

A Clinical Comparative Study of Inj. Ropivacaine 0.75% with Inj. Dexmedetomidine (1.5µg/Kg) and Inj. Ropivacaine 0.75% with Inj. Clonidine (2µg/Kg) by Epidural Route in Patients Undergoing Lower Abdominal Surgeries

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Abstract

Background: 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. **Aims:** Compared the effects of Clonidine (2 mcg/kg) with Dexmedetomidine (1.5 mcg/kg) as an adjunct to Epidural 0.75 % Ropivacaine in lower abdominal surgeries in adult patients. **Subjects and Methods:** This is a prospective study carried out in 50 patients undergoing elective lower abdominal surgeries, aged between 18-45 years of either gender, belonging to ASA grade I and II randomly divided into two groups by lottery method. **Results:** The mean time of onset of sensory blockade in Dexmedetomidine group is significantly less than Clonidine group. The 2-segment regression time in Dexmedetomidine group was significantly higher than Clonidine group. The mean duration of sensory blockade was significantly higher with Dexmedetomidine group than Clonidine group. The mean time of onset of motor blockade was significantly less in Dexmedetomidine group than Clonidine group. The mean duration of motor blockade was significantly higher with Dexmedetomidine group than Clonidine group. The duration of analgesia was significantly prolonged and highest in the Dexmedetomidine group compared to Clonidine group. Both groups were similar in haemodynamic stability and side effects (P>0.05, statistically not significant). **Conclusion:** Dexmedetomidine was a better adjuvant than clonidine in epidural anaesthesia due to better patient tolerance, stable cardio-respiratory parameters, and where intra-operative and post-operative analgesia were concerned.

Keywords: Dexmedetomidine, Clonidine, Epidural anaesthesia.

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Introduction

The International Association for the Study of Pain "IASP" defines pain as an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage. Pain during surgery is often underestimated and under treated. Being purely subjective, pain and its intensity vary widely among patients. The threshold of pain is variable largely because of its emotional component. The relief of pain during surgery is "the reason for existence" of anaesthesiology. It is right to say that the anesthesiologist's experience, acquired in the field should be extended into the postoperative period as this has many beneficial effects for the patient.^[1]

While the intra-operative pain experienced by the patient has been underestimated, that of post-operative pain relief has been neglected to a large extent. In this context many anesthesiologists have advocated various methods to counter

pain both intra-operatively and extending into the post-operative period much to the satisfaction of the patients.

The cost of general anaesthesia, the skill and specialized equipment needed for its administration coupled with an indifferent supply of anaesthetic gases and drugs and lack of monitoring equipment especially in peripheral areas in a country like India made Regional Anaesthetic techniques as choice because they are relatively inexpensive and easy to administer.^[2]

Regional anaesthesia is currently the most effective method of reducing the stress response especially in patients with surgical procedures involving the lower part of the body. In view of the wider application of regional anesthetic procedure in modern anaesthesia practice, there is a need for local anesthetic with desirable properties like longer duration of sensory blockade and lesser duration of motor paralysis.

Surgical methods and the anesthetic techniques have evolved and improved drastically over the last two decades. 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.

The fear of surgery, the strange surroundings of the operation theatre, the sight and sound of sophisticated equipment, dynamicity of an 'operation' during regional anaesthesia and the masked faces of so many strange personal makes the patient panic to any extent". The intense sensory and motor block continuous supine position for a prolonged duration and the inability to move the body during regional anaesthesia brings a feeling of discomfort and phobia in many of the patients.

Adjuvant agents are pharmacological drugs that, when co-administered with local anesthetic agents, may improve the speed of onset. The quality and or duration of analgesia with desirable sedation. A wide range of drugs has been assessed for both neuraxial and peripheral nerve blocks. Various adjuvants that can be added to local anesthetics and administered in central neuraxial blockade are Opioids - Fentanyl, sufentanyl, morphine (preservative free) α 2 agonists – dexmedetomidine, clonidine. 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 α 2 adrenergic agonist with an affinity of eight times greater than clonidine. There is no such study which has compared the dose equivalence of these drugs but the observations of various studies have stated that the dose of clonidine is 1.5-2 times higher than dexmedetomidine when used in epidural route. The anesthetic and the analgesic requirement get reduced to a huge extent by the use of these two agents.

Subjects and Methods

This is a prospective study carried out in the department of Anesthesiology, MNR Medical College and Hospital, SANGAREDDY, from December 2015 to September 2017. The study was approved by the Hospital ethical committee.

In this study 50 patients undergoing elective lower abdominal surgeries, aged between 18-45 years of either gender, belonging to ASA grade I and II randomly divided into two groups by lottery method.

After taking written informed consent from patients, they were subjected to epidural catheterization with 16/18 G size and given epidural anaesthesia.

Group RC (Control): The control group comprises of patients in whom 19ml of 0.75% Ropivacaine with Inj.clonidine 2 μ g/kg (made to 1 ml) administered epidurally.

Group RD (Study group): Consists of patients in whom 19 ml of 0.75% Ropivacaine with inj. Dexmedetomidine -1.5 μ g/kg (made to 1 ml) administered epidurally.

Inclusion criteria:

ASA grade I and II physical status, aged between 18-45 years, belonging to- both the sexes undergoing lower abdominal surgeries.

Exclusion criteria:

Patients not willing to participate in the study. Patients with ASA grade III, IV & V. Those with known sensitivity to local

anaesthetics, Patients with local infection at the site of injection and Uncooperative patients.

Method:

Pre -anaesthetic evaluation:

During preoperative visit patient's detailed history, general physical examination and systemic examination were carried out. Basic demographic data like age, sex, height and weight were recorded.

During pre-anaesthetic checkup the linear visual analogue scale (VAS) was explained to all patients using 10 cm scale. Informed consent was obtained from all the 50 patients after the detailed explanation of the procedure to be performed.

Premedication:

All the patients were pre-medicated with 0.05mg midazolam IM. 1hr prior to the procedure.

Procedure:

The pulse rate, respiratory rate, blood pressure and Spo2 were recorded before starting the case. Peripheral venous cannulation was done with 18G IV cannula and all the patients were preloaded with 10ml/kg Ringer Lactate solution. The patients were placed in left lateral position and under strict aseptic precautions, after local infiltration with 1 % Lignocaine hydrochloride the epidural space was identified with a 18/16G

Tuohy needle at L3-L4 interspace, by "loss of resistance" technique. 18/16G epidural catheter was threaded through the needle in to the epidural space for 3-4cms and secured with adhesive tapes to the back. After negative aspiration for blood and CSF, 3ml of 2% Lignocaine with 15mg of adrenaline was given as test dose and the patient was - turned to supine position. After 5 mins if there is no adverse reaction for the test dose, intravascular and intrathecal placement were ruled out and the study drugs were administered.

Group RC. n=25, were given 19ml of 0.75% Ropivacaine and Inj.clonidine 2 μ g/kg (made to 1 ml) epidurally.

Group RD. n=25, were given 19 ml of 0.75% Ropivacaine and inj. Dexmedetomidine 1.5 μ g/kg (made to 1 ml) epidurally.

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. Two segment regression time.
6. Duration of sensory block,
7. Duration of motor block,
8. Duration of analgesia were recorded.
9. Continuously SpO2, respiratory rate, heartrate were monitored.
10. Hemodynamic variables like systolic BP, diastolic BP, Mean Arterial Pressure, heart rate were recorded every 5 min until 30 min and at 15 min interval thereafter up to 90 min and then at 30 min interval till the end of surgery.

11. Sedation scores were recorded just before the initiation of surgery and thereafter every 20 minutes during surgical procedure.

12. Side effects like nausea, vomiting, bradycardia, hypotension, respiratory depression dry mouth and shivering were noted in both groups.

Bromage scale for onset of motor blockade Grading of sedation was evaluated by a Wilson's sedation scale

1. Fully awake & oriented
2. Drowsy
3. Eyes closed but arousable to commands
4. Eyes closed but arousable to mild physical stimulus
5. Eyes closed but not arousable to mild physical stimulus

If there was fall in blood pressure more than 30% below the baseline value, even after intravenous fluids administration, inj. Ephedrine was given in titrated doses. If the pulse rate was less than 30% of baseline, inj. Atropine 0.6mg IV was given. If respiratory rate was less than 10/min respiratory depression was diagnosed.

At the end of the surgery the patients were shifted to post-operative ward they were monitored for every 30 mins for the first six hours and there after every hour for 24 hours period. When patient had VAS (Visual Analogue Scale) score ≥ 4 rescue analgesia given with top up of 10 ml of 0.2% Ropivacaine with 25 mcg of fentanyl.

Statistical data:

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

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 1ml).

Table 1: Demographic Distribution in present study

Age in Years	Group RC	Group RD
16-25	5	7
26-35	8	7
36-45	12	11
Mean	33.88	34.28
SD	9.39	8.8
Gender		
Males	14	13
Females	11	12
Total	25	25
Weight (Kgs)		
Range	46-70	46-67
Mean	57.6	57.92
S.D	6.62	6.45
Height		
Height in cms	145-164	145-168
Mean	155.76	154.32
S.D	14.30	11.18
Type of surgery		
Hernioplasty	7	7
Incisional hernia	5	4
TAH	4	5
Ovariectomy	3	4
Appendectomy	6	5

The Age, gender, height, weight and surgeries done in both the groups were comparable, there is no statistical Significance.

Table 2: Onset and level of sensory block in present study

Sensory block	Group RC	Group RD	P-Value
Mean time of onset of sensory block in mins	9.5 \pm 1.69	7.92 \pm 1.63	0.0015
Highest sensory level achieved			
T4	4	5	0.714
T6	11	11	1.0
T8	10	9	0.662
Maximum sensory level in mins	14.32 \pm 2.39	12 \pm 2.68	0.0022
Mean duration of sensory block	259.4 \pm 20.98	326.0 \pm 36.91	<0.0001

The mean onset of sensory block , maximum sensory level and mean duration of sensory block is statistical analysis by unpaired t test showed that there is a very statistically significant difference (p<0.0001) between the two groups.

Table 3: Onset and level of motor block in present study

Motor block	Group RC	Group RD	P-Value
Mean time of onset of motor block in mins	20.76 \pm 2.89	18.68 \pm 2.56	0.0097
Two segment regression time in mins	142.8 \pm 10.32	124 \pm 10.61	p<0.0001
Mean duration of motor blockade	228.6 \pm 26.44	252.40 \pm 28.45	p<0.0356

The mean onset of motor block , maximum motor level and mean duration of motor block is statistical analysis by unpaired t test showed that there is a very statistically significant difference (p<0.0001) between the two groups

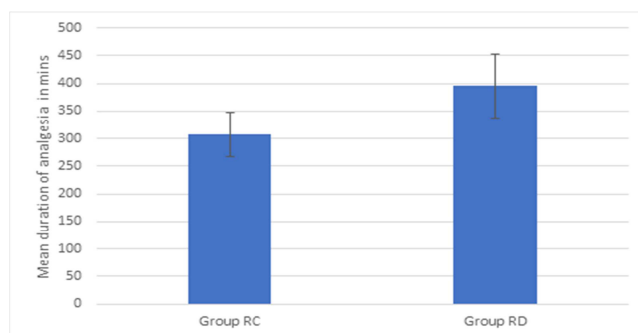


Figure 1: Mean duration of analgesia in minutes in present study.

Mean duration of analgesia on statistical analysis by unpaired t test showed that there is a very statistically significant difference (p<0.0001) between the two groups. Intra operative haemodynamics have no significance difference on comparison in both groups.

Table 4: Side Effects in present study

Side Effects	Group RC N=25	Group RD N=25	P Value
Bradycardia	5 (20%)	4 (16%)	0.58
Hypotension	6(24%)	8 (32%)	0.27
Nausea	4 (16%)	4 (16%)	1.0
Vomiting	1(4%)	1(4%)	1.0
Shivering	0	0	-
Dry mouth	6 (24%)	5 (20%)	0.60
Respiratory	0	0	

Table 5: Sedation Scores in present study

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		

Mean sedation scores were significantly higher in RD group compared to RC group as 64% patients in group RD had a sedation score of 3 as compared to 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 ($p<0.0001$). 16% patients in group RC, 20% patients in group RD had score 2 which is statistically not significant.

Discussion

The use of neuraxial opioids is associated with quite a few side effects, so various options including α -2agonists are being extensively evaluated as alternative with emphasis on opioid-related side effects such as respiratory depression, nausea, urinary retention and pruritis.

The pharmacologic properties of α -2 agonists have been extensively studied and have been employed clinically to achieve the desired effects in regional anaesthesia. Epidural administration of these drugs is associated with sedation, analgesia, anxiolysis. Hypnosis and sympatholysis. Clonidine has been used successfully over the last decade for the said purpose and the introduction of dexmedetomidine has further widened the scope of α -2 agonists in regional anaesthesia. The faster onset of action of local anaesthetics, rapid establishment of both sensory and motor blockade, prolonged duration of analgesia into the post-operative period, dose-sparing action of local anaesthetics and stable cardiovascular parameters makes these agents a very effective adjuvant in regional anaesthesia.

Adequate treatment of post-operative pain is essential because inadequately treated pain increases post-operative morbidity and duration of hospital stay and also leads to chronic surgical pain. Hence we have undertaken a study to evaluate the efficacy of Inj. Ropivacaine 0.75% with Dexmedetomidine (1.5 μ g/kg) by Epidural route compared to Inj. Ropivacaine 0.75% with Inj. Clonidine (2 μ g/kg) by Epidural route in patients undergoing Lower abdominal surgeries.

Epidural anaesthesia is considered a gold standard technique as it provides complete and dynamic anaesthesia. The benefits include suppression of stress response by sympatholysis, stable hemodynamics with reduction in cardiac morbidity, reduction in pulmonary complications due to active physiotherapy and early mobilization, reduced blood loss and decrease in thromboembolic complications following surgery.

There are no studies indicating the equipotent doses of epidural dexmedetomidine and clonidine. A number of studies have used epidural clonidine at doses of 1-4 μ g/kg and it has been suggested that epidural clonidine at a dose of

1 μ g/kg prolongs analgesia without unwanted side effects. Epidural dexmedetomidine has been studied at doses ranging from 1-2 μ g/kg and it was observed that at doses <1 μ g/kg dexmedetomidine does not prolong the block of ropivacaine. Hence, in our study we have used 1.5 μ g/kg dexmedetomidine and 2 μ g/kg clonidine as an adjunct to ropivacaine 0.75% in epidural anaesthesia. The demographic profile of our patients was comparable with respect to mean age, body weight, height, sex distribution, and types of surgeries.

In our study the mean time of onset of sensory blockade at T10 in Group RD was significantly less than Group RC (Group RD 7.92 \pm 1.63 min. Group RC 9.5 \pm 1.69 min, $P<0.05$). In a study conducted by Sukhminder Jit Singh et al, Addition of dexmedetomidine to ropivacaine as an adjuvant resulted in an earlier onset (8.52 \pm 2.36min) of sensory analgesia -at T10 as compared to the addition of clonidine (9.72 \pm 3.44min). ($P<0.05$)

In another study conducted by Sukhminder Jit Singh Bajwa et al Comparative evaluation of dexmedetomidine and fentanyl for epidural analgesia in lower limb orthopedic surgeries. Onset of sensory analgesia at T10 was earlier in dexmedetomidine group (7.12 \pm 2.44min) compared to fentanyl group (9.14 \pm 2.94min).^[3]

In our study the mean time to achieve maximum sensory level was significantly less in group RD compared to group RC (12 \pm 2.68 min for group RD, 14.32 \pm 2.39 min for group RC, $P<0.05$)

In a study by Tanmoy Ghatak et al, comparison of Magnesium sulphate Vs Clonidine, time to achieve T6 level was 16.93 \pm 3.43minutes in clonidine group of patients.^[4]

In our study the mean time to onset of motor blockade in group RD was significantly less compared to group RC (18.68 \pm 2.56 min in group RD, 20.76 \pm 2.8 min in group RC, $p<0.05$).

In our study the two segment regression time in Group RD was significantly higher than Group RC [in Group RD was 142.8 \pm 10.32min, in group RC was 124 \pm 10.61min)

According to Alves TC et al, epidural Clonidine with Ropivacaine significantly prolonged sensory, motor and post-operative analgesia, when compared to plain Ropivacaine alone.

Our study also showed that duration of motor block was significantly prolonged in group RD compared to group RC [252.40 \pm 28.45 min (4.2hrs) Vs 228.6 \pm 26.44mins (3.8hrs), $p<0.05$].^[5]

In our study duration of sensory block was significantly prolonged in group RD [326.0 \pm 36.91min (5.43 hrs)] compared to group RC [259.4 \pm 20.98min (4.31hrs)] ($p<0.0001$).

In our study duration of analgesia in group RD was; - .395.6 \pm 58.2 mins. (6.58hrs) compared to group RC 308.8 \pm 40.01 mins (5.13 hrs). It is statistically very significant as $p<0.001$. In a study conducted by Sukhminder Jit Singh et al.^[3] Addition of dexmedetomidine to ropivacaine as an adjuvant. Dexmedetomidine provided a smooth and prolonged post-operative analgesia as compared to clonidine. There was prolonged time to two segmental dermatomal regression (136.46 \pm 8.12 min) as well as return of motor power to Bromage I (246.72 \pm 30.46 min) in Dexmedetomidine group. Time for rescue analgesia was

comparatively longer in Dexmedetomidine group compared to clonidine (310.76± 23.75 min, P< 0.05)

Similar results were shown in the study by Sukhminder Jit Singh Bajwa et al establishment of complete motor blockade was 18.16±4.52 min in dexmedetomidine group compared to fentanyl group (22.98±4.78) Postoperative analgesia was prolonged significantly in the RD group (366.62±24.42).^[3]

Mukesh I Shukla et al evaluated epidural clonidine for post-operative pain relief.

They have showed that Clonidine significantly leads to rapid onset of analgesia and prolongs the duration of postoperative analgesia and reduces postoperative analgesic consumption.^[6]

F.W. Abdallah, R. BruII et al studied Facilitator effects of perineural dexmedetomidine on neuraxial and peripheral nerve block.^[7] SalgadoPF et al showed that there is clear synergism between epidural dexmedetomidine and ropivacaine.^[8] Prolonged sensory and motor block duration time (p<0.05) and postoperative analgesia (p < 0.05) and also resulted in a more intense motor block.

In a study conducted by A.M. Abd-Ehvahab et al. Addition of dexmedetomidine or clonidine to caudal bupivacaine significantly promoted analgesia.^[9] Both drugs were comparable as regards the analgesia duration. In our study the intra operative haemodynamic variables like systolic blood pressure, diastolic blood pressure, mean arterial pressure, heart rate were comparable in both the groups. 20% (n=5) of patients in group RC, 16% (n=4) in group RD had bradycardia. 24% (n=6) of patients in group RC, 32% (n=8) in group RD had hypotension. These values are statistically not significant.

Mean sedation scores were significantly higher in RD group compared to RC group as 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).

16% (n=4) of patients in both the groups had nausea, 4% (n=1) in both the groups had vomiting. 24% (n=6) of patients in group RC, 20% (n=5) in group RD had dry mouth. The occurrence of these side effects is statistically not significant. None of the patients in two groups had any other side effects like respiratory depression, shivering etc. Dexmedetomidine at doses of 1µg/kg is an effective adjuvant to ropivacaine for epidural anaesthesia, which is comparable to clonidine.

The onset of (RD- 8.53 1. ±81, RC-11.93±1.96) and duration

of sensory blockade RD- 316±31.5, RC-281±37, Sedation were found to be significantly better in the Dexmedetomidine group. No significant difference was found in terms of onset of motor blockade and hemodynamic changes.

Conclusion

It was observed that the mean time of onset of sensory blockade was less in Dexmedetomidine group, yet duration of sensory blockade was longer. Though onset of motor blockade was faster in Dexmedetomidine group, duration of motor blockade was significantly higher. Duration of analgesia for patients with RD group lasted for about 6.5 hrs and those in group RC analgesic effect lasted for 4.5 hrs. Therefore we concluded that dexmedetomidine was a better adjuvant than clonidine in epidural anaesthesia due to better patient tolerance, stable cardio-respiratory parameters, and where intra-operative and post-operative analgesia were concerned.

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