Original Article

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Comparative Study of 0.75% Ropivacaine Alone with 0.75% Ropivacaine and Dexmedetomidine Epidurally for Lower Limb & Lower Abdominal Surgery

Harpreet Babrah[1], Tushar D. Bhavar[2], Balwinder Kaur[3]

[1]Senior Resident, Deptt. of Anaesthesiology & Intensive Care, Sri Guru Ram Das Institute of Medical Sciences & Research, Amritsar - 143501, Punjab, India. [2]Assistant Professor Deptt. of Anaesthesiology & Intensive Care, Rural Medical College, Loni, Rahata, Ahmednagar, Maharashtra 413736, India. [3]Professor, Deptt. of Anaesthesiology & Intensive Care, Government Medical College & Hospital, Patiala, Punjab, 147001, India.

Abstract

Background: Neuraxial adjuvants are used with local anaesthetic agents to enhance the quality of anaesthesia. The present study aims at comparing the efficacy & safety of adding α2- adrenergic agonist, Dexmedetomidine to 0.75% Ropivacaine with Ropivacaine alone epidurally for lower limb & lower abdominal surgery. *Methodology*: 50 patients (age 20-60 years, ASA grade I or II, of either sex), were randomly allocated to: Group I (n=25) epidural bolus of 20 ml(150mg) 0.75% Ropivacaine+1 ml NS, Group II (n=25) epidural bolus of 20 ml 0.75% Ropivacaine + Dexmedetomidine 1µg/kg diluted in NS Intra operative haemodynamics; onset, level & duration of sensory & motor block; level of sedation; post op analgesia & side effects were recorded & statistically analyzed using t- test, chi- square test & Mann Whitney test. *Results:* Groups were comparable in terms of the demographic profile, pre operative haemodynamic parameters & duration of surgery ($p > 0.05$). In Group II, onset of sensory block was faster in but not statistically significant($p=0.05$), duration of sensory block was significantly prolonged ($p<0.001$), motor block onset was significantly faster ($p<0.01$) & duration significantly prolonged ($p<0.001$). Gpoup II showed significant decrease in heart rate ($p<0.001$), significantly higher ($p<0.001$) intra-op sedation scores, significantly prolonged duration of analgesia ($p<0.001$) & higher incidence of dry mouth as side effect ($p=0.02$). *Conclusion:* Addition of Dexmedetomidine to local anaesthetic agent Ropivacaine 0.75% epidurally as an adjuvant provides better sensory and motor block, intra-op sedation and prolonged post -op analgesia.

Keywords: 0.75% Ropivacaine; Dexmedetomidine; Epidural Anaesthesia; Sensory Block; Motor Block; Intra-op Sedation; Post -op Analgesia; A2 Adrenergic Agonists; Lower Limb & Lower Abdominal Surgery.

Introduction

Epidural anaesthesia is a central neuraxial block technique with applications in surgery, obstetrics and pain control. Local anesthetic agents used in epidural anesthesia are Mepivacaine, Bupivacaine, Levobupivacaine, Ropivacaine. Ropivacaine is a pure S-enantiomer having considerably lower lipid solubility & a lower affinity for myocardial channels which contribute to its low systemic toxicity. At high concentrations, it provides excellent anesthesia with profound muscle relaxation [1,2].

Neuraxial adjuvants are used to improve or prolong analgesia & decrease the adverse effects associated with high doses of a single local anaesthetic agent. These also increase the speed of onset of neural blockade, improve the quality & prolong the duration of neural blockade [3]. Due to the side effects associated with opiods, α-2 adrenergic agonists were introduced as adjuvants in neuraxial anaesthesia.Clonidine & Dexmedetomidine belong to this class of drugs. Dexmedetomidine is highly selective for α-2 receptors (α-2: α-1=1620:1) having 8 times greater selectivity for a-2 receptors as compared to clonidine [4]. It was first introduced into clinical

Corresponding Author: Dr Tushar D. Bhavar, Assistant Professor, Deptt. of Anaesthesiology & Intensive Care, Rural Medical College, At/post: Loni Bk, Tal: Rahata Dist: Ahmednagar, Maharastra 413736, India.
E-mail: tganesh55555@gmail.com

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practice as a short term intravenous sedative in ICU. Its epidural effect is dose dependant & superior than i.v due to its high affinity for a-2 receptors in the spinal cord.

Keeping in view the proposed advantages of using these drugs in epidural anaesthesia, a comparative study of 0.75% ropivacaine alone with 0.75% ropivacaine and dexmedetomidine epidurally for lower limb & lower abdominal surgery was performed on 50 adult patients in Rajindra Hospital, Patiala.

Methodology

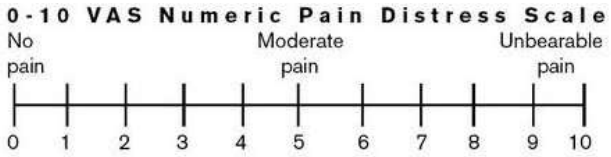
With approval of institute ethics committee & patient's written informed consent, 50 adult patients (age 20-60 yrs., ASA I/II of either sex) posted for elective lower limb and lower abdominal surgeries were included in the study. Unwilling patients, patients with spinal abnormality, local sepsis, coagulation defects or patients on anticoagulant therapy, patients with neurological or cardiovascular disorders, sensitivity to the drugs administered & those on α-2 antagonists were excluded from the study.

The patients were randomly allocated into 2 groups of 25 patients each.

GROUP I (n=25) patients received 20ml (150mg) 0.75% Ropivacaine +1 ml NS epidurally.

GROUP II (n=25) patients received 20ml (150mg) 0.75% Ropivacaine + Dexmedetomidine 1 μg /kg in NS epidurally.

VAS(Visual Analogue Scale): was used for pain scoring. The VAS score is determined by measuring in millimeters from the left hand end of the line, to the point that the patient marks. Patients were familiarized with VAS scoring & asked to grade their pain on this scale in the post-op period.



No pain Very severe pain

During pre-anesthetic check up a detailed history & thorough general physical & systemic examination (CVS, chest, CNS, renal) was done.

Baseline investigations &BP, PR, RR were recorded. All patients were kept fasting overnight or minimum 6 hrs before surgery. Inj. Midazolam (2mg) & inj. Phenergan (25mg) were given intramuscularly 30 min. before the operation in both the groups so that the groups were comparable with same baseline sedatives given.

Preloading was done with 20ml/kg Ringer lactate solution

Procedure was performed with patient in the lateral decubitus (i.e. patient lying on their side with their hips and knees maximally flexed) or sitting position. Back was cleaned with antiseptic solution & draped. Local anaesthetic, 1-2ml of 2% Xylocaine was injected subcutaneously at L3-4 or L2-3 interspace. Sise introducer was introduced & taken out. With the help of Tuohy's needle, epidural space was identified by loss of resistance technique.3 ml of 2% lignocaine with Adrenaline was injected as test dose after which epidural catheter No.18 G was inserted into the space through Tuohy's needle so that 15 cm mark disappeared from the hub of the needle. Tuohy's needle was withdrawn slowly and the catheter fixed to the patient's back with micropore. The drug was injected through the catheter according to the groups in which the patients were randomly allocated @3ml/sec.

The patients were turned supine and O2 administered via face mask.

The following parameters were observed intraoperatively:

1. Vitals

a. *Blood Pressure*: recorded every 5 min for first 30 min after epidural injection & then every 10 min till the end of surgery. Fall in systemic BP more than 20% from baseline value taken as significant hypotension. It was treated with rapid administration of intravenous fluids & use of vasopressors (inj. mephentermine 3 mg. i.v.) if needed.

b. *Pulse Rate*: recorded every 5 min for the first 30 min and then every 10 min till the end of surgery.Pulse rate less than 60 taken as significant bradycardia and treated with i/v inj. atropine .

Sensory Block

a. *Onset*: taken as time from injection of anaesthetic drug upto the time required to achieve the highest dermatomal level.

b. *Level*: assessed by pin-prick testing, bilaterally along mid-clavicular line. The assessment done every 2 min from injection till the level is stabilized for four consecutive tests. Level of highest dermatome blocked was noted.

c. *Duration*: taken as time from administration of anesthetic drug till the time for regression of two segments from the highest dermatome.

3. *Motor Block:*

Assessed by using Modified Bromage Scale (MBS)

a. *Onset*: Time taken from administration of anaesthetic drug to appearance of MBS 2

b. *Duration*: calculated from the duration between MBS-2 to return of muscle power till MBS-5

Modified Bromage Score (MBS) [5]

Score Criteria

1 Complete block(unable to move feet or knees)

2 Almost complete block (able to move feet only)

3 Partial block (just able to move knees)

4 Detectable weakness of hip flexion while supine (full flexion of knees)

5 No detectable weakness of hip flexion while supine

6 Able to perform partial knee bend

4. *Sedation*

Level of sedation assessed at 5, 10, 15, 20 & 30 mins according to sedation scale.

Sedation Scale

0 - fully awake

1 - Slightly drowsy

2 - Asleep but easily arousable

3 - Fully asleep but arousable

4 - Sleeping and not arousable

5) Duration of surgery

6) Incidence of intra operative complications like nausea, vomiting, shivering, hypotension and respiratory depression.

The following parameters were observed postoperatively:

1. Assessment of pain: with the help of VAS, every hour till 6 hrs. & every 2 hrs. Till 24 hrs.
2. Duration of analgesia: when the patient reached VAS score of 5, rescue analgesic was given epiduraly (10 ml of 0.2% ropivacaine) & study in that patient ceased.
3. Vitals: PR,BP recorded at the same intervals as VAS.
4. Complications (if any): Nausea, vomiting, respiratory depression, shivering.

Data collected was subjected to statistical analysis using Graph Pad Prism 6 software, Student's t test, chi square test & Mann Whitney tests were used. $p<0.05$ was taken as significant with $p<0.001$ as highly significant.

Results

The demographic profiles of the patients in both the groups were comparable with regards to age, weight , height and sex. The mean duration of surgery was comparable in both the groups and statistically non significant ($p > 0.05$) (Table 1). The baseline vitals (PR, SBP, DBP & MBP)were also comparable.

Addition of dexmedetomidine to ropivacaine as an adjuvant resulted in an earlier onset of sensory analgesia as compared to ropivacaine alone but it was not statistically significant. MBS - 2 was achieved earlier in patients who were administered dexmedetomidine as an adjuvant ($p < 0.05$).The upper level of analgesia achieved in both groups was comparable ; Level reaching T6 in 12 & 14 patients in Group I & II respectively ,T8 in 13 & 11 patients in Group I & II respectively. The duration of sensory block was significantly prolonged by dexmedetomidine as compared to plain ropivacaine($p<0.001$). The duration of motor block was also significantly prolonged ($p<0.001$)(Table 2)

The intra-op sedation scores were significantly higher in group II, the median sedation score being 3 as compared to a median score of 1 in group I. ($p<0.001$) (Table 3) . While 15 patients in group I needed supplemental i.v sedative to relieve anxiety, none in group II required any($p< 0.001$),thus demonstrating excellent sedative action of dexmedetomidine.

In the present study, SBP, DBP, MBP decreased from the baseline value after establishment of epidural bock in both the groups, however these were comparable at different time intervals in the intraoperative period (Figure 1,2). 4 patients in group I & 7 patients in group II required mephentermine intraoperatively.This was statistically comparable with p value of 0.72.

In the present study, PR in the intraoperative period at different time intervals, was less in group II as compared to group I. The difference being statistically highly significant till 70th minutes & significant till 140th minute of surgery (Figure 3). 1 patient in group I & 7 in Group II required iv atropine (p =0.04)

Incidence of various side effects in both the groups were observed in the intra-op and post-op period. The incidence of dry mouth was significantly higher in Group II (Table 4).

VAS scores were used in the post operative period for calculating the duration of analgesia (Table 5). In group I 44% patients had VAS score of 5 in the 3rd hr. while only 4% patients in group II .96% patients in group I had VAS score of 5 at 4th post operative hour & only 12 % patients in group II. Study continued upto 6th post-operative hr. in 52% patients in group II, while it ceased in 100% patients in group I at the 5th post-operative hr.

Patients in both groups had stable postoperative haemodynamics.

Table 1: Comparison of demographic parameters

Demographic Characteristics	Group I (n=25)	Group II (n=25)	P value
AGE (in years)	36.84±2.4	36.36±2.23	0.88
Weight(IN KGS)	67.52±1.86	63.60±1.36	0.09
Height(IN CMS)	167.5±1.11	165.2±1.20	0.15
Male/Female(M/F)	23/2	18/7	0.99
Mean Duration of Surgery (IN MIN)	102.4±8.53	93.60±9.30	0.48

Table 2: Comparasion of block characteristics

Block Characteristics	Group I (n=25)	Group II (N=25)	P value
Sensory Block Onset (Min)	15.21±0.30	14.40±0.28	0.05
Sensory Block Duration (Min)	89.66±3.32	141.4±1.6	<0.001*
Motor Block Onset (Min)	21.17±0.48	17.87±0.56	<0.001*
Motor Block Duration (Min)	147.4±2.8	254.6±1.8	<0.001*

Table 3: Comparasion of intraop score on RSS

Intra-Op Score on RSS	Group I (n=25) No. of Patients	Group II (N=25) No. of Patients
0	12	0
1	11	0
2	2	11
3	0	12
4	0	2
Median*	1	3

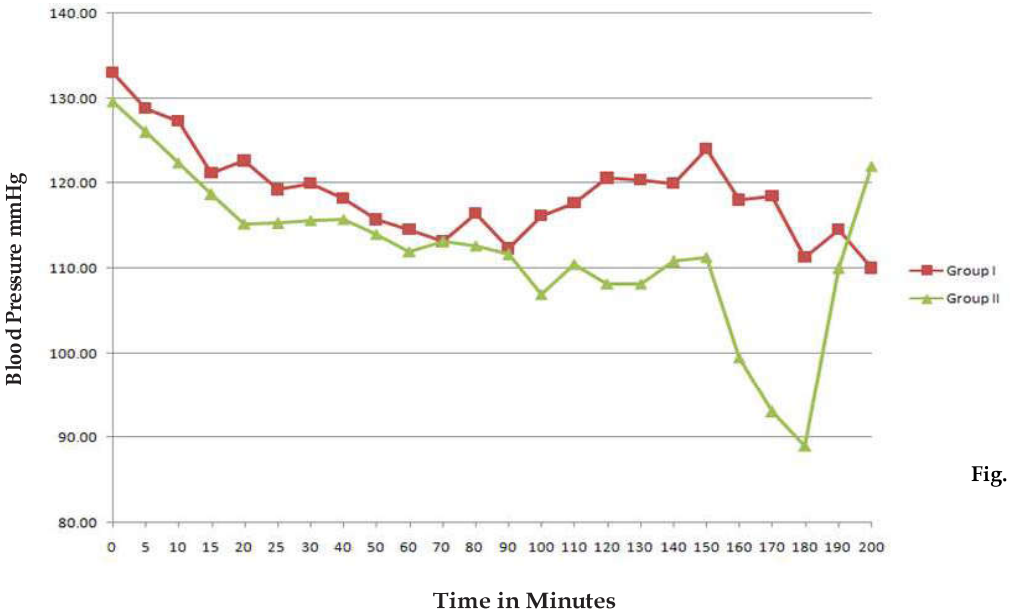


Fig. 1: Comparison of SBP

Table 4: Comparison of side effects

Side Effects	Group I (n=25)	Group II (N=25)	P value
Urinary Retention	2	5	0.41
Nausea	3	4	1
Vomiting	0	0	_
Dry Mouth	1	8	0.02
Shivering	2	3	1
Respiratory Depression	0	0	_

Table 5: Comparison of duration of analgesia

Duration of Analgesia (in min)	Group I (n=25)	Group II (N=25)	P value
	297±6.5	411.2±4.6	<0.001

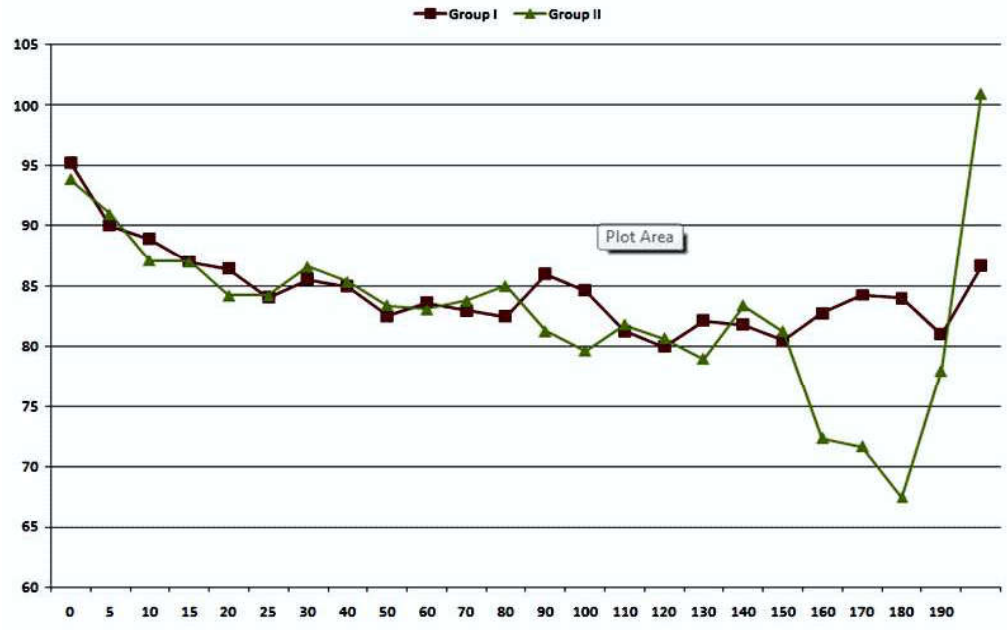


Fig. 2: Comparison of DBP

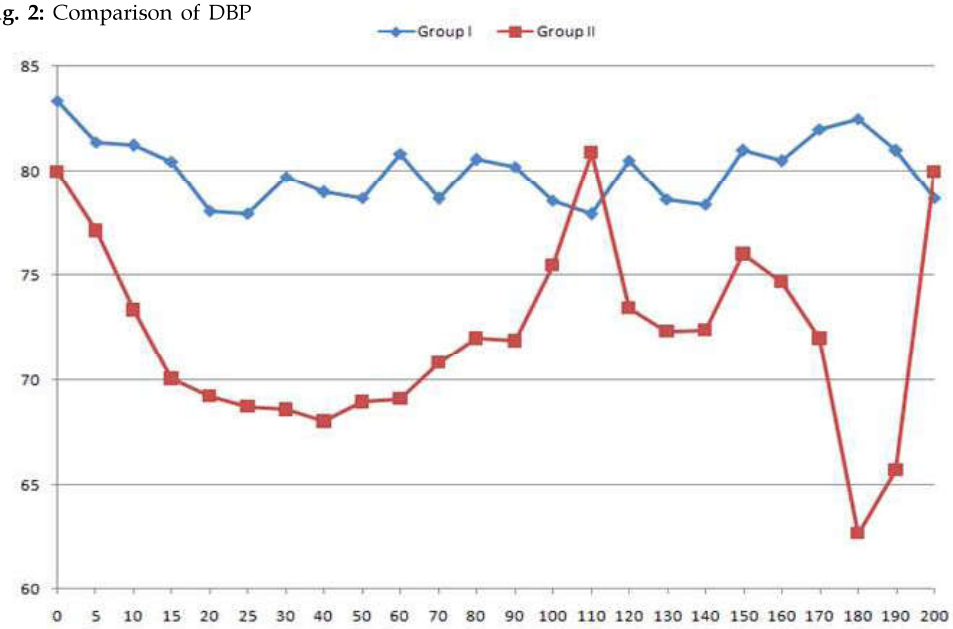


Fig. 3: Comparison of PR

Discussion

Neuraxial adjuvants are used to improve the quality of anaesthesia achieved by local anaesthetic agents. α-2 adrenoceptors agonists are being used with great interest in anaesthesia practice. Clonidine has been extensively used in regional anaesthesia Dexmedetomidine, is a highly selective α-2 adrenergic agonist, acting on locus coereulus & dorsal horn of spinal cord. With actions on receptors at these sites it provides sedation, anxiolysis, hypnosis, analgesia & sympathicolysis without causing respiratory depression [6]. Several studies have been conducted to demonstrate the efficacy of adding clonidine to local anaesthetic agent in epidural anaesthesia. However, the experience with dexmedetomidine in epidural anaesthesia is limited.

The present study was conducted to compare the efficacy & safety of adding dexmedetomidine to 0.75% ropivacaine with 0.75% ropivacaine alone.Patients were comparable with respect to the demographic variables, the duration of surgery & preoperative haemodynamic parameters. It was observed that addition of dexmedetomidine significantly prolonged the duration of sensory block, onset & duration of motor block. The upper level of analgesia achieved was not significantly altered. Similar observations were made by Oriol – Lopez SA et al (2008) [7], Paula F . Salgado et al (2008) [8], & Bajwa S et al (2011) [9].

Intraoperative sedation scores were significantly higher with dexmedetomidine as an adjuvant. These observations were in consonance with the study by Antonio Maura et al(2004) [10], Paula F . Salgado et al (2008), Oriol – Lopez SA et al (2008), Bajwa S et al (2011) & Divya Jain et al (2012) [11]. Intra & post operatively blood pressure was stable in both groups.Heart rate showed significant fall in dexmedetomidine group but it was effectively managed with atropine i.v . Duration of analgesia was prolonged with dexmedetomidine without any significant side effects except dry mouth.

Conclusion

With results from the present study, it can be concluded that Dexmedetomidine 1 μg/kg added to 0.75% ropivacaine has the potential of an excellent & safe adjuvant in epidural anaesthesia .

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