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Original Research Article

Comparative study of epidural ropivacaine with dexmeditomidine and ropivacaine with clonidine in patients undergoing lower abdominal surgeries

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Abstract

Regional Anaesthesia is an excellent choice which provides effective intra &post operative analgesia with a single technique which is being possible due to the availability of long acting amide local anaesthetics like Ropivacaine and by the addition of adjuvants like clonidine and Dexmedetomidine. A good adjuvant must improve the speed of onset, the quality and/or duration of analgesia with desirable sedation.

Method: 50 patients divided in two groups were studied. Group RC received 19ml of 0.75%Ropivacaine with Inj. clonidine $2\mu g/kg$ (made to 1 ml) and Group RD received 19 ml of 0.75% Ropivacaine with inj. Dexmedetomidine 1.5 $\mu g/kg$ (made to 1 ml) epidurally. The two groups were compared for onset and duration of sensory and motor block, sedation score and haemodynamic stability.

Results: Onset of sensory block was early in dexmeditomidine group. Duration of sensory block and duration of analgesia was prolonged significantly in Dexmeditomidine group as compared to clonidine group. Sedation score was also high in Dexmeditomidine group. There were no significant haemodynamic changes in both the group

Conclusion: Dexmeditomidine with Ropivacaine is a better adjuvant as compared to clonidine with Ropivacaine in respect to early onset and prolonged duration of motor and sensory blockade, haemodynamic stability and satisfactory sedation score.

Keywords: Ropivacaine, Dexmeditomidine, Clonidine, sensory block, motor block, sedation score.

Introduction

Pain during and after surgery is often underestimated and under treated. Being purely subjective, pain and its intensity vary widely among patients largely because of its emotional component. It is right to say that the anaesthesiologist's experience, acquired in the field, should be extended into the postoperative period, for the benefit of patients.

Many anaesthesiologists have advocated various methods to counter pain both intra-operatively and extending into the post-operative period much to the satisfaction of the patients^{1, 2}.

The cost of general anaesthesia made Regional Anaesthetic techniques as choice because they are relatively inexpensive and easy to administer. Regional anaesthesia is also the most effective method of reducing the stress response especially

in lower part of the body. In view of the wider application of regional anaesthetic procedure in modern anaesthesia practice, there is a need for local anaesthetic with desirable properties like longer duration of sensory blockade and lesser duration of motor blockade³. Many techniques and drug regimens, with partial or greater success, have been tried from time to time to calm the patients and to eliminate the anxiety component during regional anaesthesia^{4, 5}.

Adjuvant agents co-administered with local anaesthetic agents, may improve the speed of onset, the quality and/ or duration of analgesia with desirable sedation⁶. A wide range of drugs has been assessed for both neuraxial and peripheral nerve blocks⁷. Sedation, stable hemodynamic and an ability to provide smooth and prolonged post-operative analgesia are the main desirable qualities of an adjuvant in neuraxial anaesthesia.

Dexmedetomidine is a highly selective $\alpha 2$ Adrenergic agonist with an affinity of eight times greater than clonidine. Observations of various studies have stated that the dose of clonidine is 1.5-2 times higher than dexmedetomidine when used in epidural route⁸. The anaesthetic and the analgesic requirement get reduced to a huge extent by the use of these two agents. Hence this study was designed to evaluate the best adjuvant.

Material and Methods

This study was carried out in the department of Anaesthesiology, Mamata medical college, Khammam, Telangana, India from October 2015 to September 2017. The study was approved by Hospital ethical committee. 50 patients undergoing elective lower abdominal surgeries were included. Written informed consent from patients was obtained. Patients were divided in two groups.

Group RC: Patients received 19ml of 0.75%Ropivacaine with Inj. clonidine 2µg/kg (made to 1 ml) epidurally.

Group RD: Patients received 19 ml of 0.75% Ropivacaine with inj. Dexmedetomidine 1.5 μg/kg (made to 1 ml) epidurally.

Inclusion Criteria: Patients with ASA grade I and II, aged between 18-45 years, belonging toboth the sexes, undergoing lower abdominal surgeries.

Exclusion Criteria: ASA grade III, IV& V, those with known sensitivity to local anaesthetics, patients with infection at the site of injection and uncooperative patients

At the end of the study all the data was compiled and statistically analyzed. Descriptive data presented as mean \pm SD. Continuous data analyzed by paired or unpaired t test. Chi - square test used to analyze statistical difference between the two groups.

Pre -anaesthetic evaluation was carried out. Basic demographic data like age, sex, height and weight were recorded. Linear visual analogue scale for sedation (VAS) was explained to all patients using 10 cm scale and details of the procedure to be performed explained.

All patients were pre-medicated with 0.05mg/kg midazolam 1Mg 1 hr prior to the procedure. Pulse rate, respiratory rate, blood pressure and Spo2 were recorded. Peripheral venous cannulation was done with 18G IV cannula. All patients were preloaded with 10ml/kg Ringer Lactate solution. Patients were placed in left lateral position. Epidural catheter was inserted in L3-L4 inter space under strict aseptic precaution and following the protocol. After confirming proper placement of epidural catheter, drugs were administered. The level of sensory block was assessed by bilateral pinprick method, quality of motor blockade assessed by bromage scale at 5, 10, 15, 20, 25, 30 minutes. Time of injection was recorded as 0 hour. In the two groups the following are noted

1. The onset of sensory blockade at T10 level. 2. Maximum sensory level achieved. 3. Time to attain maximum sensory level. 4. Onset of motor blockade. 5. Duration of motor block. 6. Two segment regression time. 7. Duration of sensory block. 8. Duration of analgesia was recorded. 9.

Hemodynamic variables like systolic and Diastolic BP, Heart rate were recorded every 5 min until 30 min and at 15 min interval thereafter up to 90min and then at 30 min interval till the end of surgery. 10. Sedation scores were recorded just before the initiation of surgery and there after every 20 minutes during surgical procedure. 11. Side effects like nausea, vomiting, bradycardia; hypotension, dry mouth and shivering were noted in both groups.

Grading of motor blockade was done by Bromage scale

Grading of sedation was evaluated by a Wilson's sedation scale.

Duration of sensory block is defined as time taken for regression of analgesia to S1.

Duration of analgesia is defined as from point 0 to patient demanding analgesia.

Observations and Results

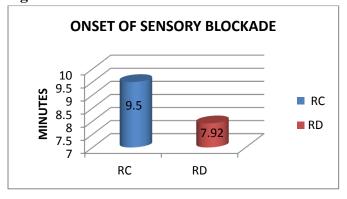
Of the fifty patients, 25 belong to group RD (19 ml of 0.75% Ropivacaine with inj. Dexmedetomidine - 1-5 μ g/kg made to 1 ml) and 25 patients belong to group RC (19ml of 0.75% Ropivacaine with Inj.clonidine 2 μ g/kg made to 1 ml)

The mean age group in both groups was 34 yrs. Surgeries done were similar in both the groups and statistically comparable. (p>0.05)

Table: 1 Comparison of Onset of Sensory Blockade in Both Study Groups

	J 1	
GROUP	MEAN	SD
RC	9.5 mins	1.69
RD	7.92mins	1.63

Figure 1



The mean time of **onset of sensory block** to T10 level in group RC was; 9.5 ± 1.69

Min, in group RD was 7.92±1.63 min. The statistical analysis by unpaired _ t_ test showed statistically significant difference (p=0.0015) between the two groups [**Table 1, Figure 1**]

Table 2: Highest Sensory Level Achieved in Both Groups

Highest Sensory	GROUP	GROUP	PVALUE
level	RC	RD	
T4	4 mins.	5mins.	0.714
T6	11mins.	11mins.	1.0
T8	10mins.	9mins.	0.662
Mean time in min	14.32	12	
SD	2.39	2.68	

The mean time to achieve **highest sensory level**-14.32±2.39 mins for group RC,

12±2.68 mins for group RD. P value calculated by unpaired t test is 0.0022 which is statistically significant. (P<0.05) [**Table 2**]

Table 3: Time of Onset of Motor Blockade:

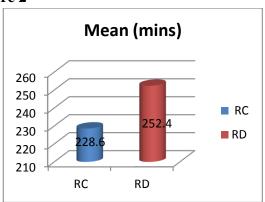
Group	Mean (mins)	SD
RC	20.76	2.89
RD	18.68	2.56

The mean duration of **onset of motor blockade** in group RC was 20.76 ± 2.89 mins, in group RD was 18.68 ± 2.56 mins. The statistical analysis by unpaired t test showed that there is a statistically significant difference (p = 0.0097) in the two groups. [**Table 3**]

Table 4: Duration of Motor Blockade

Group	Mean (mins)	SD
RC	228.6	26.44
RD	252.4	28.45

Figure 2



The **mean duration of motor blockade** in group RC was 228.6 ± 26.44 mins, in group RD was 252.40 ± 28.45 mins. Statistical analysis by unpaired t test showed that there is statistically significant difference (p <0.0356) in the two groups [**Table 4: Figure 2**]

Table 5: Two Segment Regression Time

Group	Mean (mins)	SD
RC	124	10.61
RD	142.8	10.32

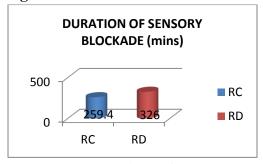
The **two segment regression time** in group RD was 142.8 ± 10.32 mins, in group

RC was 124 ± 10.61 mins. The statistical analysis by unpaired t test showed that there is statistically significant difference (p <0.0001) between the two groups. [**Table 5**]

Table 6: Duration of Sensory Blockade

Group	Mean (mins)	SD
RC	259.4	20.98
RD	326.0	36.91

Figure 3

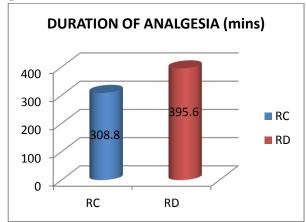


The **mean duration of sensory blockade** in group RC was 259.4 ± 20.98 mins and in group RD was 326.0 ± 36.91 mins. The statistical analysis by unpaired t test showed that there is statistically significant difference (p <0.0001) between the two groups [**Table 6: Figure 3**]

Table 7: Duration of Analgesia

Group	Mean (mins)	SD
RC	308.8	40.01
RD	395.6	58.12

Figure 4:



The **mean duration of analgesia** in group RC was 308.8±40.01 mins, in group RD is 395.6±58.12 mins. The statistical analysis by unpaired t test showed that there is statistically significant difference {p<0.0001) between the two groups. [**Table 7: Figure 4**]

Haemodynamics

Table 8: Comparison of Systolic and Diastolic Blood Pressure in Both Groups

Group	0	5	10	15	30	60	90
	mins						
RC	124	112	108/69	115/72	112	115	115/74
	/82	/72			/75	/74	
RD	122/83	110	103/68	115	111/72	112/71	113
		/72		/74			/71
PValue							
(Sys)	0.4134	0.5855	0.2273	0.9375	0.7303	0.2905	0.4518
(Dia)	0.7250	0.7266	0.9049	0.2330	0.2445	0.2277	0.1560

Figure 5:

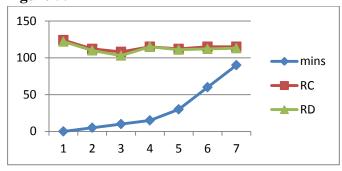


Table 9: Comparison of Heart Rate in Both Groups

Group	0 mins	5 mins	10 mins	15 mins	30 mins	60 mins	90 mins
RC	77	71	66	70	71	72	71
RD	78	76	69	74	74	74	74
Pvalue	0.5658	0.1018	0.2830	0.0789	0.2174	0.3061	0.2585

Systolic and Diastolic B.P. was stable in both groups. There is no statistical difference. Heart rate showed more stability in RD group as

compared to RC group although it is not statistically relevant. [**Table 8, 9: Figure 5**]

Table 10: Comparison of Sedation Scores in Both Groups

Sedation Score	Group RC	Group RD	P Value
1	13(52%)	4(16%)	< 0.0001
2	4(16%)	5(20%)	0.5813
3	8(32%)	16(64%)	< 0.0001
4	0	0	-
5	0	0	-

Mean **sedation scores** were significantly higher in RD group compared to RC group. 64% patients in group RD had a sedation score of 3 and 32% in group RC (P<0.0001). Only 16% of the patients in the RD group had sedation scores of 1 compared to 52% wide and awake patients in RC group, which is a highly significant statistical entity (P<0.0001). 16% patients in group RC, 20% patients in group RD had score 2 which is statistically not significant. [Table **10:**]

Table 11: Comparison of Side Effects in Both Groups

Side effects	Group RC	Group RD	Pvalue
bradycardia	5 (20%)	4 (16%)	0.58
hypotension	7 (28%)	6 (24%)	0.27
nausea	4 (16%)	4 (16%)	1.0
vomiting	1 (4%)	1 (4%)	1.0
shivering	0	0	
respiratory	0	0	

Side effects in both the groups were very low and comparable to each other

Discussion

Epidural anaesthesia is considered as a gold standard technique. Its benefits are more as compared to general anaesthesia. Most importantly, it can be performed in patients with moderate pulmonary complications. Previous studies suggest addition of adjuvants like α 2-agonists is advantageous. Hence α -2 agonists are being extensively evaluated as an alternative with emphasis on opioid-related side effects^{3, 6}.

Clonidine has been used successfully over the last decade. Dexmedetomidine has further widened the scope in regional anaesthesia^{9, 10}. The faster onset of action, rapid establishment of both sensory and motor blockade, prolonged duration of analgesia in post-operative period¹¹, dose-sparing action of local anaesthetics and stable cardiorespiratory parameters makes α -2 agonists a very effective adjuvant in neuraxial anesthesia⁷.

Therefore, this study was performed to compare the efficacy of clonidine and dexmedetomidine as adjuvants in epidural anaesthesia.

Studies were performed by different authors on this subject at different period of time, on different surgeries and with different concentration of drugs.

In our study the demographic profile was comparable with respect to mean age, body weight, height, sex distribution, and types of surgeries in both the groups of our patients.

In the study done by Bajwa et al¹² mean age was 52.06 and 50 .38yrs in RC &RD group respectively. In our study mean age were 33.88 years & 34.28 yrs in RC & RD group. Weight distribution in our study is comparable to the study done by Bajwa et al and Shaikh SI et al¹³. In all the studies demographic data was statistically insignificant in both the groups.

Type of surgery- We have selected patients undergoing Lower abdominal surgeries similar to the study done by Bajwa et al¹². Shaikh and Mahesh et al¹³ and other authors have selected patients undergoing lower limb orthopaedic surgeries.

Onset of action

Saravana babu et al¹⁴ found that addition of dexmeditomidine to ropivacaine resulted in an earlier onset (7.33 min) of analgesia compared to clonidine (8.40 min). Shaikh and Mahesh¹³ reported onset of sensory blockade with dexmeditomidine group as 8.70min and clonidine group as 11.23min which is quiet significant. Both these studies are comparable to our study. But Kaur et al.¹⁵ found that although adding dexmeditomidine decreased analgesia onset time (12.53min) compared with plain ropivacaine (14.18min), it is not very significant.

In a study by Sukhminder Singh bajwa et al¹², addition of dexmeditomidine to ropivacaine resulted in an earlier onset (8.52 min) of sensory analgesia at T10 as compared to the addition of clonidine (9.72 min). (p< 0.05) and is comparable to our study. In another study by Sukhminder Singh Bajwa et al¹⁶ for epidural analgesia in lower limb orthopaedic surgeries, onset of sensory analgesia at T10 was earlier in dexmeditomidine group (7.12min) compared to fentanyl group (9.14min)

In a study conducted by Kumar Shailesh et al¹⁷ of epidural ropivacaine (0.75%) with clonidine and ropivacaine (0.75%) with dexmeditomidine for lower abdominal and lower limb surgeries, the onset of sensory blockade at T10 was earlier in Group RD (8.75 mins) than in Group RC (10.25 mins), This study is comparable with our study.

Sruthi Arunkumar, VR Hemanth Kumar et al¹⁸also showed significantly earlier onset of sensory blockade in patients receiving dexmeditomidine (8.53 min.) when compared to clonidine (11.93 min.).

In our study the mean time of onset of sensory blockade at T10 in Group RD (7.92 min) was significantly less than Group RC(9.5min, P<0.05). Our results for onset of sensory blockade are comparable with results of above studies. This data shows that dexmed when added to ropivacaine, the time of onset of sensory block is early as compared to clonidine as an adjuvant.

Time for maximum sensory block

Shaikh and Mahesh¹³ found that mean time for maximum sensory blockade is 12.87min with dexmeditomidine and 17.13min with clonidine group. Saravana babu et al¹⁴ found that mean time for peak onset analgesia with dexmeditomidine group is 11.66min compared with clonidine group is 13.20min and there is statistically significant difference with p<0.0221. Bajwa et al¹²found that adding dexmeditomidine decreased the peak onset analgesia mean time to13.14 min when compared to clonidine with 15.80 min. (p value <0.018). But Kaur et al¹⁵found that with plain ropivacaine

mean time for peak onset analgesia is 23.24 min and when dexmeditomidine as added as adjuvant mean time is 21.63 min. These are statistically insignificant (P = 0.122). In our study the mean time to achieve maximum sensory level was significantly less in group RD compared to group RC. It was 12 min for group RD, 14.32 min for group RC, (P<0.05) and above studies are comparable to our study.

Time for complete motor blockade or bromage 3.

Bajwa et al¹² found that mean time for complete motor blockade in dexmeditomidine group was 17.24 min and in clonidine group 19.52 min [p =0.041].

Shaik SI et al¹³ reported time for modified bromage 3 with dexmedetomidine is 19.30min but with clonidine 24.87min. These values comparable and statistically significant p< 0.00001. Kour et al¹⁵ reported time to complete motor block in clonidine group is 27.34min when compared to dexmeditomidine group with mean time 25.73min. But these are statistically insignificant with p= 0.123. Except in study done by Kour et al¹⁵ all the previous studies states that there is a significant difference with shorter time for modified bromage 3 when dexmeditomidine was used as an adjuvant compared with clonidine. In the study conducted by Kumar Shailesh et al ¹⁷ time of onset of motor blockade (Modified Bromage Scale 1) was 8.7mins in Group RD while 10.05 mins in Group RC. In our study the mean time to onset of motor blockade in group RD was significantly less compared to group RC [18.68 min in group RD, 20.76 min in group RC, p<0.05], the results of our study are comparable with the results of above studies.

Two segment regression time

In our study the two segment regression time in Group RD was significantly higher than Group RC [in Group RD was 142.8 min, in group RC was 124 min]. Bajwa et al¹² found that time for two segment regression was more in the groups receiving dexmeditomidine (136.46 min.) when

compared with groups receiving clonidine (128.08 min). According to Alves TC et al¹⁹, epidural clonidine with ropivacaine significantly prolonged sensory, motor and post operative analgesia, when compared to plain ropivacaine alone. In the study by Kumar Shailesh et al ¹⁷, the mean time for two segment regression was significantly prolonged in Group RD (137.16 min.) as compared to Group RC (126.76 min).

Our study also showed that duration of motor block was significantly prolonged in group RD compared to group RC [252.40 min (4.2 hrs) Vs 228.6 min (3.8hrs), p<0.05]

In our study duration of sensory block was significantly prolonged in group RD [326.0min (5.43 hrs)] compared to group RC [259.4min (4.31 hrs)] (p<0.0001).

Duration of analgesia

Saravana babu et al¹⁴ found an increase in duration of analgesia with dexmeditomidine as adjuvant when compared to clonidine (407 and 345 min respectively). Kaur et al¹⁵ found that duration of sensory blockade is 535.18min with dexmeditomidine+ropivacaine where as it is 375.20min with plain ropivacaine. These values are statistically significant with p value < 0.0001. Shaikh and Mahesh¹³ found that mean time for sensory regression to s1 with dexmeditomidine is 314.17min and with clonidine group is 298.73min [p=0.0038]. In a study by Sruthi Arunkumar, V. R. Hemanth Kumar et al¹⁸ they found that the duration of sensory analgesia was more in group RD (316 min.) than group RC (281 min.).

Our study results are comparable with that of above studies. In our study duration of analgesia in group RD was 395.6mins,(6.58 hrs) compared to group RC 308.8 mins (5.13 hrs). It is statistically very significant as 0.0001. Addition of dexmed to ropivacaine increases the time for demand of rescue analgesic. This is of great advantage to the patient as well as to the concerned medical staff. It decreases frequent requirement of epidural dose for analgesia.

Systolic BP, Diastolic BP, Mean BP, HR, Vasopressor rescue

Bajwa et al¹² found that there was decreasing trend in heart rate and mean arterial blood pressure in both groups and decrease was statistically significant in clonidine group. Kaur et al¹⁵ found insignificant haemodynamic changes with dexmeditomidine plus Ropivacaine. Shaikh and Mahesh.¹³ did not observe any significant difference of heart rate and mean arterial BP. In their study the requirement of mephenteramine was not significant on statistical comparison. Saravana babu et al¹⁴ reported a decreasing trend of heart rate and mean arterial pressure 30min post-injection in both groups and this decrease was significant in the ropivacaine clonidine group. Kumar Shailesh et al¹⁷ observed decrease in heart rate, from baseline by 20% in 30 - 45 minutes after epidural injection in both the groups. There was significant fall in mean arterial pressure approximately by 15% in 30-45 min after epidural injection. However this change was statistically significant between two groups.

In our study intra operative systolic and diastolic blood pressure and heart rate were comparable in both the groups. 20% (n=5) of patients in group RC, 16 n=4) in group RD had bradycardia. Hypotension seen in 28% (n=7) of patients in group RC, 24% (n=6) in group RD. These values are statistically not significant. Results of our study for SBP, DBP, Mean BP, HR, Vasopressor rescue is comparable with results of above studies. Dexmed as an adjuvant does not have significant effect on haemodynamics.

Sedation Score

Bajwa et al¹² reported Ramsay sedation score more in dexmeditomidine group than in clonidine group. Shaikh and Mahesh¹³ also found mean Ramsay sedation score for clonidine group 1.2 and of dexmeditomidine group 2.8 (P < 0.0001). Sedation scores were statistically significant at 20 min (P = 0.00001), 40 min (P = 0.00001), 60 min (P = 0.0093) in dexmeditomidine group. More patients in dexmeditomidine group achieved

sedation scores of 3 when compared to clonidine group. Kaur et al¹⁵ and Saravanbabu et al¹⁴ used VAS sedation scores. They found that scores were high when dexmeditomidine was used as an adjuvant. In our study Mean sedation scores were significantly higher in RD group compared to RC group. 64% patients in group RD had a sedation score of 3 as compared 32% in group RC (P<0.0001). Only 16% of the patients in the RD group had sedation scores of 1 compared to 52% wide and awake patients in RC group, which was a highly significant statistical entity (P < 0.0001) Our study results for sedation score were comparable with that of above study. Dexmed having more sedative effect lessens the demand for sedatives and hypnotics.

Side Effects

In the study done by Bajwa et al¹² the incidence of side effect in both the groups was low and statistically comparable. In the study done by Shaikh and Mahesh¹³ the incidence of side effects like nausea, dry mouth, vomiting etc was also low. In our study the side effect like nausea, dry mouth, vomiting, hypotension and bradycardia were equal. Our study results are comparable with results of the above studies. None of the patients in two groups had any other side effects like respiratory depression, shivering etc. However, Kumar Shailesh et al¹⁷ who conducted similar type of study as ours, reported higher incidence of nausea in both groups but not statistically significant. No complications like shivering, respiratory depression, headache, dizziness, urinary retention found during intraoperative or postoperative period among both groups In a study conducted by Sruthi Arunkumar, V.R Hemanth Kumar et al ¹⁸, had two patients in group RC and one patient in group RD who had dry mouth.

Conclusion

We conclude that dexmeditomidine (1.5mcg/kg body wt) is a better adjuvant when administered epidurally with Ropivacaine 0.75% than clonidine

(2mcg/kg body wt) as there is significantly early onset of sensory and motor block, longer duration of sensory and motor block, prolonged duration of analgesia and additional benefits of intraoperative sedation with hemodynamic stability. Our experience with epidural dexmedetomidine was satisfactory as compared to clonidine as adjuvant in lower abdominal surgeries.

Declarations

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Conflict of interest: None declared Ethical approval: Not required

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