ANALGESIC EFFICACY AND SEDATIVE EFFECT OF DEXMEDETOMIDINE VERSUS CLONIDINE AS AN ADJUVANT TO EPIDURAL ROPIVACAINE IN LOWER LIMB SURGERY: A COMPARATIVE STUDY

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ABSTRACT

BACKGROUND

Epidural anaesthesia is widely accepted for lower limb surgery in terms of avoidance of laryngoscopic surge, better perioperative pain management, greater patient satisfaction and attenuation of neuroendocrine response to surgery. Among many drugs, α_2-adrenergic agonist has been used widely as an adjuvant to local anaesthetics due to its better analgesic and sedative property without significant respiratory depression.

The aim of this study was to compare the analgesic and sedative effects of dexmedetomidine and clonidine in epidural anaesthesia.

MATERIALS AND METHODS

86 patients of either sex aged 40-65 years and body weight of 40-70 Kgs of ASA class I-II, posted for elective lower limb orthopaedic surgeries were randomly allocated in two equal groups either to have 0.75% ropivacaine and dexmedetomidine (group RD) or 0.75% ropivacaine and clonidine (group RC) and were observed regarding block characteristics in term of onset and duration for maximum sensory level achieved, time to complete motor block ,intraoperative and postoperative sedation level, time to two segment regression of sensory block, time to first analgesic requirement, hemodynamic stability and adverse effects. Postoperative epidural top-up dose of 8 ml 0.2% ropivacaine was used as rescue analgesia.

Observed data were tabulated in the Excel sheet and analysed with SPSS for windows (Version 12.0). Categorical data are presented as percentage of number of patients [n (%)]; continuous data are expressed as mean ± SD. Statistical analysis was done using independent samples t test (continuous data) and Chi-square test (Categorical data). A 'p' value <0.05 has been considered as statistically significant.

RESULTS

Onset of sensory and complete motor block and time to reach maximum sensory block was earlier in dexmedetomidine group ($p<0.05$). Mean time to two segment regression of sensory block and first rescue analgesia was longer in dexmedetomidine group ($p<0.05$). Intraoperative sedation was more in dexmedetomidine group ($p<0.05$). Other variables are comparable in both groups.

CONCLUSION

Dexmedetomidine has earlier onset of sensory and motor block, provides longer duration of analgesia and better intraoperative sedation than clonidine when administered as an adjuvant in epidural anaesthesia.

KEYWORDS

Epidural Anaesthesia, Ropivacaine, Dexmedetomidine, Clonidine.

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BACKGROUND

Now a days, regional anaesthesia has become more popular than general anaesthesia for lower limb surgeries as it has so many advantages. Epidural anaesthesia for lower limb surgery is widely accepted for its greater advantages over general anaesthesia in terms of avoidance of laryngoscopic surge, better perioperative pain management and greater patient satisfaction. Epidural anaesthesia also attenuates neuroendocrine response to surgery if given well ahead of surgical stimulus.[1] Many beneficial aspects of epidural anaesthesia have been reported, including better suppression of surgical stress, positive effect on postoperative nitrogen balance.[2] However, sometimes epidural anaesthesia is limited by unwillingness of patients to remain awake during surgery.

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Moreover, operating position for long duration to a conscious patient is distressing. Intravenous or inhalational anaesthetic agents have been tried so far to maintain adequate sedation[4,5] during regional anaesthesia, as sedation increases patient satisfaction.[3]

Lower limb surgeries are sometimes associated with significant blood loss and there is greater incidence of hypotension. Epidural anaesthesia provides more stable cardiovascular haemodynamics, reduced blood loss, better peripheral vascular circulation[6] though it itself may cause hypotension. It is a major concern especially in aged patient population. In this scenario sedative drugs, either inhalational or intravenous, may potentiate the incidence of respiratory depression as well as hypotension. To avoid this and to have stable haemodynamics and postoperative analgesia, an effort has been made to have optimum sedation without respiratory depression by the drug administered in the epidural route.

Different drugs have been tried as adjuvant to local anaesthetic to overcome such problems. Local anaesthetics with opioids demonstrate significant synergy. Though they provide excellent analgesia and prolongs the time of regression of sensory block,[7] their use is limited due to serious adverse effects.

α_2-adrenergic agonist has both analgesic and sedative effect when administered in epidural route along with local anaesthetic.[8] The incidence of vomiting, pruritus and respiratory depression is less frequent as compared with that seen after epidural opioid. Both dexmedetomidine and clonidine are α_2-agonist used widely in clinical practice.

With this background, this prospective, randomized, double blind study is designed to compare the sedative effect and analgesic efficacy of these two drugs when used as an adjunct to epidural ropivacaine in lower limb surgery. We hypothesised that patients receiving ropivacaine with dexmedetomidine in comparison to those receiving ropivacaine with clonidine will achieve better intraoperative sedation and prolonged duration of analgesia with minimum adverse effects.

MATERIALS AND METHODS

After getting clearance from Institutional Ethics Committee and obtaining written informed consent from patients, eighty-six patients of either sex aged 40-65 years and body weight of 40-70 Kgs, belonging to ASA class I-II, posted for elective lower limb orthopaedic surgeries were enrolled in the study. Exclusion criteria considered were Patient's refusal, known coagulopathy, hepatic dysfunction, Hypersensitivity to any of the study drugs, Known heart disease, Chronic systemic disease-Hypertension, Diabetes mellitus, Spinal deformity, Skin infection or local cellulitis at the site of puncture, Chronic analgesic abuse, Pregnancy, Seizure disorder, Patient's psychiatric illness, Chronic alcohol abuse.

Patients were randomly allocated into two groups. Group RD received total 16 ml of drug mixture containing preservative free 0.75% ropivacaine + preservative free dexmedetomidine (1.5 µg/kg) and group RC received total 16 ml of drug mixture containing preservative free 0.75% ropivacaine + preservative free clonidine (2 µg/kg) in epidural route. On the day before surgery, each patient was attended and examined properly for a preoperative counselling and repeat anaesthetic check-up. On the day of surgery, the patients were allowed to take clear liquid until two hours prior to scheduled time of operation.: In the morning of the operation date vital parameters (HR, BP) and sedation level using Ramsay sedation scale score was noted. After shifting the patient to operating room monitoring was started with multichannel monitor having facility of heart rate, non-invasive blood pressure (NIBP), ECG and pulse oximeter. Lactated Ringer's solution was started through an intravenous line with 18 G intravenous (iv) cannula. Study drugs were prepared in un-labelled syringes as colourless solution by an anaesthesiologist who remained unaware of the study protocol. The patient who was receiving the drug, was also unaware of the drug. Patient was kept in sitting position. After aseptic draping and dressing 2ml 2% lignocaine with adrenaline was infiltrated into the skin and subcutaneous tissue at L_3- L_4 and L_4-L_5 interspaces. Epidural anaesthesia was administered by 18 G Tuohy needle at either L_3-L_4 or L_4-L_5 inter-vertebral space. Epidural space was identified by loss of resistance technique by 2 ml normal saline. A test dose of 3 ml 2% lignocaine hydrochloride with adrenaline was injected and vital parameters (HR, NIBP) were monitored. After negative aspiration patients in group RD received 15 ml of 0.75% ropivacaine + 1.5 µg/kg dexmedetomidine and 0.9% sodium chloride to make total volume of 16 ml and patients in group RC received 15 ml of 0.75% ropivacaine + 2 µg/kg clonidine and 0.9% sodium chloride to make total volume of 16 ml. The punctured site was sealed with antiseptic dressing. Patient was made supine. The surgery was allowed approximately 25-30 minutes after epidural injection with complete establishment of sensory and motor block. No sedative or analgesic was given intravenously.

HR & NIBP was recorded at 5 min interval for the first 30 mins, then at 10 min interval for the next 30 mins and thereafter at 20 min interval till the end of surgery. Intra operative sedation level was monitored and recorded at 10 min interval for first hour & thereafter at 20 min interval till the end of surgery.

Sensory block was assessed by loss of cold sensation to evaluate the sensory block level at 5 minutes interval after the epidural drug administration till to reach T_{10} level. To assess motor block modified Bromage scale was used at 5 minutes intervals after the epidural drug administration. Complete motor block was defined as Bromage scale 3.

Block characteristics were assessed on following parameters - Onset of sensory block at the level of T_{10}, maximum height of sensory block, time to reach maximum sensory block, time for complete motor block. Highest sensory level was when 3 reading at 5 minutes interval showed no further progression of sensory block level. Nausea, vomiting, dry mouth, respiratory depression, shivering, dizziness & any other adverse effects were recorded and treated accordingly. Episodes of intra

operative hypotension were treated with Inj. phenylephrine 25-100 µg iv bolus. Heart rate less than 50 beats/min was treated with inj. Atropine 0.01 mg/kg iv.

Postoperatively sensory level was assessed every 15 min for next 2 hours and then every 30 min till two dermatome regression of sensory level was observed and the time taken for 2 dermatome regression of sensory level was recorded. Intensity of pain was assessed by VAS (Visual analogue scale) score in immediate postoperative period and then every 2 hr for next 6 hours till the VAS score of >3 and rescue analgesic was given when patient complains pain at surgical site and asks for analgesic. Time for first request of rescue analgesic was recorded and pain was managed by epidural top up doses of 8 ml 0.2% ropivacaine. Post-operative sedation was assessed in immediate postoperative period and then every 2 hr for next 6 hours. In post-op period SPO_2 & Pulse rate was monitored continuously & BP was recorded in immediate postoperative period and then every 2 hr for next 6 hours.

Statistics

In a previous study,[9] 20% extra patients achieved Ramsay sedation scale score 3 in the intraoperative period with dexmedetomidine compared to clonidine as adjuvant to epidural ropivacaine. Using data from previous studies sample size was calculated by formula $\{2\times SD^2\ (Z\alpha 2+Z\beta)^2 /d^2\}$. Considering α error of 0.05 and power of the study (I-β) = 80% in a two tailed study, the required sample size is 39 in each group. So, including the possibility of dropout of 10%, total 86 patients were enrolled in the study. (n=43 in each group). They were randomly allocated in two equal groups by computer generated random number table. Observed data was tabulated in the Excel sheet and analysed with SPSS for windows (Version 12.0). Categorical data is presented as percentage of number of patients (n (%)); continuous data is expressed as mean ± SD. Statistical analysis was done using independent-samples t-test (Continuous data) and Chi-square test (Categorical data). A 'p' value <0.05 has been considered as statistically significant.

RESULTS

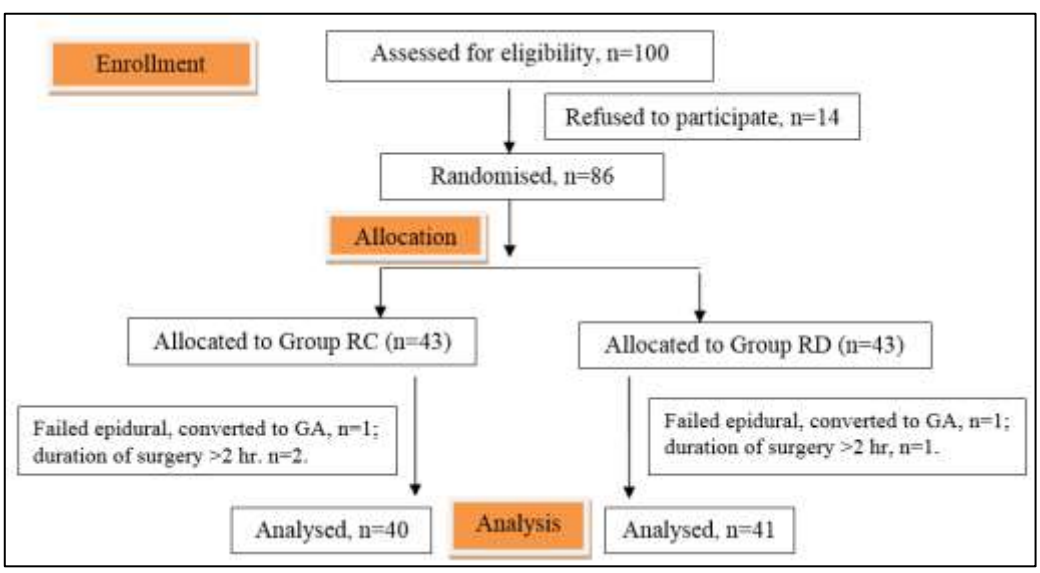

Figure 1. Study Design According to the Consort Diagram

The study was done from June 2016 to June 2017. Hundred patients were included in the study initially. In the beginning, 14 patients were excluded as they refused to participate. So we collected data from 86 patients. Due to failed epidural, one patient from each group had undergone general anaesthesia resulting in exclusion of those patients. Another two patients of group RC and one patient of group RD were excluded from our study as their procedure lasted for more than two hours. Therefore, data of remaining 81 patients were assessed for final analysis (Group RC=40, Group RD=41).

Demographic parameters and duration of surgery were comparable in two groups. . Onset of sensory block to T_{10} level was significantly earlier in dexmedetomidine group (9.34±1.407 min) than compare to clonidine group (10.60±2.134 min) (Table 3). Maximum sensory block had reached significantly earlier in dexmedetomidine group (12.76±1.997 min) than compared to clonidine group (15.03±3.117 min) (Table 3). Complete motor block was also achieved earlier in group RD (17.05±2.269) compared to group RC (19.90±3.053) (Table 3). Sensory block regressed significantly earlier in group RC (138.25±14.324 min) than group RD (157.80±21.258 min) (Table 3). Duration of analgesia was significantly prolonged in RD group (344.59±33.019 min) as compared to RC group (322.48±38.113 min) (P<0.05) (Table 3). In group RD 36.5% of patients had achieved RSS score 3, whereas in RC group just 2.5% patients had achieved RSS score 3 at 30 min after epidural anaesthesia (Table 2). Most of the patients of clonidine group could not achieve RSS score 3 at 30 min after epidural anaesthesia and so remained either RSS score 2 (62.5%) or RSS score 1 (35%) (Table 2). Reduction of

mean arterial pressure from the baseline values were noted following epidural anaesthesia in both the groups but it was not statistically significant (P>0.05) (Table 4). Heart rate changes were comparable in between the two groups (Table 4). Postoperative VAS score at 4th hour was significantly higher in group RC (3.20) compared to group RD (2.83) (Table 3). Time to first rescue top up epidural dose was also significantly shorter in group RC (322.48±38.113 min) compared to group RD (344.59±33.019 min) (P=0.007) (Table 3). Incidence of adverse effects was comparable in between two groups (Table 5).

DISCUSSION

Regional anaesthesia is now increasingly used for lower limb surgeries due to several advantages over general anaesthesia. The advantages from patient's point of views are staying awake, early family contact, early food intake and possibly early discharge.

A slower onset of action after epidural administration of local anaesthetic as compared with a subarachnoid block makes it less threatening for patients concerning sudden hemodynamic changes mainly in aged population. But epidural anaesthesia is often limited by unwillingness of patients to remain awake during surgery and uncomfortable positioning. So, sedation has been shown to increase patient satisfaction during regional anaesthesia.[3,10]

Several studies have shown that spinal[11] and epidural[12] anaesthesia can induce sedation. Requirement of anaesthetic drugs are reduced when neuraxial anaesthesia has been advocated. A decrease in afferent sensory input with consecutive inhabitation of reticulo-thalamo-cortical mechanisms is the probable cause of sedation after neuraxial block.

Many adjuvants have been tried with epidural local anaesthetics for years, but no one proved to be ideal to provide adequate sedation as well as analgesia. Opioids are commonly used adjuvant in epidural anaesthesia, and they produce some short of sedation.[13] But their use has been restricted due to multiple adverse effects like respiratory depression, early desaturation, pruritus, urinary retention which may affect the outcome of the patients specially in aged population.[14]

α_2-adrenoreceptor agonist has both sedative and analgesic properties and is devoid of respiratory depressant effect[15] even at higher doses and is preferred over opioid for this reason.

The present study was conducted to compare the sedative effect as well as duration of analgesia of two α_2-agonist drugs when used as an adjunct to epidural ropivacaine in lower limb orthopaedic surgery.

Dexmedetomidine has an eight-fold greater affinity (α_1: α_2=1: 1600) for α_2-adrenergic receptors than clonidine (α_1: α_2=1: 200), responsible for the sedative and analgesic effects with limited respiratory depression with special property of easy arousability without cloudiness of mind and better hemodynamic control.

In study of Peduto VA, et al.[16] isobaric 0.75% ropivacaine 15 ml and 0.5% levobupivacaine 15 ml was administered epidurally in two groups undergoing elective lower limb surgeries and reported that 0.75% ropivacaine and 0.5% levobupivacaine produces epidural block with same clinical profile. Bajwa SJS and co-workers[13] used 1 µg/kg dexmedetomidine and 1 µg/kg fentanyl epidurally with 15 ml 0.75% ropivacaine in lower limb orthopaedic surgery and reported that dexmedetomidine provides significantly better analgesia and sedation than fentanyl as an adjuvant. In another study, Bajwa SJS and co-workers used 1.5 µg /kg dexmedetomidine and 2 µg/kg clonidine and they has got Ramsay sedation score 3 in 20% extra patients of dexmedetomidine group than clonidine group. So, we have chosen 1.5 µg/kg dexmedetomidine with 15 ml 0.75% ropivacaine in one group and 2 µg/kg clonidine with 15 ml 0.75% ropivacaine in another group epidurally to further compare analgesic efficacy and sedative effect in our group of populations.

Dexmedetomidine has produced desired level of sedation (RSS score 3) in 36.5% of patients, whereas in clonidine group just 2.5% patients has achieved RSS score 3 at 30 min after epidural anaesthesia. Bajwa SJS and co-workers noted similar pattern of intraoperative sedation score where either 1.5 µg/kg dexmedetomidine or 2 µg/kg clonidine was administered with epidural ropivacaine in patients posted for vaginal hysterectomy. They found that in the intraoperative period 36% of patients in dexmedetomidine group achieved sedation score 3 whereas only 16% of clonidine group were equally sedated groups which was highly significant (P<0.05). Our study results are also consistent with the findings of Jain D et al,[17] who observed significant number of patients in dexmedetomidine group were sedated in the intraoperative period as compared to placebo group where 2 µg/kg dexmedetomidine was administered in the epidural space for elective lower limb orthopaedic surgery.

In this study, we have found that duration of analgesia was significantly prolonged in RD group (344.59±33.019 min) as compare to RC group (322.48±38.113 min) (P <0.05). This finding of our study are similar to the study of Bajwa SJS et al. in 2011 where analgesia was maintained in dexmedetomidine group (342.88±29.16 min) for a longer time than clonidine group (310.76±23.76 min) (P<0.05).

In a recent study, Saadawy I, et al.[18] found that total consumption of rescue analgesic was significantly lower as analgesia was prolonged (P<0.001) in bupivacaine-dexmedetomidine group than bupivacaine group in inguinal hernia repair/ orchidopexy operation.

Our study results are not similar with the study of El-Hennawy AM et al.[19] where duration of analgesia was longer in dexmedetomidine group (16 hr) than clonidine group (12 hr), but it was not statistically significant (P<0.001). Our study design, patient population and local anaesthetic that we have used are different from their study. This is the probable cause of difference of results (duration of analgesia).

In the present study, onset of sensory block at T_{10} was significantly earlier in dexmedetomidine group (9.34±1.407

min) than clonidine group (10.60±2.134 mins) and this finding is also similar to the study of Bajwa SJS et al.

Maximum sensory anaesthetic level also achieved significantly earlier in Dexmedetomidine (12.76±1.997 min) than compare to clonidine group (15.03±3.117 min). This is probably due to more lipid solubility of dexmedetomidine than clonidine resulting in rapid rostral spread of the block. Our study result is similar to the study of Bajwa SJS et al. Modified Bromage scale 3 was also achieved earlier (17.05±2.269 min) in dexmedetomidine group, which was similar to the study of Bajwa SJS et al.

Dexmedetomidine has provided superior block characteristics in terms of prolonged two segment regression (157.80±21.258 min). Time to first rescue top up epidural dose was significantly shorter in group RC (322.48±38.113 min) (P=0.007). Block characteristics are similar to the study of Bajwa SJS et al.

In our study we have noticed episode of hypotension in the intraoperative period in some patients of both the groups which was also statistically insignificant (P>0.05). El-Hennawy AM et al.[19] found no statistically significant episode of hypotension either in dexmedetomidine or clonidine group. However, in another study, the addition of clonidine or dexmedetomidine to ropivacaine 0.75% administered in the epidural space in patients undergoing upper abdominal surgery caused a decrease in systolic pressure of 25% of clonidine group and 30% in dexmedetomidine group.[20]

In this study, heart rate changes in the intraoperative period were comparable in between the two groups which was consistent with the study of El-Hennawy AM et al.[19] who had found no statistically significant episode of bradycardia.

Incidence of adverse effects were comparable in between two groups. In our study none of the patients in either the two groups suffered from respiratory depression. Postoperative sedation score also shows no significant difference between the two groups (p>0.05).

CONCLUSION

The present study concludes that epidural dexmedetomidine has earlier onset of sensory and motor block and provides longer duration of analgesia than clonidine when administered as an adjuvant in epidural anaesthesia. Dexmedetomidine (1.5 µg/kg) is better adjuvant than clonidine (2 µg /kg) in terms of intraoperative sedation. However, regarding hemodynamic profile and adverse effects, dexmedetomidine does not appear to be superior in comparison with clonidine.

Limitation of Study

One of the most important limitations of our study was that BIS (Bispectral Index) was not monitored in any case. We could not measure the plasma concentration of dexmedetomidine or clonidine. If measured, it might have corrected the possibility of inter-individual variability, so also help to comment on optimum sedative as well as analgesic plasma concentration of dexmedetomidine and clonidine. We could not document any synergism or antagonism of the study drugs by isobologram. Pain being a subjective phenomenon, measurement of pain should be individualised. We have also not studied electromyography (EMG) study or nerve conduction velocity study after offset of motor or sensory block. If studied, it might be possible to detect the actual duration of sensory and motor block.

Demographic Data	Group RC (n=40)	Group RD (n=41)	P Value
Age (Yrs.)	51.88±5.630	51.98±7.418	0.945
Height (cm)	157.75±6.101	158.15±6.267	0.774
Weight (Kg)	58.95±5.007	60.51±5.311	0.177
Sex (M/F)#	23/17	25/16	0.75
ASA (1/2)#	24/16	22/19	0.565
Duration of Surgery (min)	96.65±12.110	95.54±11.448	0.672
Data expressed as mean ± SD. #Data expressed in numbers. Tests done: Independent samples t test, # Pearson Chi-square test. (P <0.05 considered significant).			

Table 1. Demographic Parameters

RSS Score at 30 mins	Group RC	Group RD	p-Value
1	14	4	0.000*
2	25	22	
3	1	15	
4	0	0	
5	0	0	
6	0	0	
RSS Score at the End of Surgery	**Group RC**	**Group RD**	
1	18	27	0.059
2	22	14	
3	0	0	
4	0	0	
5	0	0	
6	0	0	
RSS Score in Postoperative Period	**Group RC**	**Group RD**	
Immediate Postoperative Period	1.38±0.490	1.24±0.435	0.207
2nd hr Postoperatively	1.28±0.452	1.22±0.419	0.569
4th hr Postoperatively	1.15±0.362	1.15±0.358	0.964
6th hr Postoperatively	1.08±0.267	1.10±0.300	0.722
RSS: Ramsay sedation scale score. Data expressed in numbers. Tested by Pearson Chi-square test. (*P<0.05 considered significant)			

Table 2. Perioperative Sedation Parameters

Intraoperative Block Characteristics	Group RC	Group RD	p Value
Onset of T10 Sensory Block	10.60±2.134	9.34±1.407	0.003*
Time to Reach Maximum Sensory Block (min.)	15.03±3.117	12.76±1.997	0.000*
Onset of Complete Motor Block (min.)	19.90±3.053	17.05±2.269	0.000*
Maximum Dermatomal Level of Sensory Block #	**Group RC**	**Group RD**	
T5	0	5	0.249
T6	7	6	
T7	5	6	
T8	15	11	
T9	9	11	
T10	4	2	
Postoperative Block Characteristics	**Group RC**	**Group RD**	
Mean Time to Two Segment Regression (min)	138.25±14.324	157.80±21.258	0.000*
Time to First Rescue Top-Up (min)	322.48±38.113	344.59±33.019	0.007*
VAS	**Group RC**	**Group RD**	
Immediate Postoperative Period	1.43±0.501	1.24±0.435	0.086
2nd hr Postoperatively	2.23±0.48	2.02±0.57	0.091
4th hr Postoperatively	3.20±0.564	2.83±0.543	0.003*
6th hr Postoperatively	1.95±0.552	2.10±0.490	0.208

VAS: Visual analogue scale. Data expressed as mean ± SD. Test done: Independent sample t test. (P<0.05 considered significant); # Data expressed in numbers. Test done: Pearson Chi-square test. (P<0.05 considered significant).

Table 3. Block Parameters

Time	Heart Rate			Mean Arterial Pressure (MAP)		
	Group RC	**Group RD**	**P value**	**Group RC**	**Group RD**	**p Value**
Baseline	82.88±7.328	82.78±7.076	0.953	90.15±2.568	90.73±1.950	0.255
5 Min	81.98±6.952	79.83±6.074	0.143	84.78±3.370	85.88±2.561	0.102
10 Min	80.93±7.205	79.61±5.822	0.368	81.18±2.890	81.24±3.129	0.918
15 Min	81.25±8.521	78.44±8.953	0.152	77.03±2.957	77.93±3.134	0.187
20 Min	79.00±9.624	78.39±10.084	0.782	75.90±3.053	74.95±3.301	0.183
25 Min	79.63±11.907	79.02±10.532	0.810	73.53±2.926	73.46±2.916	0.925
30 Min	81.35±11.201	80.63±9.335	0.755	72.33±2.759	72.34±2.670	0.978
40 Min	82.98±10.596	79.88±8.265	0.146	71.48±2.532	71.56±2.480	0.878
50 Min	82.43±9.128	81.15±6.639	0.472	70.75±2.204	70.90±2.142	0.753
60 Min	83.25±8.341	80.37±6.829	0.092	72.45±1.663	72.24±1.685	0.581
80 Min	83.32±7.323	81.24±5.540	0.203	73.98±1.687	74.41±1.962	0.282
100 Min	82.50±7.192	78.10±5.915	0.138	74.94±1.692	74.87±2.134	0.920
120 Min	83.33±9.609	75.67±7.371	0.334	76.60±1.949	75.14±3.185	0.350

Data expressed as mean ± SD. Test done: Independent sample t test. (P<0.05 considered significant).

Table 4. Intraoperative Hemodynamic Parameters

	Group RC		Group RD		P Value
	Yes	**No**	**Yes**	**No**	
Nausea	4	36	5	36	0.753
Vomiting	1	39	2	39	0.571
Respiratory Depression	0	40	0	41	-
Dry Mouth	9	31	7	34	0.540
Shivering	3	37	2	39	0.624
Dizziness	2	38	3	38	0.665

Data expressed in numbers. Test done: Pearson Chi-square test. (p<0.005 considered significant).

Table 5. Adverse Events

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