A Clinical Comparative Study between Epidurally Administered Ropivacaine 0.2 % and Ropivacaine 0.2 % with Clonidine for Post-Operative Analgesia in Lower Limb and Abdominal Surgeries

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ABSTRACT

BACKGROUND

There are many modalities to give postoperative analgesia. Out of them epidural analgesia offers good reliable pain relief. Addition of alpha agonist enhances the onset of analgesia and duration of analgesia is prolonged. This study was done to compare the analgesic efficacy, and the hemodynamic parameters of ropivacaine compared with ropivacaine in combination with clonidine for post-operative epidural analgesia.[1]

METHODS

30 patients of age 18 - 70 years with ASA grade of I & II, undergoing elective lower limb and abdominal surgeries were randomly taken into each of the 2 groups. Group R received 0.2 % ropivacaine and group RC received 0.2 % ropivacaine + clonidine (1 mcg / Kg) epidurally.[1,2] Patients were monitored for onset, duration, quality of analgesia, cardiorespiratory stability and side effects.

RESULTS

The onset of analgesia and quality of analgesia were better in the RC group compared to the R group. The duration of analgesia in group RC (9.43 + - 1.17 hours) was found to be significantly prolonged than group R (4.90 + - 1.03 hours) with $p < 0.001$. Blood pressure was more stable in group RC compared to group R.[3]

CONCLUSIONS

In this study we found that ropivacaine with clonidine as epidural postoperative analgesia provided superior and more effective analgesia when compared to ropivacaine. The duration of analgesia was significantly longer in group ropivacaine with clonidine.

KEYWORDS

Ropivacaine, Clonidine, Post-operative Analgesia, Epidural

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DOI: 10.18410/jebmh/2020/615

How to Cite This Article:
Vishwanath VM, Ravishankar RB. A clinical comparative study between epidurally administered ropivacaine 0.2 % and ropivacaine 0.2 % with clonidine for post-operative analgesia in lower limb and abdominal surgeries. J Evid Based Med Healthc 2020; 7(50), 3010-3015. DOI: 10.18410/jebmh/2020/615

Submission 02-04-2020,
Peer Review 12-04-2020,
Acceptance 05-06-2020,
Published 14-12-2020.

BACKGROUND

Postoperative period can be dreadful once the patient starts suffering pain if pain relief is not given. Epidural analgesia as a pain relief method for such patients can provide relief from pain for a longer duration. The facility of top up and continuous infusion of the drugs through epidural catheter thus provides a smooth recovery.[1] In recent years, ropivacaine is widely used and by adding adjuvants the duration of analgesia can be prolonged, this has made search for suitable adjuvants.[4] Ropivacaine has got lesser neurotoxicity, cardiotoxicity, lesser motor blockade compared to bupivacaine, which has made ropivacaine as drug which has beneficial role in epidural anaesthesia and analgesia.[5] Alpha-2 adrenergic agonists have both analgesic and sedative properties when used as an adjuvant in regional anaesthesia.[6] Clonidine is an alpha-2 adrenoceptor agonist which has been shown to improve analgesia when added to epidural ropivacaine.[7] Clonidine when used as an adjuvant reduces the total dose requirement of local anaesthetic and reduces the concentration of local anaesthetic required with enhancing the quality and duration of analgesia, with decreased incidence of unwanted motor blockade.[8] With keeping pharmacological property of ropivacaine and clonidine we took the study to compare the analgesic property of 0.2 % ropivacaine with addition of clonidine (1 mcg / Kg) to that of ropivacaine 0.2 % in epidural route for administration in post-operative period.

METHODS

This study was conducted to analyse the efficacy and safety of epidural 0.2 % ropivacaine in comparison with epidural 0.2 % ropivacaine in combination with clonidine (1 mcg / Kg) for postoperative analgesia in abdominal and lower limb surgeries. The study was undertaken in the Chigateri General Hospital, Women and Child Health Hospital and Bapuji 7 Hospital attached to J.J.M. Medical College, Davangere, during the period of 2017 - 2019. Sixty patients of ASA class I and II of either sex belonging to 18 - 70 years of age undergoing various elective abdominal and lower limb surgeries were selected into each of the two groups for the study after obtaining Ethical Committee clearance, institutional approval and informed consent of the patient.

The Two Study Groups

- Group R: Epidural 0.2 % ropivacaine.
- Group RT: Epidural 0.2 % ropivacaine with clonidine (1 mcg / Kg).

Pre-Anaesthetic Evaluation

Patients were visited on the previous day of the surgery, a detailed medical history was taken and systemic examination was carried out.

Inclusion Criteria

- ASA grade I and II.
- Age between 18 – 70 years.
- Patients posted for elective lower limb and abdominal surgeries.

Exclusion Criteria

- Emergency cases.
- Documented allergies to any drugs, especially local anaesthetics.
- Any abnormalities of spine or infection at epidural site.
- Patients with abnormal coagulation profile.
- Patient refusal.
- Emergency surgeries.

Basic biochemistry profile and haemogram-Hb %, RBS, blood urea and serum creatinine was done in all patients. ECG (Electro-Cardio-Gram) was done and chest X-ray was taken when ever needed.

Procedure was explained to patient before the night of surgery. Patient were taught to interpret VAS (Visual Analogue Scale). Informed consent was taken.

Premedication

Tab. Alprazolam 0.5 mg and Tab. Ranitidine 150 mg orally were given on the previous night. Patients were kept nil orally for 8 hours before surgery.

Technique

Drugs and equipment necessary for resuscitation and general anaesthesia were kept ready.

Equipment for the procedure:

An autoclaved portable tray covered with sterile towels containing -

- Sterile drape
- Sterile syringes-one 5 mL, one 10 mL
- Loss of resistance syringe
- 18G / 16G Touhy needle with Huber tip and tight fitting stylet.
- 18G epidural catheter with filter
- Bowl containing povidone iodine
- Sponge holding forceps
- Sterile gauge pieces

Patient was shifted into operation theatre and was made to lie in supine position on the operation table. Monitoring devices (pulse oximeter, NIBP-Non-Invasive Blood Pressure, and ECG) were attached. Baseline heart rate, blood pressure, respiratory rate and SpO2 were recorded. Then IV (Intra-Venous) line was secured with an 18G cannula and infusion was started with lactated Ringer's solution.

The patient was put in left lateral position, parts were painted and draped. L1 - L2, L2 - L3 and L3 - L4 space suitable for respective surgery was identified. With all aseptic precautions, a skin wheal was made at the inter space with 2 mL of 2 % lignocaine injection. By using loss of

resistance technique epidural space was identified with 16G / 18G Touhy needle. Then 18G catheter was passed through the epidural needle. The needle was removed, and catheter withdrawn till about 4 to 5 centimetres of catheter left in epidural space. Catheter was secured to the skin and the marking at the skin was noted.

Test dose was given with 3 mL of 2 % lignocaine with 1:2,00,000 adrenaline and observed for any intravascular and intrathecal injection. After correct placement of catheter in epidural space was confirmed, Combined Spinal Epidural Anaesthesia (CSEA) or epidural anaesthesia was given depending on requirement of the surgery performed[9].

No systemic analgesic drugs or opioids were given throughout the intraoperative period. Those cases where neuraxial blockade was inadequate with the need to supplement with general anaesthesia were excluded from the study.

Fluid Management

To start with, RL (Ringer's Lactate) was infused and maintained with RL and DNS (Dextrose/Sodium Chloride). Blood was transfused only when indicated. Patients' vital parameters were monitored throughout the surgery.

After surgery patients were shifted to postoperative ward and monitoring was continued. When the patient complained of pain, clinically correlating with visual analogue score > 5, patients were given 10 mL of the drug epidurally by a randomised single blinded manner.

- Group R: Received epidural 0.2 % ropivacaine.
- Group RT: Received epidural 0.2 % ropivacaine plus clonidine (1 mcg / Kg).

All the patients were monitored for onset, duration and quality of analgesia, vital parameters, motor blockade and side effects were noted.

Following parameters were recoded:

- SpO_2, heart rate, NIBP are recorded at 1, 5, 10, 15, 20, 25, 30, 45 minutes.
- Time of onset of analgesia.
- Analgesia duration.
- Analgesia quality by VAS score.
- Time for first top up.
- Time interval between postoperative supplementary analgesic.
- Total dose of ropivacaine postoperatively.
- Adverse effects if any.

Quality of analgesia was assessed at the time when rescue analgesia was given to the patient using VAS. Duration of analgesia is taken as the interval from time of injection of drug till re-appearance of pain and requiring dose of rescue analgesia (Inj. Tramadol IV or Inj. Diclofenac IM)

RESULTS

In this study, sixty patients belonging to ASA I and ASA II grades between age group of 18 - 70 years posted for elective abdominal and lower limb surgeries are studied. The objective of the study is to compare the analgesic efficacy of ropivacaine 0.2 % compared with ropivacaine 0.2 % with clonidine 1 µg / Kg.

Group	Drug Given	Number of Patients
Group R	0.2 % Ropivacaine	30
Group RC	0.2 % Ropivacaine + Clonidine 1 µg / Kg	30

Table 1. Distribution of Patients

Group R had 30 patients who received ropivacaine 0.2 % and group RC had 30 patients who received 0.2 % ropivacaine and clonidine 1 µg / Kg.

Distribution of Age in the Patients Studied

Sample size are age matched with p = 0.703. The minimum age was 21 years and maximum age was 60 years. Majority of the patients belonged to 41 - 50 years and 31 - 40 years.

Distribution of Gender in the Patients Studied

Sample size are matched with gender, p = 0.598. In group R, 56.7 % patients were males and 43.3 % patients were females. In group RC, 63.3 % patients were males and 40 % patients were females.

ASA Grade Distribution in the Two Groups of Patients Studied

In the group R, ASA I patients were 76.7 % and ASA II patients were 23.3 %. In the group RC ASA I patients were 23.3 % and ASA II patients were 26.7 %.

Comparison of Weight and Height

The mean height and weight in group R is 153.50 ± 5.463 cm and 54.63 ± 7.341 Kg. The mean height and weight in group RC is 152.33 ± 4.936 and 53.90 ± 4.788 Kg. The height and weight in both group are comparable.

Surgery Findings in the Two Groups of Patients Studied

In group R 16 patients underwent abdominal surgeries (VH-Vaginal Hysterctomy, TAH-Total Abdominal Hysterectomy, Mesh Repair, Laparotomy) and 14 patients underwent lower limb surgery (PFN - Proximal Femoral Nail, IMIL - Intra-Medullary Nailing of tibia, BKA - Below-Knee Amputation, AMP - Amputee Mobility Predictor, AKA - Above-Knee Amputation). In group RC 15 patients underwent abdominal surgeries and 15 patients underwent lower limb surgeries.

Onset of Analgesia (min) in the Two Groups of Patients Studied

The mean on set of analgesia for group R is 13.33 + - 1.67 minutes and in the group RC it was 7.33 + - 1.71 minutes.

By the chi square test P value is 0.0 which is statistically significant. Onset of analgesia is quicker in group RC compared to group R.

Mean First Top-Up (mins)

Mean time of first top up after surgery in group R is 22.27 + - 8.24 mins and in group RC is 20.00 + - 7.31. P value is 0.264 which is statistically insignificant.

Mean Duration of Analgesia (in Hours)

Mean duration of action in group R is 4.90 + - 1.03 hours and in group RC 9.43 + - 1.17 hours. P value 0.00 which is statistically significant.

Mean Supplementary Top-Up (in Hours)

Mean supplementary top ups in group R is 4.90 + - 1.03 hours and in the group RC it is 9.43 + - 1.17 hours. P value by chi square test is 0.00, which is statistically significant.

Requirement of Rescue Analgesic

In our study in group R 30 % patients required rescue analgesics compared to group RC none of the patients required rescue analgesics ($p < 0.05$).

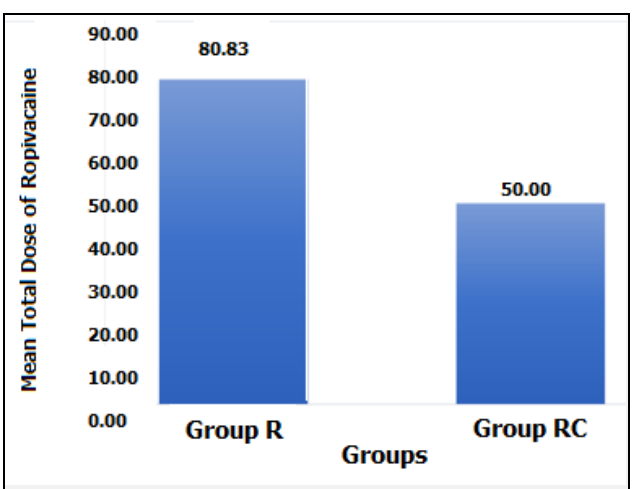

Figure 1. Mean Total Dose of Ropivacaine

Mean total dose of ropivacaine in group R is 80.83 + - 18.74 mg and in group RC is 50.0 + - 10.17 mg. By chi square test P value is 0.00 which is statistically significant.

Mean Quality of Analgesia

Mean quality of analgesia in group R is 2.47 + - 0.73 and in group RC is 1.90 + - 0.71. By chi square test P value is 0.004 which is statistically significant.

Mean SpO_2

Mean SpO_2 in the group R is 98.43 + - 0.77 and in group RC is 94.93 + -1.173. P value by chi square test is 0.246 which is statistically not significant.

	Group R		Group RC		t	p
	Mean	SD	Mean	SD	Value	Value
first top up (mins)	22.27	8.24	20.00	7.31	1.127	0.264
Supplementary top up (hrs)	4.90	1.03	9.43	1.17	- 15.974	0.000
Total dose of Ropivacaine	80.83	18.74	50.00	10.17	7.921	0.000
O.O.A. (min)	13.33	1.67	7.33	1.71	13.764	0.000
D.O.A. (hrs)	4.90	1.03	9.43	1.17	- 15.974	0.000
Q.O.A.	2.47	0.73	1.90	0.71	3.043	0.004
SpO2	98.43	0.77	94.93	16.32	1.173	0.246

Table 2. Comparison of Parameters

Comparison of Pulse Rate (Beats / Min) in the Two Groups of Patients Studied

In the group R the pulse rate at 1 minute was 85.30 + - 14.37 bpm which fell to 73.17 + - 11.96 bpm at 20 minutes and maintained at 73.90 + - 12.08 bpm. In group RC the pulse rate was 80.67 + - 12.65 bpm which fell to 72.90 bpm at 10 minutes and raised to 77.83 + - 12.08 bpm at 45 minutes. The pulse rate was more stable in group RC compared to group R.

SBP	Group R		Group RC		t-	p-
	Mean	SD	Mean	SD	Value	Value
1 Min	125.83	13.40	124.83	7.93	0.352	0.726
5 Mins	121.83	12.96	124.17	8.31	- 0.830	0.410
10 Mins	111.33	14.68	119.50	3.79	- 2.951	0.005
15 Mins	103.33	13.09	114.83	7.01	- 4.243	0.000
20 Mins	102.50	11.43	114.00	7.59	- 4.592	0.000
25 Mins	103.00	10.72	115.03	6.83	- 5.188	0.000
30 Mins	103.67	10.17	116.00	8.03	- 5.215	0.000
45 Mins	105.67	11.28	116.33	7.18	- 4.370	0.000

Table 3. Comparison of SBP in the Two Patient Groups

Mean SBP (Systolic Blood Pressure) in group R at 1 minute was 125.83 + - 13.40 mmHg which fell to 103.33 mmHg at 15 minutes and maintained at 105.67 + - 11.28 mmHg at 45 minutes. Mean SBP in the group RC at 1 minute was 124.83 + - 7.93 mmHg which fell to 114.83 + - 7.01 at 15 minutes and maintained at 116.33 + - 7.18 at 45 minutes. Blood pressure was more stable in group RC compared to group R.

DBP	Group R		Group RC		t-	P-
	Mean	SD	Mean	SD	Value	Value
1 Min	76.50	10.35	79.83	7.93	- 1.400	0.167
5 Mins	76.83	10.38	80.17	8.15	- 1.384	0.172
10 Mins	69.67	10.50	73.33	7.23	- 1.575	0.121
15 Mins	64.50	8.13	70.50	6.34	- 3.186	0.002
20 Mins	65.17	6.76	70.67	6.66	- 3.175	0.002
25 Mins	64.67	6.94	71.67	6.34	- 4.078	0.000
30 Mins	66.33	7.42	72.17	5.68	- 3.420	0.001
45 Mins	66.67	8.44	73.17	6.63	- 3.317	0.002

Table 4. Comparison of DBP in the Two Patient Groups

Mean DBP (Diastolic Blood Pressure) in the group R is 76.50 + - 10.35 mmHg and fell to 64.50 + - 8.13 mmHg at 15 minutes and maintained at 66.67 + - 8.44 mmHg till 45 minutes. Mean DBP in group RC is 79.83 + - 7.83 mmHg and maintained at 73.17 + - 6.63 mmHg at 45 minutes.

Adverse Effects

In the group R 6.7 % patients had vomiting and in the group RC 3.3 % patients had vomiting ($p = 0.554$) which is statistically not significant.

DISCUSSION

Pain relief is necessary in the view of both therapeutic and humanitarian basis. Pain in the post-operative period can have unwanted physiological changes. Pain impedes the normal respiratory physiology and causes post-operative pulmonary atelectasis, hypoxia, pulmonary infection. If patient becomes immobile due to pain it can lead to deep venous thrombosis. Pain causes increased surgical stress and catabolism which leads to malnourishment and increased release of catecholamines which leads to increase in cardiac work. Pain also causes immune suppression and delayed wound healing. Pain relief decreases mortality and morbidity. The goals of post-operative pain management are to alleviate suffering, early mobilisation after surgery, reduce length of hospital stay and good patient satisfaction.

Management of post-operative pain still poses lot of challenges to anaesthetists. Various modalities have been tried to relieve the post-operative pain. Epidural analgesia is now accepted as the prime modality of pain relief following lower abdominal and lower limb surgeries.

Here an attempt has been made in this study to assess the efficacy of epidural ropivacaine compared with ropivacaine with clonidine in the management of immediate post-operative analgesia in abdominal and lower limb surgeries. Sixty patients of ASA grade I and II, belonging to age between 18 – 80 years, of which majority were in between 31 - 40 years and 41 - 50 years of age, undergoing elective abdominal and lower limb surgeries were taken into each of the two groups. Male and female ratio was same between the 2 groups. Height and weight of the patients in both the groups were comparable. Among these, 31 patients underwent different abdominal surgeries (like laparotomy, total abdominal hysterectomy, vaginal hysterectomy, bilateral hernioplasty and mesh plasty) and 29 patients underwent lower limb surgeries (like IMIL tibia, proximal femur nailing, ORIF both bone fracture leg, above and below knee amputation and Austin Moore prosthesis).

All surgeries were performed under combined spinal and epidural anaesthesia, epidural anaesthesia or general anaesthesia. In post-op period after patient started complaining of pain, clinically correlating with visual response score of > 5, patients were given 10 mL of the drug epidurally. Group R was administered 0.2 % ropivacaine and group RC was administered 0.2 % ropivacaine plus clonidine (1µ / Kg). Patients were monitored for vital parameters like pulse rate, blood pressure and respiratory rate at regular intervals.

Onset of Analgesia

In our study mean time for onset of analgesia in group R was 13.33 + - 1.67 min. In group RC mean time was 7.33 + - 1.71 min. Statistical analysis was done by chi square test and results showed that, the difference between the two groups was not statistically significant.

Duration of Analgesia

In our study the mean duration of analgesia in the group R was 4.90 + - 1.03 hours and in the group RC it was 9.43 + - 1.17 with p value 0.00 which is statistically significant.

Indira Kumari et al in their study "Comparison of ropivacaine (0.2 %) with or without clonidine 1 µg / Kg for epidural labour analgesia: A randomised controlled study" concluded that the addition of clonidine 1 µg / Kg to epidurally administered ropivacaine 0.2 % improves the onset of analgesia, prolongs its duration. In the group R mean duration of analgesia was 70.9 + - 1 1.5 minutes and the group RC mean duration of analgesia was 108.0 + - 14.1 minutes.

Quality of Analgesia

In our study in the group R mean VAS score was 2.47 + - 0.77 and in the group RC it was 1.90 + - 0.71 ($p = 0.0040$) which is statistically significant. João Florêncio de Abreu Baptista et al, in their study to determine the safety and pain intensity correlated with age and Body Mass Index (BMI), by epidural anaesthesia with ropivacaine and clonidine in haemorrhoidectomy, inferred that in the group 0.75 % ropivacaine plus 4.0 mcg / Kg of clonidine there was statistically significant VAS compared to control group with ropivacaine 0.75 % with 0.0266 mL / Kg of 0.9 % saline solution.

First Top-Up (mins)

In our study there was no statistically significant difference in the mean top up timings.

Supplementary Top-Up (hrs.)

In the study, group R had mean supplementary interval of 4.90 + - 1.03 hours and group RC had mean supplementary interval of 9.43 + - 1.17 hours which was statistically significant ($p < 0.00$).

Total Dose of Ropivacaine (mg)

In our study group R had mean total dose of ropivacaine of 80.53 + - 18.74 mg and group RC had mean total dose of ropivacaine of 50.00 + - 10.17 mg which is statistically significant ($p < 0.05$). Sukhminder Jit Singh Bajwa et al. In their study to determine the qualitative and quantitative aspects of epidural block of ropivacaine 0.75 % versus ropivacaine 0.75 % with clonidine for elective caesarean section found that in group R the mean total dose was 230.76 ± 26.28 mg and in the group RC it was 150.34 ± 21.46 mg. The requirement of ropivacaine was reduced with addition of clonidine.[1]

Respiratory Depression

In the study mean SpO_2 in the group R was 98.43 + - 0.77 and in the group RC SpO_2 94.93 + - 1.173 which is statistically insignificant ($p = 0.246$).

Sukhminder Jit Singh Bajwa et al. in their study, comparison of epidural ropivacaine and ropivacaine clonidine combination for elective caesarean sections none of the patients had respiratory depression.[3]

Haemodynamic Effects

The baseline pulse rate and blood pressure in the group R and group RC weren't comparable. The pulse rate and blood pressure was more stable in the group RC compared to group R. Keshav Govind Rao, et al, in their study; there was no event of hypotension noticed in any group thus highlighting that the given dosages of adjuvant use of clonidine did not reduce the arterial pressure substantially.[10] Keshav Govind Rao et al in their study with respect to HR (Heart Rate) during the study period, statistically no significant differences among groups were observed for the initial part of the study, however, from 30 min onward till 120 min, group 1 (RC) had significantly lower HR as compared to group 2 (R alone).[10]

Adverse Effects

In our study in the group R 6.7 % patients had vomiting and in the group RC 3.3 % patients had vomiting ($p = 0.554$) which is statistically not significant. Keshav Govind Rao et al, in their study; "Comparison of onset, duration of sensory and motor block, and any adverse effects between 0.5 % ropivacaine with normal saline versus 0.5 % ropivacaine with clonidine (75 µg / Kg)" dry mouth and nausea / vomiting were the most common side effects observed in both the groups. None of the patient had respiratory depression. Although side effects were minimum in ropivacaine alone group, yet for none of the side effects, a significant intergroup difference was observed.[10]

CONCLUSIONS

Addition of clonidine 1 µg / Kg to 0.2 % ropivacaine gives better haemodynamics than 0.2 % ropivacaine alone. Using clonidine as adjuvant to ropivacaine gives faster onset of analgesia, better VAS score, prolonged duration of analgesia compared to ropivacaine alone. The dose of ropivacaine is reduced when clonidine is used as an adjuvant. Minor adverse effects were found in both groups which was not significant. Addition of clonidine didn't cause respiratory depression. Requirement of rescue analgesic was less when clonidine was used as adjuvant to ropivacaine in epidural top up.

Data sharing statement provided by the authors is available with the full text of this article at jebmh.com.
Financial or other competing interests: None.
Disclosure forms provided by the authors are available with the full text of this article at jebmh.com.

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