33 ±15.31	.798	.455

Table 12 shows the comparison of quality of analgesia in both groups.In group R 8(16%) patients had excellent quality of analgesia while in group RD 47(94%) had excellent analgesia.In group R 39(78%) patients had good quality of analgesia as compared to only 3(6%)in group RD. In group R 3(6%) patients had fair quality of analgesia while no patient had fair quality in group RD .On statistical analysis the difference was highly significant.(p value <0.001).

Table 13 shows the comparison of duration of analgesia in both the groups. The mean duration in group R was 305.30±43.52 minutes with a range of 210 -380 minutes while in group RD was to 428.90±39.52 minutes with a range of 340-500 minutes. On statistical analysis the difference was highly significant (p value<0.001).

Table 14 shows the duration of motor block in two groups. The mean duration of motor block in group R was 211.60±42.41minutes with a range of 100-300 minutes while in group RD was337.04±39.14minutes with a range of 250-430 minutes. On statistical analysis the difference was highly significant(p value <0.001).

Table 10: Comparison of mean SBP between two groups during intraoperative period.

INTERVALS	GROUP R Mean ±SD	GROUP RD Mean ±SD	t value	p value
0 Min	123.66 ± 7.44	126.46 ± 8.21	-1.787	.077
2 Min	123.36 ± 8.67	124.60 ± 7.95	-.746	.458
4 Min	122.52 ± 15.51	121.52 ± 8.12	.404	.687
6 Min	122 ± 9.18	118 ± 9.26	2.170	.032
8 Min	120.44 ± 9.04	114.90 ± 9.03	3.065	.003
10 Min	118.16 ± 9.80	112.28 ± 9.35	3.070	.003
15 Min	115.84 ± 10.22	109.54 ±7.84	3.458	.001
20 Min	115.48 ± 9.31	108.88 ± 8.37	3.728	.001
25 Min	113.10 ± 10.07	108.24 ± 8.10	2.659	.009
30 Min	111.82 ± 9.07	108.14 ± 8.49	2.094	.039
40 min	111.78 ± 11.35	107.96 ± 9.26	1.843	.068
50 Min	110.38 ± 7.57	108.06 ± 8.06	1.483	.141
60 Min	107.58 ± 15.46	107.24 ±8.05	.138	.891
70 min	108.10 ± 7.98	107.74 ± 9.15	.210	.834
80 min	107.88 ± 6.87	107.06 ± 9.34	.500	.618
90 Min	106.74 ± 8.20	108.04 ± 8.95	-.757	.451
120 Min	110.08 ± 8.86	109 ± 7.25	.482	.632
150 Min	115.80 ± 5.21	105 ± 7.07	2.291	.071

Table 11: Comparison Of mean DBP between two Groups during Intraoperative Period.

DBP	GROUP R Mean DBP±SD	GROUP RD Mean DBP±SD	t value	P value
0 Min	80.48 ± 6.37	81.20 ± 8.19	-.491	.625
2 Min	82.06 ± 6.37	79.70 ± 8.42	1.580	.117
4 Min	81.32 ± 6.56	79.46 ± 8.24	1.248	.215
6 Min	80.78 ± 6.31	75.14 ± 8.27	3.831	<.001
8 Min	79.32 ± 6.04	72.32 ± 8.15	4.879	<.001
10 Min	78 ± 6.09	69 ± 7.85	6.403	<.001
15 Min	77.78 ± 5.74	68.76 ± 7.85	6.560	<.001
20 Min	75.94 ± 6.06	67.66 ± 7.50	6.065	<.001
25 Min	75.46 ± 6.24	67.30 ± 7.30	6.002	<.001
30 Min	74.96 ± 4.73	66.82 ± 7.56	6.454	<.001
40 min	73.32 ± 6.26	66.68 ± 7.45	4.824	<.001
50 Min	71.72 ± 5.76	65.42 ± 8.57	4.313	<.001
60 Min	70.66 ± 6.42	66.80 ± 7.49	2.765	.007
70 min	69.64 ± 6.39	66.76 ± 7.79	2.022	.046
80 min	69.64 ± 5.71	66.64 ± 7.20	2.308	.023
90 Min	69.06 ± 5.65	68.24 ± 6.83	.654	.515
120 Min	69.72 ± 6.24	70.44 ±6.89	-.396	.694
150 Min	75 ± 3.46	72.32 ± 6.81	2.074	.083

Table 12: Quality of analgesia in both groups

QUALITY OF ANALGESIA	GROUP R N (%)	GROUP RD N (%)	P value
Excellent	8(16.0%)	47(94.0%)	<.001
Fair	3(6.0%)	0(0%)	<.001
Good	39(78.0%)	3(6.0%)	0.242

Table 13: Duration Of Analgesia in both groups

GROUP	RANGE (in minutes)	MEAN (in minutes)	t Value	P value
R	210-380	305.30±43.52	-	<.001
RD	340-500	428.90±39.52	14.867	

Table 14: Duration of Motor Block in both groups

GROUP	RANGE (In minutes)	MEAN (In minutes)	t Value	P value
R	100-300	211.60±42.41	-15.370	<.001
RD	250-430	337.04±39.14		

Table 15: Side effects in both groups

SIDE EFFECTS	R	RD	p value
Nausea	10(20%)	8(16%)	.795
V0miting	6(12%)	5(10%)	1.00
Bradycardia	5(10%)	7(14%)	.538
Hypotension	10(20%)	15(30%)	.356
Headache	9(18%)	4(8%)	.137
Dry Mouth	2(4%)	15(30%)	.001
Shivering	10(20%)	7(14%)	.424
Dizziness	1(2%)	2(4%)	1.000

Table 15 shows the comparison between side effects observed during intraoperative and post operative period in two groups. On statistical analysis all the side effects were non-significant except for dry mouth which was highly significant (p value< 0.001).

Discussion

In this study, there was no significant difference between the two groups regarding demographic factors such as age, weight, and height. The average onset time of analgesia at the T6 level was significantly shorter in Group RD compared to Group R, with a highly significant p-value ($p < 0.001$). These findings align with studies by Bajwa et al. [4,7], Babu et al. [8], Manal et al. [9], Gupta K et al. [10], Kaur S et al. [11], and Chiruvella S et al. [12]. However, the results contrast with the study by P.F. Salgado et al. [6], possibly due to differing techniques of administering dexmedetomidine and the selection of different levels for noting onset time.

The mean time to achieve maximum motor block was 22.40 ± 5.17 minutes in Group RD compared to 27.70 ± 5.10 minutes in Group R, with the difference being highly significant ($P < 0.001$). Similar results were observed by Bajwa et al. [4] and Gupta K et al. [10], although Kaur S et al. [11] found no statistically significant difference in their study.

Our study indicates that dexmedetomidine enhances the motor block of local anesthetics ($P < 0.05$), corroborating the findings of Gupta K et al. [10] and Kaur S et al. [11]. With the addition of dexmedetomidine, sedation scores of 2, 3, and 4 were achieved by 46%, 38%, and 8% of patients, respectively, whereas none of the patients receiving ropivacaine alone reached these scores. This difference was highly significant ($P < 0.001$), consistent with the results of P.F. Saravia et al. [6], Lopez SAO et al. [13], Bajwa et al. [7], Jain D et al. [14], Gupta K et al. [10], Kaur S et al. [11], and Chiruvella S et al. [12].

There was a notable difference in mean heart rate between the groups from 6 to 60 minutes ($P < 0.05$). Significant differences in SBP were observed between 6 and 60 minutes ($P < 0.05$), while DBP showed highly significant differences from 6 to 50 minutes ($P < 0.001$). Similar results were reported by Gupta K et al. [10], Babu et al. [8], and Jain D et al. [14]. However, Bajwa et al. [7] found that dexmedetomidine decreased heart rate approximately 30-35 minutes after epidural injection, with mean arterial pressure (MAP) also decreasing from baseline at 30-50 minutes post-injection. The use of a lower dose of ropivacaine in their study might explain the variations in statistical significance, and our study separately evaluated SBP and DBP rather than MAP.

In the study, the quality of analgesia was rated as excellent in 94% of patients in Group-RD in comparison to 16% in Group-R ($P < 0.001$), which is consistent with findings by Kaur S et al [11]. The mean duration of sensory analgesia was 123.60 ± 4 minutes longer

in Group RD, which was highly significant (P <0.001), indicating that dexmedetomidine prolongs sensory analgesia. Similar results were obtained by Fukushima et al. [15], P.F. Salgado et al. [16], P.F. Saravia et al. [6], Bajwa et al. [7], Xiang et al. [17], Babu et al. [8], Kaur S et al. [11], and Chiruvella S et al. [12].

The mean duration of motor block in Group R was 211.60 ± 42.41 minutes compared to 337.04 ± 39.14 minutes in Group RD, with the difference being highly significant (P < 0.001). Similar findings were reported by Bajwa et al. [7], Kaur S et al. [11], P.F. Saravia et al. [6], and Li F et al. [18].

Postoperative hemodynamic parameters showed no significant differences between the two groups, supported by studies from Bajwa et al. [7], Jain D et al. [14], Gupta K et al. [10], and Kaur S et al. [6]. Statistical analysis indicated that all side effects were non-significant except for dry mouth, which was highly significant (P < 0.001).

Conclusion

Based on the above observations it is concluded that dexmedetomidine given epidurally along with ropivicaine potentiates the effect of ropivacaine causing rapid onset of analgesia and motor blockade. Sedation, anxiolysis and prolonged postoperative analgesia are other beneficial effects providing immense patient and surgeon satisfaction. So, it is recommended that dexmedetomidine can be safely and effectively used as an adjuvant to ropivacaine in epidural anaesthesia in lower dose for major lower abdominal surgery.

Conflict of Interest:	Author declare no COI
Ethics:	There is no ethical violation as it is based on voluntary anonymous interviews
Funding:	No external funding
Guarantor:	Dr. Sahil Garg will act as guarantor of this article.

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